His Majesty Sultan Qaboos Bin Said
## TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Sr</th>
<th>Contents</th>
<th>Page No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Preface</td>
<td>7</td>
</tr>
<tr>
<td>2</td>
<td>Introduction</td>
<td>8</td>
</tr>
<tr>
<td>3</td>
<td>Acknowledgment</td>
<td>9</td>
</tr>
<tr>
<td>4</td>
<td>Approval Process</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>Acronyms</td>
<td>11</td>
</tr>
<tr>
<td>6</td>
<td>Pharmaceutical Care Policies &amp; Procedures</td>
<td></td>
</tr>
<tr>
<td></td>
<td>P&amp;P/001 • Pharmaceutical care Scope of Services</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/002 • Pharmacy Staff Orientation Policy</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/003 • Pharmacy Professional Development</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/004 • Pharmacy Staff Competency Assessment</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/005 • Pharmacy Departmental Meetings</td>
<td>31</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/006 • Pharmacy Departmental Safety Policy</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/007 • Pharmacy Emergency Preparedness and Response Plan</td>
<td>42</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/008 • Pharmacy Duty Rostering Policy</td>
<td>49</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/009 • Pharmacy Quality Management System</td>
<td>52</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/010 • Drug Information Services</td>
<td>72</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/011 • Procurement of Medical Supplies</td>
<td>77</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/012 • Managing Medical Supplies</td>
<td>83</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/013 • Response to Out-of-Stock Formulary Medications</td>
<td>96</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/014 • Medications Returned by Patients</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/015 • Floor Stock Medication Guidelines</td>
<td>103</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/016 • Patient’s Own Medications</td>
<td>106</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/017 • Medication Reconciliation Policy</td>
<td>110</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/018 • Medication Order Review</td>
<td>113</td>
</tr>
<tr>
<td></td>
<td>P&amp;P/019 • When required (PRN) Medications</td>
<td>117</td>
</tr>
<tr>
<td>Sr</td>
<td>Contents</td>
<td>Page No</td>
</tr>
<tr>
<td>----</td>
<td>--------------------------------------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>1</td>
<td>P&amp;P/020 • Discharge Medication Order</td>
<td>119</td>
</tr>
<tr>
<td>2</td>
<td>P&amp;P/021 • Medication Dispensing Guidelines</td>
<td>122</td>
</tr>
<tr>
<td>3</td>
<td>P&amp;P/022 • Patient Counselling</td>
<td>132</td>
</tr>
<tr>
<td>4</td>
<td>P&amp;P/023 • Unit Dose Dispensing System</td>
<td>137</td>
</tr>
<tr>
<td>5</td>
<td>P&amp;P/024 • Drug Utilization Review</td>
<td>143</td>
</tr>
<tr>
<td>6</td>
<td>P&amp;P/025 • Drug and Therapeutics committees</td>
<td>148</td>
</tr>
<tr>
<td>7</td>
<td>P&amp;P/026 • Off Label Use of Medications</td>
<td>157</td>
</tr>
<tr>
<td>8</td>
<td>P&amp;P/027 • Restricted Formulary Medications</td>
<td>160</td>
</tr>
<tr>
<td>9</td>
<td>P&amp;P/028 • Handling of Non-Formulary requests</td>
<td>163</td>
</tr>
<tr>
<td>10</td>
<td>P&amp;P/029 • Emergency Crash Cart Medications</td>
<td>168</td>
</tr>
<tr>
<td>11</td>
<td>P&amp;P/030 • Handling Patient Drug Allergy</td>
<td>172</td>
</tr>
<tr>
<td>12</td>
<td>P&amp;P/031 • Drug - Food Interactions</td>
<td>175</td>
</tr>
<tr>
<td>13</td>
<td>P&amp;P/032 • Drug - Drug Interactions</td>
<td>183</td>
</tr>
<tr>
<td>14</td>
<td>P&amp;P/033 • Management of Adverse Drug Reactions</td>
<td>190</td>
</tr>
<tr>
<td>15</td>
<td>P&amp;P/034 • Medication Error Reporting</td>
<td>197</td>
</tr>
<tr>
<td>16</td>
<td>P&amp;P/035 • High Alert Medications</td>
<td>203</td>
</tr>
<tr>
<td>17</td>
<td>P&amp;P/036 • Look-Alike/ Sound-Alike Medications</td>
<td>211</td>
</tr>
<tr>
<td>18</td>
<td>P&amp;P/037 • Handling Hazardous Medicines</td>
<td>216</td>
</tr>
<tr>
<td>19</td>
<td>P&amp;P/038 • Handling Drug Recalls</td>
<td>226</td>
</tr>
<tr>
<td>20</td>
<td>P&amp;P/039 • Extemporaneous Pharmaceutical Preparations</td>
<td>231</td>
</tr>
<tr>
<td>21</td>
<td>P&amp;P/040 • Compounding Sterile Preparations</td>
<td>236</td>
</tr>
<tr>
<td>22</td>
<td>P&amp;P/041 • Total Parenteral Nutrition preparations</td>
<td>244</td>
</tr>
<tr>
<td>23</td>
<td>P&amp;P/042 • Compounding of Bevacizumab For Ophthalmic Use</td>
<td>249</td>
</tr>
<tr>
<td>24</td>
<td>P&amp;P/043 • Drug Quality Reporting Program</td>
<td>255</td>
</tr>
<tr>
<td>25</td>
<td>P&amp;P/044 • Medical Devices Quality Reporting</td>
<td>260</td>
</tr>
<tr>
<td>26</td>
<td>P&amp;P/045 • Medical Representative Visits</td>
<td>266</td>
</tr>
</tbody>
</table>
PREFACE

Pharmaceutical Care is vital for the achievement of the intended medical outcomes which ultimately is envisaged to improve the quality of life of patients. The important role of pharmacists in managing drug therapy accentuate a need for an efficient and continuous pharmacy professional development programs to further heighten their qualifications, skills, and competence.

The strategic Human Resources Planning trend for Pharmacy profession in MOH has shown a remarkable success in the past years through influencing pharmacy career path with a particular focus on specialization in clinical pharmacy and continual upgrading of the status of assistant pharmacists holder of pharmacy diploma to an advanced bachelor in pharmacy.

In 2015 the Ministry clearly defined the specialties and responsibilities of various pharmaceutical care departments. This effort has been boosted further with the establishment of a department earmarked for Pharmaceutical Care in (DGMS) with an aim to empower, support, and integrate the professional practice of pharmaceutical care across the health care system in line with the international standards.

Having standardized operational pharmaceutical care policies and procedures in place ensure that the pharmacy professionals in the Ministry of Health follow an approved and unified standards of practice, and are expected to promote efficiency, effectiveness, and consistency.

Concomitantly, this manual serves as a guide for the pharmaceutical care providers to enhance the quality of their day-to-day tasks, and to act as catalyst for the spread of good practices that ensure safe and well-informed therapy for the patients.

I hope that this manual proves its worth and importance as an indispensable guide to practitioners in the constitutive domain of pharmaceutical care and is able to add to the body of knowledge of health care management in general.

Dr. Darwish Bin Saif Al Maharbi
The Under Secretary for Administration and Finance
INTRODUCTION

As per the Pharmaceutical Care Department Strategy Execution Plan 2017-2020, I am pleased to enclose herewith the Pharmaceutical Care Policies & Procedures Manual - 2018 intended for the internal use by the Pharmaceutical care providers in MOH Healthcare units as a tool to help individuals accomplish their work within each institution and to facilitate decision-making, with the aims of ensuring appropriate consistency and serve as a guide and educational informative reference as well.

This manual describes standardized 45 policies and procedures based on most functions that all Pharmacists and Assistant Pharmacists should perform for individual patient care in organized health systems. The use of these policies would foster consistency in the provision of pharmaceutical care and support continuity of care within a practice setting. Further, a standardized method would establish consistent documentation so that patient-specific and medication-related information could be shared between pharmacy staff and among other health care professionals in various healthcare units.

These policies and guidelines are carefully developed based on the available resources in the Ministry and are best tailored from the related pharmaceutical care guidelines established by WHO, FIP, FDA, NHS, MHRA, ASHP, ACCP, APhA, ISMP, NICE, NIOSH, NCBI and other international guidelines on pharmacy practice from Health authorities in Australia, Canada, Malaysia etc. Further, they had been shared with the Pharmaceutical care service providers in Regional Hospitals and Departments of Pharmacy and Medical Stores in the Governorates in the Ministry of Health and accordingly, the valuable feedback and inputs received are incorporated in this manual as needed.

Through our many years working without standard pharmaceutical care policies and procedures, it has become clear to us that it is of utmost important and it is the right time to have a unified standardized guidelines to provide clarity when dealing with issues and activities that are critical to health and patients safety.

This first edition of Pharmaceutical care Manual is considered as the starting point, aiming to bring together all necessary policies and procedures which has been written in response to a need to develop and generate a safe and efficient standing pharmaceutical care at all levels in the Ministry.

The content of this manual will be kept under review as more experience is gained and practical information is obtained on fundamental professional responsibilities and advanced pharmacy practice.

Ph. Nussaiba Habib Mohammed,
Director General of Medical Supplies
ACKNOWLEDGEMENT

The Ministry of Health represented by the Directorate General of Medical Supplies is very grateful and expresses great appreciation and thanks to the following pharmacy professionals for their genuine efforts in bringing out this valuable manual:

- Sr.Ph. Hassan Ali Mohd., Quality Management & Medicine Safety Section
- Sp.Ph. Sara Al Balushi, Director, Pharmaceutical Care Dept.
- Ph. Sumaiyya Al Zaabi, Hospital Pharmaceutical Care Section
- Ph. Wala Ahmed Atout, Hospital Pharmaceutical Care Section
- Ph. Noura Al Shabibi, PHC Pharmaceutical Care Section
- Ph. Maiya Al Mawaali, PHC Pharmaceutical Care Section

Gratitude is extended also to the following Pharmaceutical care service providers in MOH Health Units for their valuable comments and feedback:

- Pharmaceutical Care & Med Stores Dept., Sultan Qaboos Hospital-Salalah
- Pharmaceutical Care & Med Stores Dept., Al Nahdha Hospital
- Pharmaceutical Care & Med Stores Dept., Nizwa Hospital
- Pharmaceutical Care & Med Stores Dept., Sohar Hospital
- Pharmaceutical Care & Med Stores Dept., Sur Hospital
- Pharmaceutical Care & Med Stores Dept., Ibri Hospital
- Pharmaceutical Care & Med Stores Dept., Khasab Hospital
- Pharmaceutical Care & Med Stores Dept., Ibri Hospital
- Pharmaceutical Care & Med Stores Dept., Al Buraimi Hospital
- Pharmaceutical Care & Med Stores Dept., Rustaq Hospital
- Pharmacy & Med Stores Dept. – DGHS, Dhofar Governorate
- Pharmacy & Med Stores Dept. – DGHS, Muscat Governorate
- Pharmacy & Med Stores Dept. – DGHS, Al Wosta Governorate
- Pharmacy & Med Stores Dept. – DGHS, North Sharqiya Governorate
- Pharmacy & Med Stores Dept. – DGHS, South Sharqiya Governorate
# APPROVAL PROCESS

<table>
<thead>
<tr>
<th>Written by</th>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sp.Ph. Sara Al Balushi</td>
<td>Director, Pharmaceutical Care, DGMS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reviewed by</th>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ph. Sumaiyya Al Zaabi</td>
<td>Clinical Pharmacist, Hospital Pharmaceutical Care, DGMS</td>
</tr>
<tr>
<td></td>
<td>Ph. Wala Ahmed Atout</td>
<td>Clinical Pharmacist, Hospital Pharmaceutical Care, DGMS</td>
</tr>
<tr>
<td></td>
<td>Ph. Noura Al Shabibi</td>
<td>PHC Pharmaceutical Care, DGMS</td>
</tr>
<tr>
<td></td>
<td>Ph. Maiya Al Mawaali</td>
<td>PHC Pharmaceutical Care, DGMS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Validated by</th>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ph. Nussaiba Habib Mohd.</td>
<td>Director General of Medical Supplies</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Approved by</th>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dr. Darwish Bin Saif Al Maharbi</td>
<td>The Under Secretary for Administration and Finance</td>
</tr>
</tbody>
</table>
## ACRONYMS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCP</td>
<td>American College of Clinical Pharmacy</td>
</tr>
<tr>
<td>ADR</td>
<td>Adverse Drug Reaction</td>
</tr>
<tr>
<td>APHA</td>
<td>American Pharmacists Association</td>
</tr>
<tr>
<td>ASHP</td>
<td>American Society for Health-System Pharmacists</td>
</tr>
<tr>
<td>BSC</td>
<td>Biological Safety Cabinet</td>
</tr>
<tr>
<td>CACI</td>
<td>Compounding Aseptic Containment Isolator</td>
</tr>
<tr>
<td>CCPD</td>
<td>Center for Continuing Professional Development</td>
</tr>
<tr>
<td>CDC</td>
<td>Central Drug Committee</td>
</tr>
<tr>
<td>CPD</td>
<td>Continuing Professional Development</td>
</tr>
<tr>
<td>C-PEC</td>
<td>Containment Primary Engineering Control</td>
</tr>
<tr>
<td>CPOE</td>
<td>Computerized Prescriber Order Entry</td>
</tr>
<tr>
<td>CSP</td>
<td>Compounded Sterile Preparation</td>
</tr>
<tr>
<td>D&amp;TC</td>
<td>Drug &amp; Therapeutic Committee</td>
</tr>
<tr>
<td>DDI</td>
<td>Drug-Drug Interaction</td>
</tr>
<tr>
<td>DGHS</td>
<td>Directorate General of Health Services</td>
</tr>
<tr>
<td>DGMS</td>
<td>Directorate General of Medical Supplies</td>
</tr>
<tr>
<td>DGPA&amp;DC</td>
<td>Directorate General of Pharmaceutical Affairs &amp; Drug Control</td>
</tr>
<tr>
<td>DGQAC</td>
<td>Directorate General of Quality Assurance Center</td>
</tr>
<tr>
<td>DIC</td>
<td>Drug Information Center</td>
</tr>
<tr>
<td>DUR</td>
<td>Drug Utilization Review</td>
</tr>
<tr>
<td>EDQM</td>
<td>European Directorate for Quality of Medicines and Healthcare</td>
</tr>
<tr>
<td>FEFO</td>
<td>First Expiry First Out</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practices</td>
</tr>
<tr>
<td>HCPs</td>
<td>Health Care Professionals</td>
</tr>
<tr>
<td>HDs</td>
<td>Hazardous Drugs</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>ISMP</td>
<td>Institute for Safe Medication Practices</td>
</tr>
<tr>
<td>LAFH</td>
<td>Laminar Air Flow Hoods</td>
</tr>
<tr>
<td>LASA</td>
<td>Look Alike Sound Alike</td>
</tr>
<tr>
<td>LMW</td>
<td>Low Molecular Weight</td>
</tr>
<tr>
<td>MHRA</td>
<td>Medicines &amp; Healthcare Products Regulatory Agency</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MR</td>
<td>Medication Reconciliation</td>
</tr>
<tr>
<td>MSDS</td>
<td>Material Safety Data Sheet</td>
</tr>
<tr>
<td>MSH</td>
<td>Management Sciences for Health</td>
</tr>
<tr>
<td>NCBI</td>
<td>National Center for Biotechnology Information</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Services</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
</tr>
<tr>
<td>NIOSH</td>
<td>National Institute for Occupational Safety and Health</td>
</tr>
<tr>
<td>OMSB</td>
<td>Oman Medical Specialty Board</td>
</tr>
<tr>
<td>P&amp;P</td>
<td>Policies &amp; Procedures</td>
</tr>
<tr>
<td>POM’s</td>
<td>Patient’s Own Medications</td>
</tr>
<tr>
<td>PPE</td>
<td>Personal Protective Equipment</td>
</tr>
<tr>
<td>PQMT</td>
<td>Pharmacy Quality Management Team</td>
</tr>
<tr>
<td>PRN</td>
<td>Pro Re Nata (When required)</td>
</tr>
<tr>
<td>QMS</td>
<td>Quality Management System</td>
</tr>
<tr>
<td>SOPs</td>
<td>Standard Operating Procedures</td>
</tr>
<tr>
<td>STG</td>
<td>Standard Treatment Guidelines</td>
</tr>
<tr>
<td>TPN</td>
<td>Total Parenteral Nutrition</td>
</tr>
<tr>
<td>UDDS</td>
<td>Unit Dose Distribution System</td>
</tr>
<tr>
<td>USP</td>
<td>United States Pharmacopeia</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

Pharmaceutical Care is the responsible pharmacist’s practice, which provide safe and best available therapy for the patient. It is the professional activity in which the pharmacist, using his knowledge and experience, revealing patients’ needs, set priorities in the treatment process, and takes responsibility for a positive outcome of drug therapy.

Pharmaceutical care is a quality philosophy and working method for professionals within the medication process. It is indispensable for helping to improve the good and safe use of medicines, thus realizing the best possible outcome of medicines for the patient. It contributes to the optimization of outcomes from medicines and the prevention of harm and inappropriate use. This is achieved through the promotion of medication-related health literacy, the involvement and participation of patients in their medications, and the assignment and acceptance of responsibilities in an appropriate manner within the medication process. Together, these factors improve the quality of life of patients and their families, the utilization of resources and help reduce inequalities in healthcare. By increasing the cost-efficiency of medicine use, pharmaceutical care will contribute to efficient and effective consumption of existing resources.

2.0 SCOPE

Outline the main pharmaceutical care services provided by Pharmaceutical Care and Medical Stores Departments in MOH Health Units.

3.0 PURPOSE

To provide an introductory information and brief overview on the responsibilities of the Pharmaceutical Care Departments / Pharmacy and Medical Stores Departments in MOH Health Units.

4.0 DEFINITION

Pharmaceutical care is defined as the direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient’s quality of life. The outcomes sought are:

- Cure of a patient’s disease.
- Elimination or reduction of a patient’s symptomatology.
- Arresting or slowing of a disease process.
- Disease prevention.
5.0  POLICY

5.1  Pharmaceutical Care Department in DGMS and Pharmaceutical Care /Pharmacy and Medical Store Departments in Health Units are delegated to lead and drive safe, effective and efficient health care outcomes through optimal and safe medication use, and advance, support, and integrate the professional practice of pharmaceutical care across the healthcare systems in the Ministry of Health.

5.2  The goal of Pharmaceutical Care is to optimize the patient’s health-related quality of life, and achieve positive clinical outcomes, within realistic economic expenditures.

To achieve this goal:

• A professional relationship must be established and maintained.
• Patient-specific medical information must be collected, organized, recorded, and maintained.
• Patient-specific medical information must be reviewed, monitored, and modified as appropriate
• The pharmacist assures that the patient has all supplies, information and knowledge.

6.0  PROCEDURE / ORGANIZATIONAL STRUCTURES:

6.1  Pharmaceutical Care Department, DGMS

6.1.1  A dedicated central Pharmaceutical Care Department in Ministry of Health has been established in 2015 within the organization structure of the Directorate General of Medical Supplies (DGMS), to ensure that the pharmaceutical care services provided continues to be a progressive division that responds to the existing and emerging pharmaceutical requirements and trends of the Omani health care system.

6.1.2  Pharmaceutical Care Department in DGMS has adopted a Strategic Plan of Action (2017-2020) with the intention to work in partnership with both Pharmacy professionals and other healthcare professionals, to ensure they make the best and safest use of medicines with following main objectives:

• Empowering the Pharmaceutical Care Department to take the lead in critical decisions (e.g. standards of practice, resources and manpower requirements and allocations, job descriptions, etc.).
• Enhance Joint effective collaboration communication between Ministry of Health Hospitals and other Governmental Institutions.
• Expand manpower lines and qualifications of clinical pharmacy services at all Regional Hospitals.
• Develop a high level business policies, procedures and guidelines that will lead the standardization of Pharmaceutical Care and Medication Safety practices across MOH Healthcare Units.
• Develop Key Performance Indicators (KPIs) to monitor compliance with the approved policies and procedures and the standard pharmacy practice.
• Improve implementation of safe dispensing system that ensure appropriate review of prescriptions for Polypharmacy, High Alert & Look Alike and Sound Alike (LASA) medications, Allergy, ADRs, contraindications, duplications etc.

• Development of pharmacist’s professional competency system to keep up to date with developments in different fields of pharmaceutical practices.

• Set up an annual Continuing Professional Development (CPD) programs for pharmacy staff in different pharmaceutical care domain according to the requirements of OMSB.

• Follow up and advance the implementation of efficient unit dose dispensing system (UDS) to in all tertiary & regional hospitals throughout all shifts.

• Boost patient education activities and public health campaigns implemented at organizational, as well as national level.

• Issuance of drug information newsletters highlighting updated pharmaceutical news.

• Participate in periodic field visits to MOH Health Units to identify the gaps in pharmaceutical care and provide guidance and support.

6.2 Pharmaceutical Care & Medical Stores Departments, in Health Units:

6.2.1 Multi-departmental units are delegated within MOH organization structure to supervise and implement pharmaceutical care services provided by the Ministry to enhance the provision of drug therapy and other health related services. These departments are organized as follows:

6.2.1.1 Pharmaceutical Care & Medical Stores Depts, DGHS – in the Governorates:

• Work under the administrative control of the Director General of Health Services, in the respective Governorate.

• Responsible for supervision of implementation of pharmaceutical care services in Local, Wilayat hospitals, Polyclinic and Health Centers as well as private pharmacy institutions, throughout the Governorates.

6.2.1.2 Pharmacy & Medical Stores Departments in Regional Hospitals:

• Work under the administrative control of the Director Generals/ Directors of the Hospitals.

• Responsible for providing specialized pharmaceutical care services in the Regional/ Tertiary Hospitals

• Provide the pharmaceutical services to various consumers, including in-patient, ambulatory care patients as integrated part of patient care program within MOH Mission. Pharmacy & Medical Stores staff coordinated and integrated with other caregiver’s effect improved patient outcomes by preventing or detecting and resolving drug related problems, and utilizing the available resources.

6.2.1.3 Pharmacy & Medical stores in the Extended Health Centers and Health Centers:

• Work under the administrative control of the Director Generals of Health Services in the Governorates.
• The Pharmacy & Medical Stores Department in the Extended Health Centers and Health Centers is providing the pharmaceutical services in the primary health care settings to meet the needs of most of patient population in their catchment areas.

6.3 The Pharmacy services are provided through medical stores, outpatient pharmacy and inpatient pharmacy (in hospitals). In addition, the Pharmacy Departments provides the following:

• Clinical pharmacy services.
• Medication therapy monitoring.
• Preparation of sterile and non-sterile compounding.
• Cytotoxic preparations.
• Unit dose dispensing.
• Patient education and counseling.
• Medication Safety and Quality Management Services.
• Training program and educational activities.
• Drug Information Services.
• Participate in research projects related to pharmaceutical services and therapeutic outcomes etc.
• Participate in Drug & Therapeutic Committees.

7.0 RESPONSIBILITY

Pharmaceutical Care Department, DGMS:

• Standardization of pharmaceutical care in MOH Healthcare Units and developing evidence based policies and procedures.
• Support the ongoing efforts to establish the medication safety program in MOH.
• Development of professional competency system in different fields of Pharmacy practice.
• Participate in setting an implementation of the MOH Five Year Health Development Plans for Pharmaceutical care domain.

Pharmacy & Medical Stores Departments in Healthcare Units:

• Effective implementation of the MOH approved policies and procedure based on the level of health services provided.
• Optimized medication therapy i.e., medication order review, interventions, dispensing, counseling, monitoring, reporting and documenting etc.
• Efficient medication distribution and control, i.e., storage, compounding, packaging.
• Support the provision of CPD activities to develop competencies of pharmacy practitioners.
Pharmaceutical Care & Medical Stores, DGHS:

- Pharmacy practice management in PHC settings as per the approved standards and guidelines.
- Support the provision of CPD activities to develop competencies of pharmacy practitioners.
- Participate in setting and implementation of the MOH Five year Health Development plan for Pharmaceutical care domain in their respective governorates.

8.0 RELATED DOCUMENTS

N/A

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principles of Practice of Pharmaceutical Care (APhA)</td>
<td>APhA Pharmaceutical Care Guidelines Advisory committee</td>
<td>1995</td>
<td>2</td>
</tr>
<tr>
<td>ASHP Statement on Pharmaceutical Care</td>
<td>ASHP Council on Professional Affairs</td>
<td>1998</td>
<td>3</td>
</tr>
<tr>
<td>Pharmaceutical Care– Policies &amp; Practices for a safer, more responsible and cost-effective Health System</td>
<td>European Directorate for Quality of Medicines and Healthcare (EDQM)</td>
<td>2012</td>
<td>62</td>
</tr>
<tr>
<td>ASHP Guidelines for Minimum Standards for Pharmaceutical services in Ambulatory care</td>
<td>Jennifer Askew Buxton</td>
<td>2015</td>
<td>9</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

Orientation process is intended to assist new staff members to adapt to working in the organization and to make that transition as easy as possible. Much of the learning which takes place during this period occurs on-the-job and offers a number of initiatives to support new staff during this induction period. This process is supported by an orientation checklist for systemic implementation and documentation. Some elements of orientation need to occur before staff provide care, treatment, and services. Other elements of orientation can occur when staff is providing care, treatment, and services.

2.0 SCOPE

2.1 All new employees joining the Pharmacy and Medical Stores Departments in MOH Healthcare Units.

2.2 Pharmacy professionals moving from one position to another within the Ministry.

3.0 PURPOSE

3.1 To provide orientation for new employees to the Pharmacy & Medical Stores Departments in MOH Healthcare units about the job responsibilities and tasks required for competent provision of quality pharmaceutical care within the scope of services provided.

3.2 To outline the supports available to new staff during the induction period and the roles and responsibilities of those involved.

4.0 DEFINITIONS

4.1 Orientation: Is a process in which a new employee is introduced to co-workers, and is given information such as working hours, place of work, job responsibilities, performance standards, benefits and facilities, and names of the immediate and other employees.

5.0 POLICY

5.1 All new employees to the Pharmacy and Medical Stores Departments in MOH Health Units shall be properly oriented and trained on their respective assignments within the department. The orientation time frame should be 5 days in PHCs and 10 days in hospitals.

5.2 The completed orientation program should be followed with a structured inclusive in-service training program for three months or when deemed necessary according to the criticality of assigned responsibilities.

6.0 PROCEDURE

6.1 Pharmacy and Medical Stores Department’s new Staffs shall be thoroughly oriented to the department activities, including department layout, policies and procedures, equipment, drug distribution system and patient consideration, such as confidentiality of patient records.
6.2 The departmental assigned training person/coordinator shall orient and document the orientation process of all new personnel.

6.3 The attached New Employee Orientation Checklist (Annex A) shall be customized by each institution based on their scope of specialty to include all essential topics need to be covered.

6.4 New employees shall be provided with the orientation checklist for guidance in completing the tasks. He/She must confirm by signature on the orientation check list on completion of each task.

6.5 The person conducting the orientation in each section must sign also on the Orientation Checklist.

6.6 The new employee should be provided with his individual copy of Pharmaceutical Ethics & Professional Code of Conduct for Pharmacists and Assistant Pharmacists as his own reference. Note: An electronic copy is available also as ready reference in the MOH Oman website. (www.moh.gov.om/en/web/directorate-general-of-medical-supplies/resources)

6.7 On completion of the orientation program the checklist should be handed over by the new employee to the Head of Pharmacy & Medical Store for approval.

6.8 Orientation documentation should be kept with Professional Development and Career Guidance Section with a copy in the employee file.

7.0 RESPONSIBILITIES

Professional Development & Career Guidance Departments:

- Conduct and document the orientation program for all new employees in Pharmacy & Medical Stores.

Heads/Directors of Pharmacy and Medical Stores Departments in Healthcare Units:

- Ensure that all new employees to the Pharmacy & Medical Store departments are properly oriented and trained on their respective assignment.

8.0 RELATED DOCUMENTS:

8.1 Pharmacy Professional Development Policy (MOH-DGMS-PH-03)

8.2 Pharmacy Staff Competency Assessment Policy (MOH-DGMS-PH-04)

9.0 REFERENCES:

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Pharmacy Department ReConnect Staff Orientation Checklist</td>
<td>Pharmacy, NSW Health</td>
<td>2007</td>
<td>4</td>
</tr>
<tr>
<td>Staff Orientation Policy, UCD Human Resources, Dublin Ireland</td>
<td>UCD HR</td>
<td>2013</td>
<td>3</td>
</tr>
<tr>
<td>Hospital Pharmacy Orientation guidelines, NSW-Health, Australia</td>
<td>Joanne Rimington</td>
<td>2016</td>
<td>13</td>
</tr>
</tbody>
</table>
Annex-A

NEW STAFF ORIENTATION CHECKLIST

<table>
<thead>
<tr>
<th>Task</th>
<th>Time Frame</th>
<th>New employee signature</th>
<th>Section Head Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Departmental</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tour of pharmacy department.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Includes:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Outpatient Pharmacy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Inpatient Pharmacy (Hospital)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Medical Store</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tour (and map) of hospital, including the library</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Introduction of staff &amp; their roles.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discussing the duty timings, rosters &amp; on call list.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Receiving and discussing handouts of the organizational structure.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Receiving staff contact details.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discussing values, missions and objectives of the Organization/Department</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orientation about the computer &amp; inventory system</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reading departmental policies &amp; procedures.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discussing departmental statistics &amp; documentations.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MOH Policies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical Ethics &amp; Code of Conduct (Copy to be provided. Electronic copy is also available at MOH website)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CDC and D&amp;TC Term of Reference</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection Control policies &amp; procedures</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The following are the tasks to be covered according to the specialty of each Health unit. Upon completion, each task should be signed off by the new staff and the in-charge of each section.

** The orientation time frame should be 5 days in PHCs and 10 days in hospitals.
<table>
<thead>
<tr>
<th>Task</th>
<th>Time Frame</th>
<th>New employee signature</th>
<th>Section Head Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fire Safety</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incident Reporting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Personnel</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uniform/ Dress code &amp; identification badge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leave regulations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>General Distribution</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dealing with prescriptions / requisitions &amp; Treatment Sheets</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Telephone Practice</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dispensing Procedure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Counseling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Departmental Safety Policy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High alert Medications Policy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Look alike/Sound alike Medications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Handling hazardous Medications Policy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schedules &amp; Restricted Drug Policies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ward Systems in general</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterile &amp; Non-sterile compounding arrangements</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Recall System</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Checking Expiry Dates</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Documentations</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

To be filled by the new staff:
I have completed the above duly signed tasks in the Orientation checklist.

Signature: Date:

To be filled by the Head of Pharmacy / Medical Stores Dept.
The staff has successfully completed the above designated tasks in the orientation program and he/she is recommended for in-service training program.

Signature: Date:
1.0 INTRODUCTION

Continuing Professional Development (CPD) is a holistic multidimensional approach to lifelong learning which is an integral requirement for all health care professionals (HCPs) not only to develop but more importantly to maintain their professional standards. With the rapid expansion of medical knowledge and technology, it is essential for all the health care professionals (HCPs) to update their knowledge in order to maintain their competencies in their specialties and enhance the quality of health care delivered to the patients and community.

CPD focuses not only on advancement in knowledge but also the acquisition and development of essential competencies necessary to provide optimum quality of medical care. Other competencies that enhance professional development may include acquisition of skills in the domains of communication, collaboration, management, health advocacy, research and safety.

The Center for Continuing Professional Development (CCPD) in Directorate General of Human Resources development serve as the central focal point for CPD’s in the Ministry of Health for all Healthcare professionals and other professionals engaged in health care delivery, through continuously updating their knowledge, skills and attitudes in their relative fields of practice.

Oman Medical Specialty Board (OMSB) is the regulatory body responsible for promoting, regulating and accrediting CPD activities for all health care professionals in the Sultanate of Oman. It has created a system designed to help health professional keep abreast of advances in their field, develop better practice systems and demonstrate a commitment to lifelong learning.

2.0 SCOPE

All employed pharmacists and assistant pharmacists in MOH, Health Units

3.0 PURPOSE

3.1 Promote excellence in the quality of health care delivery through the implementation of a standardized accreditation system.

3.2 Ensure that pharmacy staff participate in educational activities which are effective in their practice context.

3.3 Promote CPD practice where all pharmacy staff receive equal opportunities for professional development.

3.4 Demonstrate that all health professionals are committed to life-long learning.

3.5 Provide an ongoing program of in-service training for Pharmacy Staff and other Healthcare providers engaged in the process of medication, procurement, storage, dispensing to foster safe and effective medication use, promotes and maintains competence to improve satisfaction with work role.
4.0 DEFINITION

Continuing Professional Development (CPD): A range of learning activities through which healthcare professionals maintain and develop their knowledge and skills throughout their career to ensure that they retain their capacity to practice safely, effectively and legally within their evolving scope of practice.

Orientation Program: Is a process in which a new employee is introduced to co-workers, and is given information such as working hours, place of work, job responsibilities, performance standards, benefits and facilities, and names of the immediate and other employees.

In-Service Training: On the job training programs that are given to employees during the course of employment.

Accreditation System: A formal system to evaluate the quality of services and competency of organizations, systems, staff, training programs or healthcare facilities.

5.0 POLICY

5.1 The Heads of Pharmacy and Medical Stores and Professional Development & Career Guidance Departments are both committed to carrying out educational, training and development programs for their employees through the contribution of all staff in the achievement of such goals, improving knowledge, patient safety, job performance and the application of new skills on drug therapy and related matters.

5.2 Participation in the OMSB-CPD program is mandatory for all health care providers in Oman. CPD credit points could be one of the criteria to be considered for:

- Annual staff performance appraisals.
- Applying for promotion.
- Applying for any higher studies (Omanis).
- Transferring from one department to another.
- Tenure of service (Omanis).
- Renewal of Contract (Non-Omanis).
- Applying for sponsorship for International Conferences and Courses.
- Renewal of license to practice (Health Care Professional Councils).

5.3 Health professionals exempted from CPD are the following:

- Health care professionals who are registered in training programs.
- Health information management personnel.
- Medical record technicians.
- Medical secretariat technicians.
- Medical equipment and health supervision technicians.

5.4 The Pharmacy and Medical Stores and Professional Development Departments shall also provide orientation and in-service training programs for all new employees and Pharmacy Professionals moving from one position to another within the organization as well as students and interns, to improve their professional competency and skills in pharmacy concepts with corresponding documentation of such activities and attendance.
5.5 Orientation of new employees shall be carried out as per the Pharmacy Staff Orientation Policy (MOH-DGMS-PH-02).

5.6 A structured inclusive in-service training program should be provided for all new employees to the Pharmacy and Medical Stores Departments after completion of their orientation phase. It should be properly designed within the scope of their respective assignments within the department.

5.7 In addition to the Pharmaceutical Ethics & Professional Code of Conduct for Pharmacists and Assistant Pharmacists provided during the orientation phase, the new employees should be provided with their written Job Description & Responsibilities, copies of policies and procedures and standard operation procedures related to their work.

5.8 The performance and competence of new employees should be evaluated after three months and reassessed annually as per Competency Assessment Policy (MOH-DGMS-PH-04).

6.0 PROCEDURE

6.1 OMSB-CPD Registration and Accreditation Process:

6.1.1 Online application for CPD activities must be filled by the organizer and submitted to the Professional Development & Career Guidance Department for approval at least 6 weeks prior to event.

6.1.2 Professional Development & Career Guidance Department reviews the CPD activities submitted. Category I activities are then submitted online by Professional Development & Career Guidance Department to OMSB-CPD office for accreditation; while category II activities are accredited internally by the Professional Development & Career Guidance Department.

6.1.3 The OMSB-CPD office will assigns a credit value to the program considering the information available on objectives; content, educational contact hours, and target audience, expertise of speakers, venue, and scheduling of sessions.

6.1.4 The organizer can then announce the activity once the event is accredited by OMSB-CPD Office, indicating the accreditation status along with the number of credit hours.

6.1.5 The organizers of an activity to ensure documentation of records of attendance of all participants.

6.1.6 The CPD organizer then issues a certificate of attendance to all participants, including the title of the activity, OMSB registration number, name of participant, number of CPD credits and organizing body.

6.2 Earning CPD credit points: To earn OMBS CPD credit points, the participants can combine from a variety of learning activities. The participants are encouraged to select activities based on professional needs identified through his practice area of specialty.

6.3 Reporting Activities

6.3.1 All health care providers who are participating in the OMSB-CPD program are required to maintain a record of their learning activities. The recording of activities can be done online through the website (https://portal.omsb.gov.om/CPD/Index.aspx)
6.3.2 Participants must ensure that all the activities are reported regularly into the CPD website in the credit point portal section. At the end of each year (December), participants are allotted extra time of (4 weeks) to record all their activities for that year. Participants will not be able to report backdated activities beyond the extra time allotted.

6.4 Credit Point System:

6.4.1 Participation in CPD program will be linked to a credit point system. Credit points will be accumulated from each activity the participant attended or was involved in as speaker, moderator, facilitator or organizer.

6.4.2 Depending on the specialty, all health care providers will be expected to acquire minimum credit points within each year of the 3-year cycle in the relevant discipline as outlined in the Table 1. (Annex A).

6.5 Structure Of CPD Learning Activities

All activities are subdivided into two categories (I&II) as outlined in the Table 2. (Annex A)

6.5.1 Category I activities - Formal and highly structured learning activities provided by recognized educational or scientific institutions or professional bodies that are accredited by OMSB or other recognized accreditation bodies.

6.5.2 Category II activities - Self-learning planned activities commonly conducted individually or in groups to address the needs identified by specific specialty or department.

7.0 RESPONSIBILITY

Professional Development & Career Guidance Department:

• Conduct educational, training activities as per the CCPD & OMSB- CPD Programs.

All employees of Pharmacy & Medical Stores Departments:

• Strive to obtain the required credit points within their specialty.

8.0 RELATED DOCUMENTS

8.1 Pharmacy Staff Orientation Policy (MOH-DGMS-PH-02)

8.2 Pharmacy Staff Competency Assessment Policy (MOH-DGMS-PH-04)

9. REFERENCES:

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuing Professional Development in Pharmacy - Journal of the American Pharmacists Association Vol -44</td>
<td>Michael J. Rouse</td>
<td>2004</td>
<td>4</td>
</tr>
<tr>
<td>Continuing Professional Development/Continuing Education in Pharmacy - FIP</td>
<td>Christina J. Cross &amp; Toyin Tofade,</td>
<td>2014</td>
<td>46</td>
</tr>
<tr>
<td>CPD Guidelines for Health Professionals in Sultanate of Oman, OMSB</td>
<td>Oman Medical Specialty Board</td>
<td>2014</td>
<td>41</td>
</tr>
<tr>
<td>Continuing Professional Development (CPD) Manual, MOH Oman</td>
<td>CCPD, DGHRD</td>
<td>2015</td>
<td>202</td>
</tr>
</tbody>
</table>
Annex – A

Table 1:
OMSB CPD program credit point requirements for all health care professionals

<table>
<thead>
<tr>
<th>Professions</th>
<th>Number of CPD credits/category/year</th>
<th>Length of each cycle</th>
<th>Minimum Number of total CPD credits/cycle</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians</td>
<td>25 Category 1 15 Category 2</td>
<td>3 years</td>
<td>75 Category 1 45 Category 2</td>
<td>120</td>
</tr>
<tr>
<td>Dentists</td>
<td>25 Category 1 15 Category 2</td>
<td>3 years</td>
<td>75 Category 1 45 Category 2</td>
<td>120</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>20 Category 1 10 Category 2</td>
<td>3 years</td>
<td>60 Category 1 30 Category 2</td>
<td>90</td>
</tr>
<tr>
<td>Nurses and Midwives</td>
<td>15 Category 1 5 Category 2</td>
<td>3 years</td>
<td>45 Category 1 15 Category 2</td>
<td>60</td>
</tr>
<tr>
<td>Assistant pharmacists</td>
<td>12 Category 1 8 Category 2</td>
<td>3 years</td>
<td>36 Category 1 24 Category 2</td>
<td>60</td>
</tr>
<tr>
<td>Technicians</td>
<td>6 Category 1 4 Category 2</td>
<td>3 years</td>
<td>18 Category 1 12 Category 2</td>
<td>30</td>
</tr>
</tbody>
</table>

Table 2:
Structure of CPD learning Activities

<table>
<thead>
<tr>
<th>Category I activities</th>
<th>Category II activities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Section 1: Structured Learning Activities</strong></td>
<td><strong>Section 4: Other Learning Activities</strong></td>
</tr>
<tr>
<td>a. Large group learning</td>
<td>a. Group learning activities</td>
</tr>
<tr>
<td>b. Institutional activities</td>
<td>b. Departmental activities</td>
</tr>
<tr>
<td>c. Small group learning</td>
<td>c. Self-reported and E-learning</td>
</tr>
<tr>
<td><strong>Section 2: Personal Education Development</strong></td>
<td><strong>Section 5: Personal Learning Projects</strong></td>
</tr>
<tr>
<td>a. Teaching – formal presentation at accredited events</td>
<td>Self-initiated learning events stimulated by practice where an outcome is identified and recorded.</td>
</tr>
<tr>
<td>b. Research – publication in scientific peer reviewed journals and grant proposals</td>
<td><strong>Section 6: Personal Practice Review</strong></td>
</tr>
<tr>
<td>c. Standard setting activities</td>
<td>Activities that assist to review personal performance in relation to a defined standard</td>
</tr>
<tr>
<td><strong>Section 3: Accredited Self-assessment Programs</strong></td>
<td></td>
</tr>
<tr>
<td>a. Knowledge assessment programs</td>
<td></td>
</tr>
<tr>
<td>b. Performance assessment programs</td>
<td></td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

Many organizations including healthcare organizations assess competence prior to hiring staff and assigning responsibilities. Healthcare organizations now realize that periodic competence assessment programs increase the likelihood of effective, appropriate, and safe patient care.

It is important to note that competence is the ability to use essential rather than advanced knowledge and skills. Assessing competence does not necessarily determine if an individual has a high level of knowledge and proficiency. A sound pharmaceutical knowledge base, effective problem-solving, organizational, communication and interpersonal skills, together with an ethical and professional attitude, are essential to the practice of pharmacy.

Measuring performance level may be defined also as a measurable level of accomplishment that reflects the depth of expertise of the individual based on their training and experience. The competency standards describe in generic terms, the knowledge, skills and attributes that are central to pharmacists performing effectively and to an acceptable standard in contemporary professional practice. This allows the competency standards to serve as the external measure of expected performance against which actual performance can be assessed for enhancing the pharmacist’s capacity to contribute to health care.

2.0 SCOPE

All employed pharmacists and assistant pharmacists in MOH Health Units.

3.0 PURPOSE

To outline the competency assessment requirements for the Pharmacy and Medical Stores staff in relation to their job responsibilities.

4.0 DEFINITION

Competence Assessment: Is to assess the ability to use essential knowledge and skills of a person to perform job functions according to defined expectations.

5.0 POLICY

5.1 The organization shall define the required qualifications and competence of those staff who provide care, treatment, and services, and recommend a sufficient number of qualified and competent staff to provide care, treatment, and services based upon its mission and service needed.

5.2 The health unit should provide staff orientation and in-service training to promote safe and effective job performance in accordance with their job responsibilities.

5.3 Pharmacy Staff as appropriate, can describe or demonstrate their roles and responsibilities relative to safety as the human element is the most critical factor in any process, determining whether the right things are done correctly.
5.4 Ongoing education, including in-services, training, and other activities, maintains and improves competence. Staff participation in ongoing in-services, training, or other activities to increase knowledge of work-related issues is obligatory.

6.0 PROCEDURE

6.1 Staff competence to perform job responsibilities is assessed, demonstrated, and maintained periodically. Information used as part of competence assessment may include data from performance evaluations, performance improvement, and aggregate data on competency, as well as the assessment of learning needs, and performance expectations described in the job descriptions.

6.2 Competence can be assessed through written or verbal tests, simulations, observations, or any combination of these methods. Actual on-the-job assessments of daily work are preferred; however, simulated assessments may be necessary.

6.3 Requiring pharmacy staff to be competent in the best interest of patients, he/or she should be able to:

- Review orders and intervene, document & report when necessary.
- Prepare and dispense medications accurately.
- Counsel patients and their families about medications effectively.
- Understand the unique needs of various patient types and age groups.
- Operate equipment properly.
- Handle hazardous materials safely.
- Minimize opportunities for contamination and transfer of infection.
- Respond promptly and properly to medical emergencies and disasters.
- Monitor drug therapy for inappropriate prescribing, allergies, ADR’s, interactions, and contraindications and, when necessary, act accordingly.

6.4 Competency assessment should address the following areas:

- Knowledge, skills, ability to perform job (i.e. medication dispensing, IV admixture, drug information).
- Compliance with safety precautions (i.e. Hazardous Materials, Fire Safety, MSDS).
- Ability to use equipment/software safely and effectively.
- Prevention of contamination and transfer of infection (Infection control).
- Disaster plan (Emergency Management).
- Cardiopulmonary resuscitation and advanced cardiac life support as required by job description.
- Needs of patient age groups (i.e. neonates, pediatrics, adolescents, adults and elderly).
- Needs of patient types served by the hospital (i.e. oncology, obstetric, transplant, cardiac, surgical).
- Confidentiality and patient rights.
• Monitor drug therapy for inappropriate prescribing, allergies, interactions and contraindications and when necessary act accordingly.

• Identification, reporting and preventing of adverse drug events (Adverse Drug Reactions, Medication Errors)

6.5 Competence assessment checklists are to be maintained for competence areas of job responsibilities. The checklists are to be designed to document the assessment of specific elements of competence through tests, simulation, and direct observation. The completed checklist should be retained in the employee’s personnel file.

6.6 Written tests are provided for many competence areas. The tests are designed to assess the basic knowledge that is expected of the employee. They are not intended to quantify the higher level of knowledge expected of a specialist.

6.7 To ensure that performance evaluations are based on standards of performance in job descriptions, templates are to be provided for developing customized job descriptions for pharmacy positions. The format is designed to provide the following functions within a single document:

• Job description.

• Competence assessment summary.

• Performance evaluation.

• Follow-up for performance deficiencies.

6.8 For each staff position and area of assignment, critical tasks—may involve serious consequences if performed incorrectly—critical knowledge base(s) to be identified and evaluated periodically during the assessment process. Each critical task—knowledge base, will also have minimum standards necessary for competent performance.

6.9 Each general competency assessment subject will have predetermined criteria (acceptable standards of achievement). Failure to meet these criteria will require retraining, education, and reassessment until successful completion is obtained.

6.10 Assessment Tools

• Direct Observation: The manual performance aspect of tasks involving manual procedures, techniques, computer software, or equipment operation should be assessed by the direct observation of the pharmacist and by the manager/designee.

• Simulations/Oral Testing: Methods in this category include oral exams, oral queries, and case studies. This may involve an evaluator who asks the employee questions regarding procedural steps, medication order handling, drug information, patient education, etc. Questions may also be in the form of case studies.

• Written Cognitive Testing: Types of questions tend to be multiple choice, true/false, fill-in-the blank and short answer, and may pertain to all assessment areas.

6.11 Assessment Records

• Where direct observation is used, a check-off list of critical steps will be identified and utilized.
• Written and oral tests should be well thought out and established with acceptable answers verified and set prior to use. Every effort will be made to phrase questions carefully and explicitly to avoid ambiguity and multiple possible answers.
• All criteria used to evaluate employees, regardless of methodology, must be written and will be included with other records of competency assessment.
• The Managers/designees are responsible for assuring that all records of competency evaluation are complete and accurate and that the evaluation summary is submitted to the Department Head for final review.
• Records of competency assessment and evaluation are to be maintained in the employee’s personal file.
• A documented corrective action plan is required should a staff member fail to meet the minimum competency criteria. The corrective action plan shall outline the step taken to re-train and re-assess the employee.

7.0 RESPONSIBILITY

Health Units Top Management:
• Conduct periodic competence assessment to ensure that all Pharmacy and Medical Stores staff including the Heads of the sections and Directors of the Departments possess the skills attitude and behaviors necessary to deliver comprehensive medication management.
• Ensure that assessment is assigned to senior staff who have demonstrated competency in the area to be assessed.

8.0 RELATED DOCUMENTS

Pharmacy Professional Development policy (MOH-DGMS-PH-03)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/journal/articles/Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competence Assessment tools for Health System Pharmacists - ASHP</td>
<td>Lee B Murdaugh</td>
<td>2015</td>
<td>700</td>
</tr>
<tr>
<td>Competence Standards for Pharmacy Profession</td>
<td>Pharmacy Council of New Zealand</td>
<td>2015</td>
<td>43</td>
</tr>
<tr>
<td>National Competency Standards Framework for Pharmacist in Australia</td>
<td>Pharmaceutical Society of Australia</td>
<td>2016</td>
<td>112</td>
</tr>
<tr>
<td>ACCP Clinical Pharmacist Competencies</td>
<td>American College of Clinical Pharmacy</td>
<td>2017</td>
<td>6</td>
</tr>
</tbody>
</table>
# Pharmacy Departmental Meetings

**MOH/DGMS - PH/P&P/005/Vers.001**

**Effective date:** 15/01/2019

**Review date:** 14/01/2022

## 1.0 INTRODUCTION

The departmental meetings engage people on areas of their interest and give each team member a voice in topics related to their day-to-day practice and help identify and solve the work related problems on-the-ground through integration of ideas from members. Regularly held, properly run team meetings can help pharmacy staff to solve workflow problems, build positive cooperative relation and improves communication and ultimately improves patient care.

## 2.0 SCOPE

Regular Pharmacy Departmental meetings.

## 3.0 PURPOSE

3.1 Provide a means for the dissemination of information (administrative and clinical) to the Pharmacy & Medical Stores Department staff.

3.2 Development of discussions and consensus and sharing ideas for problem solving and creating stronger bonds between the team members that contribute to improving the pharmacy practice within the institution.

## 4.0 DEFINITION

Departmental meetings: Are meetings that bring all members of the practice in the department together to analyze the way their work is done and take steps to improve their processes.

## 5.0 POLICY

5.1 Each Pharmacy as well as Medical Stores Departments in the Health Units shall conduct a separate weekly brief meeting for their staff for discussion of their own related issues.

5.2 Both Pharmacy & Medical Stores Departments shall conduct joint monthly meetings to discuss management updates and common issues.

## 6.0 PROCEDURE

6.1 The Head of Pharmacy/ Medical Stores shall develop an agenda and meeting notice at least two (2) days prior to monthly meeting dates or as required.

6.2 Agenda and minutes of the routine weekly meeting are not generally required unless the topics covered during a specific meeting are important in the operation of the work and needs to be documented and disseminated.

6.3 Minutes of the monthly meetings will be recorded and made available to the staff.
6.4 Discussion in the monthly meeting may include but will not be limited to the following topics:
   • Policies and Procedures.
   • Operational problems and information.
   • Changes in legalities concerning hospital pharmacy practice or hospital operations.
   • CDC and D&TC decisions updates.
   • Quality Assurance (QA), Performance Improvements (PI) Medication Errors and ADR incidents.
   • Changes in Health Information System.
   • Update on drug protocols.
   • Controlled substance problems.
   • Staffing issues.
   • Infection control.
   • Education and instruction.
   • Drug recalls.
   • Information Technology upgrades and training.

6.5 For Conducting Effective Team Meetings
   • Meet regularly and “on the clock”
     Pick a set the most suitable time to meet during the working day that results in fewer distractions. When possible, the meeting should occur away from the clinical area to minimize interruptions.
     • Provide notice to attendees on these meeting aspects:
       ✓ Date, time and length.
       ✓ Purpose.
       ✓ Location.
       ✓ Agenda.
       ✓ Attendees.
   • Agenda Guidelines
     ✓ Include the objective of the meeting.
     ✓ Allocate time for introductions of attendees (in the first meeting).
     ✓ Put agenda items in order and allocate time to items.
     ✓ Follow up action items in the last meeting and review the status of the actions taken.
   • Agree on ground rules
     To form a supportive, respectful environment for your team meeting, establish ground rules from the beginning to strengthen teamwork. Signing a charter or statement of purpose can help the team connect with the ground rules and their commitment to the group. Some suggestions for ground rules to implement in team meetings are listed below:
Meeting Room: Ensure in advance that the meeting room is appropriately prepared with enough seats.

Start on time, end on time: Come to the meeting on time and ready to work. End on time so that team members grow to trust their commitment.

Be present: Leave devices behind. Don’t check your phone or your laptop during the meeting unless doing so adds to the topic at hand.

Stay on topic and focus on the issue, not the individual: The goal is to work together to improve the work, not to blame or incriminate individual people.

Step up or step back: Step back and let others speak if you’ve been speaking often.

Give thanks: Thank each other for contributing during the meeting and afterward.

• Set a consistent meeting agenda

Many teams use an agenda template to set a consistent agenda for each meeting. Post the meeting agenda ahead of time, either online or on a bulletin board. Allow all team members to write in or submit agenda items online. If there are many items on the agenda you may opt to prioritize the items at the beginning of the meeting.

• Rotate Meeting Roles

Assign a different team member to the roles of the minutes recording for each meeting. This approach can help build team culture and confidence among the staff.

• Solve problems as a group

Team meetings are a time for everyone to actively engage in problem solving to make their collective work better.

• Practice good meeting skills

  ✓ Good habits make meetings more productive.
  ✓ Stay on task.
  ✓ Focus lengthy discussions by identifying important topic items.
  ✓ Avoid side conversations
  ✓ Make a point to respond constructively rather than negatively
  ✓ Maintain respect and understanding for others’ points of view
  ✓ Encourage equal participation so that no one dominates the discussion.
  ✓ One helpful adage to keep in mind is: “If you oppose, you must propose.” That is, if you are opposed to one solution it is helpful to propose an alternative solution.

• Create and distribute a short-written minutes that includes:

  ✓ Meeting date, purpose, attendees.
  ✓ Key points covered.
• Decisions made.
• Action items.
• Persons responsible for action items
• Proposed completion date for actions.

• Recognize your successes

Keep a running list of things the team has accomplished and periodically refer back to it. Share stories of successful achievements particularly about meaningful patient interactions made recently.

7.0 RESPONSIBILITY

Heads/Directors of Pharmacy and Medical Stores Departments in Healthcare Units:

• Plan the appropriate time for departmental meetings in coordination with the staff.
• Nominate a person to record the minutes of each meeting
• Follow up guidelines for running a productive meeting and
• Follow up the implementation of meeting’s recommendations.

8.0 RELATED DOCUMENTS

N/A

9.0 REFERENCE

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducting effective Team Meetings (American Medical Association) (AMA-USA)</td>
<td>Christene Synkie</td>
<td>2015</td>
<td>15</td>
</tr>
<tr>
<td>How to have an effective team meeting</td>
<td>Buffalo Niagra Partnership</td>
<td>2017</td>
<td>6</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

Safety in dispensing and administering pharmaceutical agents is important to prevent personal and patient illness or injury. Personal safety from physical harm require proper dealing with substances, supplies chemicals, poisons, equipment, follow proper procedures in handling pharmaceutical agents that may pose a hazard to the pharmacy staff and patients and know and apply the policies and procedures in case of emergency. Environmental safety measures include clean work place, proper ventilation and lighting.

The Pharmacy hazards should either be removed or, if this is not possible, then its risk should be minimized. This could be achieved by, for example, changing a procedure to a less risky option, preventing access to a hazard, or issuing protective equipment. Pharmacy hazards include:

- Biological agents - Risk of infection.
- Chemical Agents - Risk of Health effects such as poisoning, allergies, dermatitis, cancer or effects on the unborn child.
- Electricity - Risk of Electric shock, Burns, Death, and Fire.
- Ergonomic hazards - Risk of Pain in neck, back or arms & musculoskeletal disorders such as carpel tunnel syndrome.
- Equipment - Risk of Burns, Electricution.
- Ionizing radiation - Risk of Genetic effects, Reproductive effects, Cancer.
- Lone working - Risk of Cuts & Infection.
- Slip, trips and falls - Risk of Physical injury ranging from minor cuts to more serious injuries such as broken bones.
- Violence and aggression - Risk of Physical and/or psychological effects.

2.0 SCOPE

Safety measures related to Pharmacy and Medical stores Departments.

3.0 PURPOSE

3.1 Provide specific guidance and information to department staff regarding safety practices and procedures and necessary precautionary measures to be followed to minimize accidents or injury while performing duties.

3.2 Maintain a safe work place to ensure that the employee, patients and premises are secured and safeguarded.
4.0 DEFINITION
Safety Policy: Is a written statement by an organization stating their commitment for the protection of the health and safety of the employees and to the public.

5.0 POLICY
5.1 All MOH employees are required to adhere to the regulations addressed in the MOH Safety Plan as well as to Departmental Safety Policy, and all other safety related measures.

5.2 All hazardous materials/chemicals shall be classified, labeled, and listed in areas where they are safely stored or used, as per department policy.

5.3 Personnel protective clothing and equipment (gowns, gloves, eye & face protection) shall be readily available for use, where hazardous materials are stored.

5.4 Staff exposed to handling hazardous materials should be trained on how to handle spills and on the appropriate use of the personnel protective clothing and equipment.

5.5 The Event (Incident) Reporting Form must be completed for all safety incidents including hazardous materials and waste spills exposures, and to be sent to the head of the department for review and analysis and further action.

5.6 Material Safety Data Sheet (MSDS) is to be obtained for every chemical stored and identified hazardous. A master file of all (MSDS) shall be kept and made available at the unit for those who are exposed to hazardous materials.

5.7 Eating and drinking is prohibited inside the Pharmacy & Medical Stores. Food stuff should not be kept in the refrigerator.

5.8 Smoking is strictly prohibited in all Pharmacy and Medicals Stores areas including washrooms and all other MOH premises.

5.9 Chairs, stools and cartons should not be used for step ladder in placing or removing the items from shelves.

5.10 All fire exits shall be regularly maintained kept clear and not blocked by cartons or any other objects, staff should know the location of fire extinguishers and the procedures to follow in the event of a fire and drill.

6.0 PROCEDURE
6.1 Key points on safety in pharmacy to be considered are:

6.1.1 Employee safety responsibilities
• Maintain a safe work place.
• Apply principles of proper body mechanics.
• Wear appropriate Personal Protection Equipment (PPE) when indicated.
• Follow proper procedures in handling pharmaceutical agents that may pose a hazards.
• know and apply the policies and procedures in case of emergency.
• Strengthen mechanisms to support health personnel to practice safely.
6.1.2 Environmental safety:

- Clean work place.
- Proper ventilation & lighting.
- Adequate set-up and layout of work place.
- Proper functioning equipment.
- Promote a culture of reliability and safety through redesign of systems and processes of care.
- Optimize the work environment e.g. reduce noise and change shifts to reduce worker fatigue.

6.1.3 Pharmacists are trusted by patients to:

- Provide accurate and competent service.
- Safe and effective medications.
- Dispense according to prescriber’s directions.

6.1.4 Pharmacists must ensure:

- Right drug,
- Right patient,
- Right dosage,
- Right route,
- Right time, and
- Right attitude.

6.2 The main safety standards to be followed:

6.2.1 The Governance Arrangements:

- The risks associated with providing pharmacy services are identified and managed.
- The safety and quality of pharmacy services are reviewed and monitored.
- Pharmacy services are provided by staff with clearly defined roles and clear lines of accountability.
- All necessary records for the safe provision of pharmacy services are kept and maintained.
- Information is managed to protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services.
- Health unit staff and patients are safeguarded.

6.2.2 Staff Empowerment:

- Availability of enough staff, who are suitably qualified and skilled, for the safe and effective provision of the pharmacy services provided.
• Staff have the appropriate skills, qualifications and competence for their role and the tasks they carry out, or are working under the supervision of another person while they are in training.

• Staff can comply with their own professional and legal obligations and are empowered to exercise their professional judgement in the interests of patients and the public.

• There is a culture of openness, honesty and learning.

• Staff are empowered to provide feedback and raise concerns about meeting these standards and other aspects of pharmacy services.

6.2.3 The environment and condition of the premises:

• Premises are safe, clean, properly maintained and suitable for the pharmacy services provided.

• Premises protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services.

• Premises are maintained to a level of hygiene appropriate to the pharmacy services provided.

• Premises are secure and safeguarded from unauthorized access.

• Pharmacy services are provided in an environment that is appropriate for the provision of healthcare.

6.2.4 Management of medicines and medical devices:

• The pharmacy services provided are accessible to patients and the public.

• Pharmacy services are managed and delivered safely and effectively.

• Medicines and medical devices are obtained from a reputable source, safe and fit for purpose, stored securely, safeguarded from unauthorized access, supplied to the patient safely and disposed of safely.

• Concerns are raised when it is suspected that medicines or medical devices are not fit for purpose.

6.2.5 The equipment and facilities

• Equipment and facilities needed to provide pharmacy services are readily available.

• Equipment and facilities are obtained from a reputable source, safe to use and fit for purpose, stored securely, safeguarded from unauthorized access and appropriately maintained.

• Equipment and facilities are used in a way that protects the privacy and dignity of the patients and the public who receive pharmacy services.

6.3 General Good Storage Guidelines:

• Do not store any product directly on the floor, use pallets or other means of storage.
• All chemicals shall be stored in a separate place on low shelves, and in the original labeled container.

• Always inspect chemical containers for cracks or leaking caps in the storage area or during receiving or issue.

• Large amounts of strong chemicals shall be stored just above floor, smaller bottles that stored on shelves must be kept back from the edge and lip of restrainer should be at the shelf edge.

• Incompatible chemicals should be kept separately.

• All materials considered as fire hazard (flammable) should be stored in a cold dry place, well ventilated and away from areas of fire hazards, and shall also be kept away from oxidizing agents (materials susceptible to spontaneous heating, explosives, etc.).

• Oxidizers shall not be stored close to liquids of low flash point.

• Sensitive material such as acids and acid-fumes shall be stored in a cool dry, well-ventilated area, preferably wooden.

• Materials which are toxic or which can be decomposed into toxic components from contact with heat, moisture, acids, or acid fumes shall be stored in a cool, well-ventilated place, out of the direct rays of the sun. Incompatible toxic materials will be isolated from each other.

• Corrosive materials will be stored in a cool ventilated area (above their freeze point); should be isolated from other materials.

• Double check the container’s label when obtaining the medication/ chemicals from shelves, when filling the order, and when replacing the stock bottle.

• To protect the label of chemicals, pour from the side of the bottle opposite the label and pour below eye level to avoid splashing and possible eye injury.

• Do not combine the contents of partially used medication bottles.

• Cytotoxic drugs and biohazardous materials should be handled and disposed of according to approved policy of safe handling of High Alert and Hazardous Drugs.

• Unit dose packaging machine, compounding machines counting trays, etc. must be completely cleaned after use.

6.4 Management of Chemical/Waste Spills:

• Spill kits shall be available where hazardous material are stored or used, and staff is trained on how to handle spills.

• If a leak or spill is found, the following actions should be taken:
  ✓ Identify the chemical before attempting to clean up any hazardous chemical spills
  ✓ Obtain Material Safety Data Sheet (MSDS) on chemical, and apply the procedures for cleaning up that kind of chemical leak, or chemical spill.
  ✓ Alert people in the immediate area of spill.
Evacuate all personnel from the area and close all doors.
Ensure adequate ventilation.
Wait by the spill area in a safe distance, until assistance arrives to provide guidance to the Safety Officer.
Complete the Incident Reporting Form for spill or leak.

6.5 Fire Safety:
- All pharmacy employees are required to attend the fire and safety classes.
- Firefighting equipment should be kept at the storage areas and to be serviced regularly.
- When using electrical equipment, operate machinery in accordance with the manufacturer’s recommendations.
- Effective fire drills shall be conducted periodically and documented, including an evaluation of the drill and the corrective action recommended or taken for any deficiency found.
- All personnel should be trained to perform assigned tasks and should be familiar with the location of fire extinguishers and emergency exits within the pharmacy.
- Pharmacy personnel should be aware of the need for constant attention to the electrical safety aspects of the apparatus they use. They can look for cracks in power cord insulation, broken receptacles and plugs, etc. and report such deficiencies to the proper authorities.
- Any electrical equipment suspected as being faulty will be removed from service until approved by the Biomedical Department for use.

6.6 Pharmacy Accidents:
- The person(s) involved shall be referred to the Emergency Department urgently for appropriate treatment.
- Don’t move injured body part. In case of back or neck injury don’t move the injured person and call the emergency personnel.
- In case any staff’s eyes contact with chemicals, there’s in the Pharmacy Department a sink available for eye washing.
- An accident report shall be filled and referred to the Health Unit Director as per regulation inforce.

6.7 Disposal of Pharmacy Material:
- All sharps, including hypodermic needles and syringes, suture needles, knife blades, trocars from drains and opened glass ampoules of medicines will be disposed of into puncture-resistant sharp containers.
- Broken and chipped glassware will be discarded in heavy cardboard containers for disposal.
- Broken glassware will be swept up by using the broom, brush and dust-pan and placed in a large “Sharps” bin.
• Non-contaminated materials from the pharmacy will be placed in a waste containers lines with plastic bags. This material will be removed daily by the Housekeeping Department.

7.0 RESPONSIBILITY

Heads/Directors of Pharmacy and Medical Stores Departments in Healthcare Units:
• Ensure that a safe work environment as per the safety standards is in place.
• Ensure that all pharmacy personnel are appropriately trained to deal with pharmacy hazards.

All employees in the Pharmacy & Medical Stores Departments:
• Shall strictly adhere to the safety regulation, standards and protective measures.

8.0 RELATED DOCUMENTS

8.1 Pharmacy Quality Management (MOH-DGMS-PH-09)
8.2 High Alert Medication (MOH-DGMS-PH-35)
8.3 Handling of Hazardous Drugs (HDs) (MOH-DGMS-PH-37)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety in the Pharmacy, Texas Education Agency</td>
<td>Texas Education Agency</td>
<td>2013</td>
<td>13</td>
</tr>
<tr>
<td>Pharmacy Hazards – Health &amp; Safety Authority</td>
<td>H&amp;SA, USA</td>
<td>2018</td>
<td>3</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION
Pharmacy staff must strongly exercise their responsibilities in preparing for and responding to an emergency or disasters by participating in the full range of issues related to medical supplies. This policy should be used in conjunction with existing MOH emergency operations plans, procedures, guidelines, resources, assets, and incident management systems. This policy is not a substitute for the MOH emergency and crisis preparedness & planning policies.

In developing an emergency or disaster preparedness and response plan, the emergency planning team should evaluate the probability or risk that specific disasters or emergencies may impact the services provided. Threats could include both natural and man-made, ranging from floods and power outages to technological threats etc.

2.0 SCOPE
Emergency or disaster situations in the Sultanate necessitating the involvement of healthcare system.

3.0 PURPOSE
3.1 Enhances the capacity of the Pharmacy & Medical Stores Departments and the overall health care system to prevent, prepare for, respond to, and recover from the adverse health effects of public health emergencies and disasters.

3.2 Provide specific guidelines and information to the staff of Pharmacy & Medical Stores Departments on practices and procedures to be followed in the event of an emergency or disaster such as outbreaks, floods, hurricanes, earthquakes, and acts of terrorism and war, these guidelines aim to:

- Ensure the safety of staff and customers
- Maintain the supply of dispensed medicines to patients
- Speedily restore the pharmacy services.

4.0 DEFINITION
Emergency preparedness and response: Is a continuous cycle of planning, organizing, training, equipping, exercising, evaluating, and taking corrective action in an effort to ensure effective coordination to prevent, protect against, quickly respond to, and recover from health emergencies, particularly those whose scale, timing, or unpredictability threatens the routine capabilities.

Response: Mobilizing and activating the Emergency Plan
Recovery: Actions to recover and return to business as usual, and to review the Plan.
5.0 POLICY

5.1 DGMS shall stockpile sufficient quantities of life-saving drugs and vital medical consumables in the Strategic Reserve Store at Bausher, to cover the needs of MOH health units for 2-4 months based on the criticality and the shelf-life of the items.

5.2 DGMS shall ensure that the DGMS Emergency Preparedness & Crisis Management Plan and pharmaceutical components of the institutions emergency plans are coordinated with overall MOH preparedness plan.

5.3 An Emergency Action Plan report should be maintained regularly as per the attached report as guidance. (Annex-A)

5.4 All employees are required to adhere to the regulations addressed in the Ministry wide Emergency Preparedness Plan (EPP) and to follow all other related departmental emergency and safety and security policies and procedures.

5.5 Health Units should maintain a generator back up connected to fuel tank with sufficient capacity to operate the top priority medical departments and cold rooms and refrigerators, preferably for one month in case of power outage.

5.6 Refrigerated drugs and medical supplies shall be moved to alternative cold storage facilities as appropriate in case of cold chain failure.

5.7 The level of ground floor in the medical stores should be high enough at least two meters above the ground to avoid entry of water during heavy rains, floods and hurricane.

6.0 PROCEDURE

6.1 Emergency Preparedness plan

6.1.1 In developing a forceful emergency or disaster preparedness and response plan, the emergency planning team should evaluate the probability or risk that specific disasters or emergencies may impact the pharmacy and medical supplies.

6.1.2 Pharmacy & Medical Stores Department responsibilities within Emergency Preparedness Plan include:

- Develop and implement an emergency preparedness operations plan for management of medical supplies specifically for the pharmacy and medical stores department;
- Prepare emergency call list of focal points and their telephone numbers and distribute to the Administration, Medical Departments and Pharmacy & Medical Store Department and posting the same in the hospital announcement board;
- Quickly act and efficiently in emergencies and disasters during the acute phase, intermediate and the recovery;
- Manage pharmaceutical assets of the Health Units;
- Establish communications with key health and medical organizations;
- Engage pharmacists to serve special populations following a disaster;
- Maximize appropriate use of medication for management of chronic medical conditions.
• Use intact pharmaceutical supply chains to assist local and nearby disaster response teams, when possible.

• Coordination with Central & Regional Medical Stores, Directorate General of Medical Supplies (DGMS) and the nearest Health Units as required.

• Participate in mass dispensing of medical supplies & vaccines.

• Ensure the quality and accessibility of health services.

• Develop program for utilization of mobile pharmacy if needed.

• Extend pharmacy hours during disaster and recovery.

• Document all response activities during the emergency incident.

• Collect and analyze data that are becoming available through health surveillance.

• Review and update the preparedness plan annually whenever needed.


6.2.1 The Head of Pharmacy & Medical Stores or his designee is responsible for communication with DGMS and the Emergency Control Center in the Health Unit to implement and monitor the effectiveness of pharmacy activities during the activation of the Emergency Preparedness Plan.

6.2.2 The Pharmacy & Medical Stores Department staff will be briefed about the overview of the emergency situation, the types and number of patients expected and anticipated drugs and services requirements.

6.2.3 The Head of Pharmacy & Medical Stores shall activate the Pharmacy emergency or disaster response plan, place the pharmacy and medical stores members on “standby;”

6.2.4 Upon activation of a building fire alarm system, or drill notification, the staff shall evacuate the building immediately or to seek a temporary protective shelter inside the building (Assembly Area) as per the pre-planned evacuation drill plans.

6.2.5 If it is necessary to evacuate due to an emergency, fully cooperate with Safety and Security/emergency personnel and:

• Take only keys, wallets and essential belongings with you

• Leave the building immediately

• Use stairs, not elevators

• Assist people with special needs

6.2.6 The Fire Extinguisher may be used only by trained staff when there is little smoke or flames and the staff must evacuate immediately.

6.2.7 Relocation Plan may be short term, but if the main premises are damaged then expect the relocation to be for weeks if not months. A suitable potential premises to operate a pharmacy at the new location is to be pre-determined.

6.2.8 Pharmacists can play a vital role in educating their patients to plan for emergencies. You can advise your patients to:
• Keep an up-to-date list of their medications, including dose and indicated use.
• Obtain early refills if they anticipate access to their pharmacies will be disrupted.
• Have ice available for medications that need refrigeration.

6.2.9 In situations where lifesaving drugs have been exposed to water and replacements are not readily available, the drugs may be used if the container is contaminated but the contents appear unaffected. However, when replacement drugs become available, the drugs that may have become contaminated should be immediately discarded.

6.2.10 For drugs that have to be reconstituted, only bottled water should be used when clean tap water is unavailable. Liquids other than water should not be used to reconstitute these products.

6.2.11 If electrical power has been off for a long time, refrigerated drugs should be used or discarded as per manufactures instructions. However, if the drug is absolutely necessary to sustain life (insulin, for example), it may be used until a new supply is available.

6.2.12 Many medical devices require specific storage conditions. The manufacturer’s instructions, in the product labeling will explain specific needs for refrigeration, freezing, or controlled room temperature. If the power goes out do not open refrigerators or freezers until the power is restored. Most refrigerators and freezers will maintain their temperatures for at least one day if they have not been opened. If you must remove products from a refrigerator or freezer, keep the products on ice or dry ice at the required temperature until use.

6.2.13 The majority of reagents used for laboratory testing are temperature sensitive, with most requiring routine refrigeration. A small subgroups of materials require freezer, or below freezer-level conditions (ranging from freezing to 70 degrees below freezing). Run control solutions to determine whether or not your reagent is still potent. See also product labeling/manufacturer’s instructions for specific storage temperature information.

6.2.14 When the power is restored measure the temperature of the refrigerator or freezer. If you are not sure whether or not a product is safe to use, send an incident report to DGMS to run quality control checks and contact the manufacturers when necessary.

6.3 Recovery Plan

6.3.1 The Pharmacy should continue the efforts that began immediately following the disaster depending on the disaster, the recovery plan may be as short as up to 30 days or as long as 12 months.

6.3.2 Recovery actions is an extension of service which can begin as soon as the incident is under control. These actions include working to speedy restore and maintain critical pharmacy operations, sustaining communications with important stakeholders. A prompt and efficient recovery will have a positive impact on the business.

6.3.3 A general recovery plan prepared before an incident can be adapted during the event much more efficiently than trying to start from scratch while the team is trying to respond to the incident.
6.3.4 A situation analysis report including damage assessment of the building, including supplies and utilities to be sent to the relevant coordinating organizations like Health Unit administration and DGMS.

7.0 RESPONSIBILITY

Directorate General of Medical Supplies.

- Quickly act and efficiently in emergencies and disasters.
- Maintain a regular supply of vital and essential medical supplies throughout the emergency phases.
- Developing and maintaining an Emergency Contact List for local agents and pharmaceutical manufacturers to facilitate acquisition of urgent emergency supplies when needed.

Heads of Pharmacy and Medical Stores Departments in Healthcare Units:

- Creating an emergency and disaster preparedness and response plan specifically for the health unit.
- Ensure that all pharmacy personnel are trained to implement the institution’s Emergency plans.
- Quickly act and efficiently in emergencies and disasters

8.0 RELATED DOCUMENTS

8.1 MOH Emergency Preparedness Plan
8.2 Health Unit Emergency Preparedness Plan

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/journal/articles/Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASHP Statement on the Role of Health System Pharmacists in Emergency Preparedness</td>
<td>Council on Pharmacy Practice, ASHP</td>
<td>2013</td>
<td>2</td>
</tr>
<tr>
<td>Strategic Reserve Store Policy for Management of Medical Supplies</td>
<td>DGMS, MOH Oman</td>
<td>2015</td>
<td>40</td>
</tr>
</tbody>
</table>
## Annex-1

### Emergency Action Plan Report

<table>
<thead>
<tr>
<th>Sr.</th>
<th>Situation / Issue</th>
<th>Recommendations</th>
<th>Action Taken by the Pharmacy &amp; Medical Stores Department in response to the emergency situation</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Update the staff as information comes available from the Emergency Operations Centre</td>
<td>Regular updates</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Activation of emergency or disaster response plan</td>
<td>• Place the pharmacy and medical stores members on “standby;”         &lt;br&gt;• The pre-prepared and distributed list of focal points should be available.   &lt;br&gt;• Quickly act and efficiently in emergencies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Assess safety of all persons</td>
<td>• Maintain sufficient PPE                                                  &lt;br&gt;• Set up infection control measures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Availability of essential medical supplies</td>
<td>• Maintain sufficient stock of essential items before the emergency.   &lt;br&gt;• Coordinate with DGMS or nearest health unit in case of shortage.     &lt;br&gt;• Review operation of pharmacy and identify immediate needs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sr.</td>
<td>Situation / Issue</td>
<td>Recommendations</td>
<td>Action Taken by the Pharmacy &amp; Medical Stores Department in response to the emergency situation</td>
<td>Dates</td>
</tr>
<tr>
<td>-----</td>
<td>-------------------</td>
<td>----------------</td>
<td>------------------------------------------------------------------------------------------------</td>
<td>-------</td>
</tr>
</tbody>
</table>
| 5   | Assessment of building damage and operational status of building and essential equipment. | • Total or partial evacuation of building may be required  
• Decide if pharmacy needs to relocate and if so initiate the Relocation Plan.  
• Manage pharmaceutical assets of the Health Units  
• In floods the level of ground floor in the medical stores more than meters | | |
| 6   | Power failure effect on refrigeration, Lighting, heating and Computer failure i.e. inventory managements | • Follow the guidelines for refrigerated items  
• A generator back up connected to fuel tank with sufficient capacity is to be maintained. | | |
| 7   | Loss of water, gas, sewage | • Consider relocation if warranted Health and safety breaches  
• Arrange use of neighbouring toilet facilities | | |
| 8   | Incidents documenting and reporting | • Commence incident reporting.  
• Quarantine the affected medical supplies until they can be assessed for safely or destruction  
• Photograph and document damage for later insurance claim. | | |
| 9   | Situation Analysis Reports | • Situation analysis report including damage assessment of the building, and medical supplies and utilities to be sent to the Head of the Health Unit and DGMS including lessons learned and the recommended preventive and corrective actions | | |
1.0 INTRODUCTION

Rostering has the potential to solve a number of workforce challenges. Effective rosters take into consideration factors such as patient need, staff needs, organisational needs, the workforce and skills required to deliver services and workforce availability. Rostering is therefore, a pivotal function in healthcare delivery, as it is a mechanism which ensures that staffing resources are appropriately allocated in order to provide a high quality and efficient health service.

The workforce, its availability and how it is deployed, is affected by many factors. Service transformation, national policy, local care needs and staff supply all evolve and all impact workforce deployment. It is therefore essential that organisations continue to re-evaluate the rosters over time to ensure it is used to reflect the changing needs of services and the organisation.

2.0 SCOPE

All concerned Pharmacy & Medical Staff in MOH Health Units

3.0 PURPOSE

3.1 Maintain and operate fair and consistent pre-scheduled rosters that meet patient, staff and organizational needs and improve the utilization of existing staff.

3.2 Provide on-call services to ensure continuity of operations in the pharmacy and facilitate problem solving during hours when the pharmacy is closed.

4.0 DEFINITION

4.1 Pharmacy Duty Roster: Is a list of pharmacy staff members indicating the times they are scheduled to work during a specific period (e.g. weekly/ Monthly).

4.2 Duty Rostering: Is the task of creating a duty roster.

5.0 POLICY

5.1 Rosters must ensure that there are sufficient and appropriately skilled staff rostered to work, in order to provide appropriate patient care and to meet anticipated service demands.

5.2 Rosters must conform to relevant regulatory frameworks and specialty health networks’ policies.

5.3 Rostering processes should ensure staff are rostered fairly, while still providing appropriate flexibility to facilitate meeting unit staffing needs.

5.4 Rosters must make appropriate provision for adequate staff supervision, training and clinical handover.
5.5 The organisation must have appropriate governance structures in place to oversee roster planning, creation, approval, monitoring and reporting.

5.6 Rostering practices in the health institutions are based on co-operation between rostering managers and staff, in order to promote fairness in rostering and to deliver appropriate care to patients.

5.7 The compensation for after duty shifts i.e. Off duty hours should be provided, as per the applicable regulations.

5.8 Employees are responsible for ensuring their commitment and adherence to the formally approved roster list, and are expected to make all reasonable efforts to support effective rostering shifts.

6.0 PROCEDURE

6.1 The Roster List should be prepared and approved by the Head of Pharmacy / Medical Stores Department in the Hospitals and Primary Health Care settings in coordination with the staff in the light of service needs. The equity for staff members with active participation of pharmacists in shifts after duty hours must be taken into account in the roster.

6.2 The roster list/on-call list should contain, mobile number, and any other telephone number where the individual may be reached.

6.3 In Health Units where the Pharmacy is closed after normal duty hours and holidays, the pharmacy will continue to provide on-call Pharmacist & Assistant Pharmacists coverage during off duties. Clinical Pharmacists will be scheduled also for on-call, as needed, to provide clinical services.

6.4 Apart from pharmacy on-call coverage, a 24 hour on-call clinical pharmacy coverage to be established to address clinical pharmacy queries after working hours or during weekends.

6.5 The Head of Pharmacy & Medical Stores or the Pharmacist/Asst.Pharmacist shift Incharge has the authority to make the decision to contact and/or call back the on-call Clinical Pharmacist/ Pharmacist/ Assistant Pharmacists when deemed necessary.

6.6 Senior Pharmacy staff and other staff who are crucially involved in critical or vital responsibilities during the normal working hours may be exempted from inclusion in the roster list, subject to the decision of Head of Pharmacy/ Medical Stores, except when they are specifically required to be available during holidays.

6.7 Consideration should be given to flexible working, however, this needs to be fair and equitable to all staff and should be regularly reviewed.

6.8 In areas where the workload is known to vary according to the day of the week staff numbers and skill mix should reflected in the list.

6.9 Staff may be required to work a variety of shift patterns. All staff if required to do so should work nights, unless exempted by prior agreement with their department manager based on a valid reason. If there is a valid reason this must be reviewed on monthly basis and documented.

6.10 Shifts with a high priority must be filled first, i.e. nights and weekends or locally recognized high priority shifts e.g. National Holidays.
6.11 Roster list should be circulated seven days before the next roster is primed to enable any last minute requests. A copy of the roster is to be printed for all staff to view preferably one week prior to the roster start date. This will enable staff to better manage their personal arrangements.

6.12 Daily staffing adjustments to the Rota should be kept to the minimum and follow best practice utilization of staff with close monitoring to identify deficiencies, sickness and absence.

7.0 RESPONSIBILITY

Heads/Directors of Pharmacy and Medical Stores Departments in Healthcare Units:

- Develop, approve, disseminate and follow up the execution of the monthly rosters and on-call lists in coordination with the other concerned staff.

All Pharmacy & Medical Stores Staff:

- Adhere strictly to the roster and On-call list.

8.0 RELATED DOCUMENTS

N/A

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good Practice Guide: Rostering – NHS</td>
<td>Lyn McIntyre</td>
<td>2016</td>
<td>26</td>
</tr>
<tr>
<td>Nurse Rostering Policy – Royal U. Hospital, NHS</td>
<td>Elizabeth Cowdrey</td>
<td>2016</td>
<td>22</td>
</tr>
<tr>
<td>Principles of Rostering – Rostering Best Practices</td>
<td>NSW Government</td>
<td>2018</td>
<td>3</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

Pharmacy Quality Management System (QMS) provide key performance benchmarks, raise the bar on quality improvement efforts, and support patient protection and empowerment. It facilitates the approach to the accreditation process and leading to improved operations and regulatory compliance activities.

Pharmacists are responsible for delivering numerous products and services, enhancing patient safety and ensuring that pharmacy practices are both efficient and effective. In addition, a focus on continual improvement is required to identify and manage all risks in the practice setting. A Quality Management System (QMS) assures the effective management of quality in pharmacy practice, enables the organization to establish goals for its critical operations and provides a means for measuring the performance in each area, encourage customer satisfaction, ensure compliance with regulatory requirements as well as internal and external standards and adds value for the pharmacy and its patients and enables pharmacists to meet the ever increasing demands for better services.

Directorate General of Medical Supplies (DGMS) has successfully implemented Quality Management System and acquired ISO 9001:2008 certification in February 2011 and upgraded to the latest version ISO 9001:2015 in February 2018 that is valid up to February 2020.

Organizations that have implemented an efficient and effective QMS have realized several benefits. The top five benefits are improvements in:

- **Organizational effectiveness.** A QMS enables the organization to establish goals for its critical operations and provides a means for measuring the performance in each area.

- **Customer satisfaction.** A QMS encourages customer feedback from multiple sources and the information is used to improve the delivery of products and services.

- **Compliance.** Pharmacies have to comply with regulatory requirements as well as internal and external standards. These can be integrated into the functional QMS and compliance can then be monitored through management reviews, audits and corrective and preventive actions.

- **Organizational culture.** A QMS facilitates the development of a quality culture and creates an environment and a sense of belonging where the staff can take pride in their work.

- **Documentation.** A QMS facilitates the management of documentation so that relevant documents are made available to those who need them.
2.0 SCOPE
Vital processes and activities performed in Pharmacy & Medical stores Departments in Healthcare Units.

3.0 PURPOSE
Regularly and systemically examining, monitoring, and improving core pharmacy and medical stores workflow and processes, which can potentially eliminate sources of inefficiencies, suboptimal quality of care and services to patients, and enhance operational excellence.

4.0 DEFINITION
Quality Management System (QMS):

4.1 A measurement and assessment system designed to regulate variations in equipment, procedures, processes, or evaluations.

4.2 Management of processes & programs within health care institutions that focuses on improving patient care, patient safety, patient satisfaction, resource utilization, and ancillary services.

5.0 POLICY
5.1 The Pharmacy and Medical Stores Departments in all MOH Health Units shall implement an ongoing quality management program to monitor, evaluate and assure quality services in the department in coordination with Quality Management & Patient Safety Departments. The program shall be integrated in the Ministry of Health / Health Unit overall quality management systems.

5.2 The Head of Pharmacy and Medical Stores has to establish a dedicated “Pharmacy Quality Management Team” (PQMT) that responsible for implementation of the Pharmacy Quality Management System in the Department. The team may be composed of the the following based on the organization structure:

- The Head of the Department of Pharmacy & Medical Stores.
- The incharge of the outpatient pharmacy.
- The incharge of the inpatient pharmacy (in hospitals).
- The incharge of medical stores.
- Medication Safety Officer (MSO).
- Quality Management coordinator.

5.3 The Pharmacy Quality Management Team (PQMT) shall be responsible for:

- Develop, coordinate, implement and review departmental quality management system plan.
- Promote and maintain a values-based departmental culture committed to caring through excellence that supports continuous quality improvement.
- Enhance operational excellence including clinical outcomes, financial outcomes and patient satisfaction.
• Conduct periodic internal audits in the Pharmacy & Medical Stores premises in coordination with the Quality Management & Patient Safety Department. Audit checklists are attached herewith as guidance. (Forms A, B, C & D)
• Monitor the implementation of approved policies and procedures, external standards and/or references for benchmarking performance.
• Utilize assessment activities as the basis for developing and implementing action plans responsive to findings.
• Communicate results of quality improvement activities to and across all levels of the department and the Director/ Key departments in the Health Unit.
• Leadership by evaluating the effectiveness of staff to promote safety and quality through Performance Planning and Evaluation.

5.4 All Pharmacy staff are required to report medication and non-medication incidents in the Health Unit Incident Reporting System. Process for reporting, investigating and conducting root cause analysis of incidents and Corrective and Preventative Action (CAPA) and documentation.

6.0 PROCEDURE
The following are general guidelines for processing a Quality Management System in pharmacy departments.

6.1 The basic requirements to be fulfilled in the QMS are:
• Periodic Internal Audits.
• Key Performance Indicators (see the recommended KPIs in point 6.2 below).
• Periodic Customer Satisfaction Survey e.g. annually.
• Customer complaints handling.
• Non conformance identification and corrective actions.
• Risk assessment and mitigation.
• Training and skill Competence.
• Vendor Performance Evaluation (by medical stores).
• Management Review Meeting.

6.2 Key Performance Indicators (KPI) may include:
• Life saving and emergency medications availability.
• Medication Errors rate.
• High-Alert Medication / Look alike Errors rate.
• Adverse Drug Reactions.
• Expired, spoiled drugs
• Medication Dispensing Discrepancies.
• Dispensing time.
• Interventions.
• CPD activities.

6.3 Operational Areas of Importance in the OMS include:

• Has policies and procedures in place to ensure consumers have access to appropriate drugs/medications.
• Has policies and procedures in all important aspects of pharmaceutical care that ensure adherence to medication safety protocols.
• Availability of Standard Operating Procedures (SOPs).
• Maintains methods to measure customer satisfaction.
• Protects consumer health information.
• Follows a well-defined quality management, maintenance, and reporting system.
• Meets the standard performance measures for accuracy and turnaround time of dispensed prescriptions.
• Has a patient-centered strategy for its patient management program that includes coordination of care, communication and education, patient rights and responsibilities.
• Ensures the timeliness and performance of customer service center operations, including time to answer telephone inquiries.
• Reports mandatory performance measures, internal audits results to the top management and more.

6.4 Areas of the pharmacy that will be reviewed as part of the department’s quality assessment plan include (but are not necessarily limited to):

• In-Patient medication dispensing activities.
• Clinical activities (Intervention, drug interaction screening, D&TC meetings, etc.)
• Out-Patient Medication dispensing activities.
• Medication errors and ADVs detection, managing, documenting and reporting.
• High Alert, look Alike/Sound Alike, Hazardous drugs and drug recall measures.
• Storage conditions e.g. cold chain, temperature daily monitored and documented.
• Surveillance, prevention and control of infection.
• Provision for drug information.
• Handling and control of controlled substances.
• Instrument preventive maintenance and safety assessments Calibration.
• Patient/family education.
• Patient confidentiality.
• Patient satisfaction.
7.0 RESPONSIBILITY

Pharmacy Quality Management Team (PQMT):

- Development and provision of a quality management system in coordination with Quality Management & Patient Safety Departments for evaluating the overall quality of pharmacy and medical stores departments, nursing care units, which are integrated with the hospital/system.

- Establishment of indicators aligned with key performance indicators and institution’s operations goals, as necessary.

8.0 RELATED DOCUMENTS

N/A

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Quality Improvement Plan Stellar Hospitals</td>
<td>Ashpmedia.Org</td>
<td>2013</td>
<td>4</td>
</tr>
<tr>
<td>Continuous Quality Improvement (CQI): ISMP, Canada</td>
<td>Mi Qi Liu</td>
<td>2015</td>
<td>4</td>
</tr>
<tr>
<td>A Quality Management System for Pharmacy Practice, Pharmacy Management Volume 31 UK</td>
<td>Titus De Silva</td>
<td>2015</td>
<td>5</td>
</tr>
</tbody>
</table>
# FORM – A (HOSPITAL PHARMACY AUDIT CHECKLIST)

**Hospital:**

**Governorate:**

**Date of Visit:**

<table>
<thead>
<tr>
<th>No of Pharmacy Staff</th>
<th>Clinical Pharmacists:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pharmacists:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Assistant Pharmacists:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total number of beds</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Average no. of Prescriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

## A. Policies & Guidelines availability

<table>
<thead>
<tr>
<th>Policy Description</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Pharmacy code of ethics manual</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Policies &amp; Procedures manual</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Pharmacy job description manual</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Extemporaneous Preparations MOH Manual</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Narcotics &amp; Psychotropics Guidelines</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Approved Antibiotic Policy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Non/Slow moving items Policy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Authorized reference to the focal point of each task &amp; the deputy</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## B. Drug Information sources

<table>
<thead>
<tr>
<th>Source</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. MOH Approved Formulary</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. British National Formulary</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Other references</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Micromedex Online link</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Internet access</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## C. Premises

<table>
<thead>
<tr>
<th>Premise</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>14. Electricity &amp; light adequacy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Satisfactory cooling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Satisfactory ventilation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. Cleanliness</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
18. Sufficient Dispensing area
19. Sufficient Waiting area
20. Adequate storage space available with enough shelving
21. Patient Counselling area (Private/Semiprivate)
22. Does the Aseptic preparations room meet the USP standards
23. Notice board available
24. Secured Entry Access Available

<table>
<thead>
<tr>
<th>D</th>
<th>Equipment / instruments</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>25.</td>
<td>Computers &amp; Printers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>26.</td>
<td>Availability of fridge (Medical / household)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27.</td>
<td>Labelling machine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28.</td>
<td>Counting machine/tray</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29.</td>
<td>Availability of Extemporaneous preparation equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30.</td>
<td>Availability of fridge thermometer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31.</td>
<td>Availability of wall thermometer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>32.</td>
<td>Are Fire safety devices available and maintained</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>E</th>
<th>Consumables</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>33.</td>
<td>Availability of medicine bags</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>34.</td>
<td>Availability of medicine envelopes (large &amp; small)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>F</th>
<th>Forms &amp; Documents</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>35.</td>
<td>Monthly duty roster list / On call list</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>36.</td>
<td>ADRs forms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>37.</td>
<td>Drug quality reporting form</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>38.</td>
<td>Controlled drug prescriptions retained (Narcotics &amp; Psychotropic)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>39.</td>
<td>Circular file is available.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40.</td>
<td>Patient education pamphlets</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>G</th>
<th>Training and education</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>41.</td>
<td>Does the staff received orientation/induction program to cover the essential components of the service provided</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>42.</td>
<td>Are the Staff trained in infection control</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>43.</td>
<td>Are the staff trained adequately in Sterile Preparations.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S.N</td>
<td>Pharmacy Services</td>
<td>Y</td>
<td>N</td>
<td>Remarks</td>
</tr>
<tr>
<td>-----</td>
<td>-----------------------------------------------</td>
<td>---</td>
<td>---</td>
<td>---------</td>
</tr>
<tr>
<td>44.</td>
<td>Are the staff trained adequately in Extemporaneous Preparations.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>45.</td>
<td>Are the Staff trained in first aid/BLS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>46.</td>
<td>Are the Staff participating in CPE program</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>47.</td>
<td>Are the Staff trained for conducting Counselling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>48.</td>
<td>Adequate number of staff available</td>
<td>Y</td>
<td>N</td>
<td>Remarks</td>
</tr>
<tr>
<td>49.</td>
<td>Is Clinical Pharmacy Service available</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50.</td>
<td>Is Unit dose dispensing system being followed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>51.</td>
<td>Whether TPN Preparations made</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>52.</td>
<td>Whether Cytotoxic preparations made</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>53.</td>
<td>Whether all shifts covered by Pharmacy staff</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>54.</td>
<td>Are Drug &amp; Therapeutic Committee meetings conducted periodically and documented?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>55.</td>
<td>Whether counselling is conducted in a private, confidential and understanding manner</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S.N</td>
<td>Risk Management</td>
<td>Y</td>
<td>N</td>
<td>Remarks</td>
</tr>
<tr>
<td>56.</td>
<td>The approved dispensing procedure followed (Cross Checking) / poster displayed.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>57.</td>
<td>High alert medications identified and monitored while dispensing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>58.</td>
<td>Look alike/Sound alike identified and necessary precautions taken while dispensing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>59.</td>
<td>Are all hazardous substances correctly labelled to allow easy identification and safe use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>60.</td>
<td>Does a pharmacist interpret and evaluate prescriptions for correctness and completeness and the interventions made are documented</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>61.</td>
<td>Whether Extemporaneous preparations made appropriately</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>62.</td>
<td>Cold room / Refrigerator temperature monitored and documented (Chart)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>63.</td>
<td>Expired drugs / Medical Items kept separately with labelling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>64.</td>
<td>Does the pharmacy follow an appropriate a procedure for handling medicines recalls</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S.N</td>
<td>Stock Management Process</td>
<td>Y</td>
<td>N</td>
<td>Remarks</td>
</tr>
<tr>
<td>-----</td>
<td>---------------------------------------------------------------</td>
<td>---</td>
<td>---</td>
<td>---------</td>
</tr>
<tr>
<td>65.</td>
<td>Does the Pharmacy follow appropriate SOP’s for managing, documenting and reviewing Pharmacy incidents (including but not limited to Emergency, Security and dispensing incidents)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>66.</td>
<td>Controlled items are stored in a lockable safe metal cabinet</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>67.</td>
<td>No stock directly contact an electric or heat generating device</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>68.</td>
<td>No stock obstruct fire safety device</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>69.</td>
<td>Whether staff undertaking compounding are experienced &amp; qualified</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>S.N</th>
<th>Stock arrangement</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>70.</td>
<td>Limited access to pharmacy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>71.</td>
<td>Only medical items are stored (No food stuff stored)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>72.</td>
<td>Appropriate labelling for pre packed items</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>73.</td>
<td>Controlled drugs issued against formal Rx</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>74.</td>
<td>First Expiry First Out (FEFO) system adopted</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>75.</td>
<td>Loose drugs are not handled by bare hands</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>76.</td>
<td>Report of expired/damaged items available</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>77.</td>
<td>Controlled drug Narcotics &amp; Psychotropic registers up to date</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>78.</td>
<td>Physical stock quantities tallying with computer records</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments & Recommendations of Head of Pharmacy:

VISITORS NAMES & SIGNATURES

-------------------------------------------------------------------------------------------------------------
# FORM – B (HOSPITAL MEDICAL STORE AUDIT CHECKLIST)

**Hospital:**

**Governorate:**

**Date of Visit:**

<table>
<thead>
<tr>
<th>No of Pharmacy Staff</th>
<th>Clinical Pharmacists:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pharmacists:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Assistant Pharmacists:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Staff Nurses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lab Technicians</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total number of beds</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

## A Policies & Guidelines Availability

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Pharmacy code of ethics manual</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Policies &amp; Procedures manual</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Pharmacy job description manual</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Narcotics &amp; Psychotropic Guidelines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Non/Slow moving items Policy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Regulation for dealing with Expired items/disposal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Authorized reference to the focal point of each task &amp; the deputy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## B Drug Information sources

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.</td>
<td>MOH, Approved Formulary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>British National Formulary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Micromedex Online link</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>Internet access</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## C Premises

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.</td>
<td>Electricity &amp; light adequate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>Satisfactory cooling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>Satisfactory ventilation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td>Cleanliness</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
16. **Storage area protected from direct sunlight, and free from insects, animals, vermin etc.**

17. **Adequate storage space available with enough shelving**

18. **Notice board available**

19. **Secured Entry Access available**

### D. Equipment / instruments

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>20. <strong>Computers &amp; Printers</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21. <strong>Cold Room with alarm linked with maintenance department</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22. <strong>Availability of Medical fridge / house hold</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23. <strong>Labeling machine</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24. <strong>Counting machine/tray</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25. <strong>Availability of fridge thermometer</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>26. <strong>Availability of wall thermometer</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27. <strong>Are Fire safety devices available and maintained</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### E. Forms & Documents

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>28. <strong>Monthly duty roster / On call list</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29. <strong>Updated list of Home care patients</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30. <strong>Drug quality reporting form</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31. <strong>Surgical/Lab items Quality reporting Form</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### G. Training and education

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>32. <strong>Does the staff received orientation/induction program to cover the essential components of the service provided</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>33. <strong>Are the Staff trained in material management</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>34. <strong>Are the Staff trained in fast aid/BLS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35. <strong>Are the Staff participating in CPE program</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### H. Stock Management Process

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>36. <strong>Limited access to Store</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>37. <strong>Only medical items are stored (no food stuff)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>38. <strong>First expiry first out (FEFO) system adopted</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>39. <strong>Report of expired/damaged items available</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40. <strong>Controlled drug Narcotics &amp; Psychotropic registers upto date</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td><strong>41.</strong></td>
<td>Physical stock quantities tallying with computer records</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>42.</strong></td>
<td>Statistical reports of Narcotics and Psychotropic are sent quarterly to Drug Control?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>I</strong></td>
<td><strong>Stock availability</strong></td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td><strong>43.</strong></td>
<td>Availability of Out of Stock computer generated report</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>44.</strong></td>
<td>Availability of computer generated report for Non and Slow moving/ short expiry items</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>45.</strong></td>
<td>Availability of computer generated report for over stocked items</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>J</strong></td>
<td><strong>Stock arrangement</strong></td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td><strong>46.</strong></td>
<td>Stock Arrangement system (code/ pharmacology-wise)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>47.</strong></td>
<td>No stock on corridor / floor</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>48.</strong></td>
<td>No stock directly contact the ceilings</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>49.</strong></td>
<td>Attractive/Expensive / Referral items are stored in a lockable cabinet</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>50.</strong></td>
<td>Liquid stock are arranged with the opening top facing upward</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>51.</strong></td>
<td>Inflammable items &amp; Chemicals stored separately</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>52.</strong></td>
<td>Gas Cylinders stored separately</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>K</strong></td>
<td><strong>Risk Management</strong></td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td><strong>53.</strong></td>
<td>Contingency Plan in Emergency situation (Generator back up available during power outage etc.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>54.</strong></td>
<td>Cold room / Refrigerator temperature monitored and documented (Chart/graph)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>55.</strong></td>
<td>High alert medications identified and monitored while dispensing</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>56.</strong></td>
<td>Look alike/Sound alike identified and necessary precautions taken while dispensing</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>57.</strong></td>
<td>Are all hazardous substances correctly labelled to allow easy identification and safe use</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>58.</strong></td>
<td>Expired drugs / Medical Items kept separately with labeling</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>59.</strong></td>
<td>Does the Store follow an appropriate a procedure for handling medicine recalls</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No.</td>
<td>Policy</td>
<td>Comments</td>
<td>Recommendations</td>
</tr>
<tr>
<td>-----</td>
<td>----------------------------------------------------------------------------------------------------</td>
<td>----------</td>
<td>-----------------</td>
</tr>
<tr>
<td>60.</td>
<td>Controlled items are stored in a lockable safe metal cabinet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>61.</td>
<td>No stock directly contact an electric or heat generating device</td>
<td></td>
<td></td>
</tr>
<tr>
<td>62.</td>
<td>No stock obstruct fire safety device</td>
<td></td>
<td></td>
</tr>
<tr>
<td>63.</td>
<td>Is there an appropriate SOP for safe and appropriate storage and disposal of waste, infectious and hazardous material</td>
<td></td>
<td></td>
</tr>
<tr>
<td>64.</td>
<td>Does the Stores follow appropriate SOP’s for managing, documenting and reviewing Store incidents (including but not limited to Emergency, Security and dispensing incidents)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments & Recommendations of Head Medical Stores:

VISITORS NAMES & SIGNATURES

--------------------------------------    --------------------------------------    --------------------------------------
**FORM – C (PHC PHARMACY AUDIT CHECKLIST)**

**Name:**  
**Governorate:**  
**Date of Visit:**

<table>
<thead>
<tr>
<th>No of Pharmacy Staff</th>
<th>Pharmacists:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Assistant Pharmacists:</td>
<td></td>
</tr>
</tbody>
</table>

**Working time**

**Average no. of Prescriptions**

### A  Policies & Guidelines availability

<table>
<thead>
<tr>
<th>No</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pharmacy code of ethics manual</td>
</tr>
<tr>
<td>2</td>
<td>Policies &amp; Procedures manual</td>
</tr>
<tr>
<td>3</td>
<td>Pharmacy job description manual</td>
</tr>
<tr>
<td>4</td>
<td>Narcotics &amp; Psychotropics Guidelines</td>
</tr>
<tr>
<td>5</td>
<td>Approved Antibiotics Policy</td>
</tr>
<tr>
<td>6</td>
<td>Extemporaneous Preparations Manual</td>
</tr>
<tr>
<td>7</td>
<td>Non/Slow moving items Policy</td>
</tr>
<tr>
<td>8</td>
<td>Authorized reference to the focal point of each task &amp; the deputy</td>
</tr>
</tbody>
</table>

### B  Drug Information sources

<table>
<thead>
<tr>
<th>No</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>MOH Approved Formulary</td>
</tr>
<tr>
<td>10</td>
<td>British National Formulary</td>
</tr>
<tr>
<td>11</td>
<td>Other references</td>
</tr>
<tr>
<td>12</td>
<td>Micromedex Online link</td>
</tr>
<tr>
<td>13</td>
<td>Internet access</td>
</tr>
</tbody>
</table>

### C  Premises

<table>
<thead>
<tr>
<th>No</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>Electricity &amp; light adequacy</td>
</tr>
<tr>
<td>15</td>
<td>Satisfactory cooling</td>
</tr>
<tr>
<td>16</td>
<td>Satisfactory ventilation</td>
</tr>
<tr>
<td>17</td>
<td>Cleanliness</td>
</tr>
</tbody>
</table>
18. Sufficient Dispensing area
19. Sufficient Waiting area
20. Adequate storage space available with enough shelving
21. Patient Counselling area (Private/Semiprivate)
22. Notice board available
23. Entry lock access system installed (ALARM)

<table>
<thead>
<tr>
<th>D</th>
<th>Equipment / instruments</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>24.</td>
<td>Computers &amp; Printers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25.</td>
<td>Availability of fridge (Medical / household)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>26.</td>
<td>Labelling machine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27.</td>
<td>Counting machine/tray</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28.</td>
<td>Availability of fridge thermometer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29.</td>
<td>Availability of wall thermometer</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>E</th>
<th>Consumables</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>30.</td>
<td>Availability of medicine bags</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31.</td>
<td>Availability of medicine envelopes (large &amp; small)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>F</th>
<th>Forms &amp; Documents</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>32.</td>
<td>Monthly duty roster / On-call List</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>33.</td>
<td>ADRs forms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>34.</td>
<td>Drug quality reporting form</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35.</td>
<td>Circular file is available.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>36.</td>
<td>Patient education pamphlets</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>G</th>
<th>Training and education</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>37.</td>
<td>Does the staff received orientation/induction program to cover the essential components of the service provided</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>38.</td>
<td>Are the Staff participating in CPE program</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>39.</td>
<td>Are the Staff trained for conducting Counselling</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>S.N</th>
<th>Pharmacy Services</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>40.</td>
<td>Whether Extemporaneous preparations made</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>41.</td>
<td>Whether all shift covered by Pharmacy staff</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>42.</td>
<td>Are Drug &amp; Therapeutic Committee meetings conducted periodically and documented?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S.N</td>
<td>Risk Management</td>
<td>Y/N</td>
<td>Remarks</td>
<td></td>
</tr>
<tr>
<td>-----</td>
<td>-----------------</td>
<td>-----</td>
<td>---------</td>
<td></td>
</tr>
<tr>
<td>43.</td>
<td>Whether counselling is conducted in a private, confidential and understanding manner</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>44.</td>
<td>The approved dispensing procedure followed (Cross Checking) / poster displayed.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>45.</td>
<td>Look alike/Sound alike identified / kept separately and necessary precautions taken while dispensing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>46.</td>
<td>Are all hazardous substances correctly labelled to allow easy identification and safe use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>47.</td>
<td>Do the Pharmacist / Asst. Pharmacists interpret and evaluate prescriptions for correctness and completeness and the interventions made are documented</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>48.</td>
<td>Refrigerator temperature monitored and documented (Chart)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>49.</td>
<td>Expired drugs / Medical Items kept separately with labelling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50.</td>
<td>Does the pharmacy follow an appropriate a procedure for handling medicines recalls</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>51.</td>
<td>Does the Pharmacy follow appropriate SOP’s for managing, documenting and reviewing Pharmacy incidents (including but not limited to Emergency, Security and dispensing incidents)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>52.</td>
<td>Controlled items are stored in a lockable safe metal cabinet</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>53.</td>
<td>No stock directly contact an electric or heat generating device</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>54.</td>
<td>Are Fire safety devices available and maintained</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>55.</td>
<td>No stock obstruct fire safety device</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>S.N</th>
<th>Stock Management Process</th>
<th>Y/N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>56.</td>
<td>Limited access to pharmacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>57.</td>
<td>Latest inventory management system followed Alshifa 3+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>58.</td>
<td>Only medical items are stored (No food stuff stored)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>59.</td>
<td>Daily thermometer reading are recorded</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>60.</td>
<td>Appropriate labelling for pre packed items</td>
<td></td>
<td></td>
</tr>
<tr>
<td>61.</td>
<td>First Expiry First Out (FEFO) system adopted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>62.</td>
<td>Loose drugs are not handled by bare hands</td>
<td></td>
<td></td>
</tr>
<tr>
<td>63.</td>
<td>Controlled drug Narcotics &amp; Psychotropic registers up to date</td>
<td></td>
<td></td>
</tr>
<tr>
<td>64.</td>
<td>Physical stock quantities tallying with computer records</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H</td>
<td>Stock availability &amp; arrangement</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>65.</td>
<td>Stock Arrangement system (code/ pharmacology-wise)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>66.</td>
<td>No stock on floor.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>67.</td>
<td>No stocks directly contact the ceilings.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments & Recommendations of  Head of Pharmacy & Medical Stores

VISITORS NAMES & SIGNATURES

-------------------------------------------------  -----------------------------  -----------------------------
## FORM – D (PHC MEDICAL STORE AUDIT CHECKLIST)

Name:  
Governorate:  
Date of Visit:  

<table>
<thead>
<tr>
<th>No of Store Staff</th>
<th>Pharmacists:</th>
<th></th>
<th>Assistant Pharmacists:</th>
</tr>
</thead>
</table>

| Working time |  |  |  |

### A. Policies & Guidelines Availability

<table>
<thead>
<tr>
<th>Policies &amp; Guidelines Availability</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Pharmacy code of ethics manual</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Policies &amp; Procedures manual</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Pharmacy job description manual</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Narcotics &amp; Psychotropics Guidelines</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Non/Slow moving items Policy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Authorized reference to the focal point of each task &amp; the deputy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Regulation for dealing with Expired items/disposal</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### B. Drug Information sources

<table>
<thead>
<tr>
<th>Drug Information sources</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. MOH Approved Formulary</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. British National Formulary</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Micromedex Online link</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Internet access</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### C. Premises

<table>
<thead>
<tr>
<th>Premises</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. Electricity &amp; light adequate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Satisfactory cooling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Satisfactory ventilation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Cleanliness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Storage area protected from direct sunlight, and free from insects, animals, vermin etc.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. Adequate storage space available with enough shelving</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S.N</td>
<td>Equipment / instruments</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>-----</td>
<td>------------------------</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>18.</td>
<td>Notice board available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19.</td>
<td>Entry lock access system installed (ALARM)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20.</td>
<td>Computers &amp; Printers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21.</td>
<td>Availability of Medical fridge / house hold</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22.</td>
<td>Availability of fridge thermometer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>23.</td>
<td>Availability of wall thermometer</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>S.N</th>
<th>Forms &amp; Documents</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>24.</td>
<td>Drug quality reporting form</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25.</td>
<td>Surgical/Lab items Quality reporting Form</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>S.N</th>
<th>Training and education</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>26.</td>
<td>Does the staff received orientation/induction program to cover the essential components of the service provided</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27.</td>
<td>Are the Staff trained in material management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28.</td>
<td>Are the Staff participating in CPE program</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>S.N</th>
<th>Stock Management Process</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>29.</td>
<td>Limited access to Store</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30.</td>
<td>Online with DGMS for indenting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31.</td>
<td>Only medical items are stored (no food stuff)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>32.</td>
<td>First Expiry First Out (FEFO)System adopted</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>33.</td>
<td>Report of expired/damaged items available</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>34.</td>
<td>Controlled drug Narcotics &amp; Psychotropic registers up to date</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35.</td>
<td>Physical stock quantities tallying with computer records</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>36.</td>
<td>Statistical reports of Narcotics and Psychotropics are sent quarterly to Drug Control?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>S.N</th>
<th>Stock availability</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>37.</td>
<td>Availability of Out of Stock computer generated report</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>38.</td>
<td>Availability of computer generated report for Non slow moving/ short expiry items</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>39.</td>
<td>Availability of computer generated report for over stocked items</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Stock Arrangement

<table>
<thead>
<tr>
<th></th>
<th>Stock arrangement</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>40.</td>
<td>Stock Arrangement system (code/pharmacology-wise)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>41.</td>
<td>No stock on corridor/floor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>42.</td>
<td>No stock directly contact the ceilings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>43.</td>
<td>Liquid stock are arranged with the opening top facing upward</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>44.</td>
<td>Inflammable items &amp; Chemicals stored separately</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>45.</td>
<td>Gas Cylinders stored separately</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Risk Management

<table>
<thead>
<tr>
<th></th>
<th>Risk Management</th>
<th>Y</th>
<th>N</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>46.</td>
<td>Contingency plan for emergency (Power outage etc.)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>47.</td>
<td>Refrigerator temperature monitored and documented (Chart)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>48.</td>
<td>Expired drugs / Medical Items kept separately with labelling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>49.</td>
<td>Are all hazardous substances correctly labelled to allow easy identification and safe use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50.</td>
<td>Does the Store follow an appropriate a procedure for handling medicine recalls</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>51.</td>
<td>Controlled items are stored in a lockable safe metal cabinet</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>52.</td>
<td>No stock directly contact an electric or heat generating device</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>53.</td>
<td>No stock obstruct fire safety device</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>54.</td>
<td>Does the Stores follow appropriate SOP’s for managing, documenting and reviewing Store incidents (including but not limited to Emergency, Security and dispensing incidents)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>55.</td>
<td>Are Fire safety devices available and maintained</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Comments & Recommendations of Head of Pharmacy & Medical Stores**

**VISITORS NAMES & SIGNATURES**

--------------------------------------    --------------------------------------    --------------------------------------
1.0 INTRODUCTION

The provision of drug information (DI) is among the fundamental professional responsibilities of all pharmacists. Recent practice trends, including increased provision of medication therapy management services and efforts to obtain provider status, have placed pharmacists in increasingly complex patient-care roles and necessitated a higher level of competence by all pharmacists in meeting the drug information (DI) needs.

Access to authoritative and independent information is fundamental for the rational and effective use of drugs. WHO recognizes independent drug information centers as a core component of national programs to promote the rational use of drugs. Drug information centers support the functions of healthcare professionals to deliver high quality drug use. They focus on resources and specialist staff to answer complex questions, provides education and training in drug information practices, and assist with other public health initiatives.

2.0 SCOPE

Established drug information services / centers in pharmacy departments in MOH Healthcare units.

3.0 PURPOSE

3.1 To provide healthcare practitioners with timely, evidence-based drug information to support specific medication-use practices to enhance the quality of patient care, improve patient outcomes, and ensure the prudent use of resources.

3.2 Responding to enquiries on therapeutic drug use from health professionals or the public. In some cases toxicology information is also provided.

4.0 DEFINITION

Drug Information Center (DIC): Is an operational unit dedicated to provide objective, independent and current information on drugs and their use, and communicate to the different categories of users for better understanding and benefit of patients.

5.0 POLICY

5.1 The Pharmacy Department in Tertiary and Regional Hospitals shall have at least a basic Drug Information Services, using the latest and most updated drug references.

5.2 The pharmacist to be an effective provider of drug information (DI), must exercise excellent oral and written communication skills and to anticipate and evaluate the DI needs of patients and health care professionals; appropriately synthesize, communicate, document, and apply pertinent information to the patient care situation.

5.3 It is the responsibility of the pharmacist to commit to lifelong learning and make an effort to keep abreast of advances both in the methods of delivering DI and the information itself.
5.4 Dispensed drugs should always be accompanied by appropriate directions for consumers, and pharmacists should have the skills and resources to provide basic information to other health professionals. These functions can be described as drug information services and can be distinguished from the more specialized activities of a drug information center (DIC).

6.0 PROCEDURE

6.1 The pharmacist in the basic Drug Information Unit should have the skills to perform the following DI activities:

- Providing DI to patients, caregivers, and health care professionals.
- Creating and maintaining currency of a variety of print and online educational resources for patients (e.g., tip sheets, pamphlets) and health care professionals (e.g., in-service documents, newsletters) on topics such as optimal medication use, general health, or select clinical questions.
- Educating health care professionals on safe and effective medication-use policies and processes, including development of resources to communicate this information.
- Participating in continuing education services for health care professionals.
- Educating pharmacy students and residents.
- Participating in quality improvement research projects and drug cost analysis.

6.2 Specific activities of a specialized Drug Information Centre (DIC) may include some or all of the following:

- Providing information when there is not sufficient time for other health care professionals to appropriately research the DI question, when there is a knowledge gap, or when the question requires more thorough research.
- Participate in review, establishing and maintaining a formulary based on scientific evidence of efficacy and safety, pharmacoeconomics, and institution-specific factors.
- Coordinating programs to support population-based medication practices that maximize patient outcomes (e.g., development of pharmacotherapeutic guidelines, medication-use evaluation criteria, and therapeutic interchange protocols).
- Developing and participating in efforts to prevent medication errors and adverse drug events.
- Monitoring and assessing the clinical significance of medication safety alerts communicated by the FDA, drug manufacturers, and other sources.
- Providing advanced DI education and training to interprofessional and pharmacy students and residents.

6.3 It is important for pharmacists providing drug information is to keep current on changes in pharmacy practice as the health care system evolves and keeping up to date with clinical knowledge. Recommendations for staying current include the following:

- Subscribe to table of contents of or full access to relevant journals, as appropriate.
- Subscribe to appropriate email list servers (e.g., Food and Drug Administration Drug Information Updates, National Guideline Clearinghouse, Centers for Disease Control and Prevention, Medline Plus).
• Receive email alerts from relevant health-related websites (e.g., MedWatch, Medline Plus).

• Bookmark important websites and check regularly for updates (e.g., Institute for Safe Medication Practices,).

• Choose pertinent continuing education activities and methods that challenge learning.

• Maintain active membership in local, state, and national pharmacy associations/societies.

• Pursue board certification from the Board of Pharmacy Specialties.

6.4 A systematic approach for responding to Drug Information Requests may be outlined as follows.

• Identify the requestor. In order to obtain complete information and develop a response with the appropriate perspective, consider the health literacy and professional background of the requester.

• Define the true question and information need. Identify the true question and information needed by asking probing questions of the requester. For example, “Why is the question being asked?” and “Does the question pertain to a specific patient?” may help reveal important details of the true question.

• Obtain complete background information. Obtain more complete background information, including examining the medical record for patient data, if applicable, to individualize the response to meet the requester’s need.

• Categorize the question. Classify requests as patient specific or academic and by type of question (e.g., product availability, adverse drug event, compatibility, compounding/formulation, dosage/administration, drug interaction [drug-drug, drug-disease, and drug-laboratory], drug product identification, pharmacokinetics, therapeutic use/efficacy, safety in pregnancy/nursing toxicity/poisoning) to aid in tailoring the search strategy and selecting resources.

• Perform a systematic search. Perform a systematic search of appropriate tertiary, secondary, and primary resources, including electronic resources, as necessary.

• Analyze the information. Evaluate, interpret, and combine information from the resources used. Other information needs should be anticipated as a result of the information gathered.

• Disseminate the information. Provide an oral or written response, or both, as needed by the requester that specifically applies the information to the particular situation. The information, its urgency, and its purpose may influence the method of response. Supporting documentation (e.g., primary literature) should be included when possible.

• Document. Document the request, information resources used, the information found in each source, time spent on the response, and the response itself as appropriate for the request and the practice setting.

• Follow-up. Perform a follow-up assessment to determine the utility of the information provided and whether the information resulted in changes in medication-use practices or patient outcomes.
6.5 General Drug information questions may include, but are not limited to:

- Therapeutic use of drugs and therapeutic alternatives.
- Appropriate dosing and administration.
- Toxicity of drugs (i.e., adverse effects).
- Drug-drug, drug-food interactions.
- Dosing adjustments for renal/ hepatic insufficiency.
- Drug use in pregnancy and lactation.
- Pharmacokinetics.
- Drug monitoring for efficacy and toxicity.
- Intravenous compatibility.

6.6 The received DI requests should be entered immediately on the suggested attached Drug Inquiry Form (Annex A). The answer is to be recorded later in the answer box in the form, and the time taken to answer the inquiry is also recorded. An electronic Drug Inquiry Form may be generated in the computer system for better monitoring.

6.7 The Pharmacist In-Charge will answer the inquiry depending on the urgency of the answer required, the references used, the category of question, and the means by which the answer is required (i.e. verbal, written, or literature sent giving priority to poisoning and critical care patients).

7.0 RESPONSIBILITY

Pharmacists providing Drug Information services:

- Receiving queries from health care professionals or public and give them the answer whether being verbal, written, or a literature sent.
- Educating healthcare professionals on safe and effective drug therapy.
- Participating in quality improvement researches and drug cost analysis.

8.0 RELATED DOCUMENTS

N/A

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>How to Establish a Drug and Toxicology Information Center in Developing Countries</td>
<td>Ossy J.Kasilo, Charles F.B. (WHO Essential Drug Monitor)</td>
<td>1993</td>
<td>2</td>
</tr>
<tr>
<td>Requirements for Drug Information Centers</td>
<td>Drug Information Working Group, Pharmacy Information Section, FIP</td>
<td>2005</td>
<td>5</td>
</tr>
<tr>
<td>ASHP Guidelines on the Pharmacist’s Role in Providing Drug Information</td>
<td>American Society of Health System Pharmacists</td>
<td>2015</td>
<td>5</td>
</tr>
<tr>
<td>Tips for Managing a Drug Information Center</td>
<td>Jennifer Gershman</td>
<td>2018</td>
<td>2</td>
</tr>
</tbody>
</table>
## Annex A

### Drug Inquiry Form

<table>
<thead>
<tr>
<th>Requester:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Details:</td>
<td></td>
</tr>
<tr>
<td>Location:</td>
<td></td>
</tr>
<tr>
<td>Date:</td>
<td>Time:</td>
</tr>
<tr>
<td>Type of Request</td>
<td>Example: Toxicology, Dosage/Administration, Drug Interaction</td>
</tr>
<tr>
<td>Age:</td>
<td></td>
</tr>
<tr>
<td>Sex:</td>
<td></td>
</tr>
<tr>
<td>History:</td>
<td></td>
</tr>
<tr>
<td>Diagnosis:</td>
<td></td>
</tr>
<tr>
<td>Drug regimen:</td>
<td></td>
</tr>
<tr>
<td>Laboratory tests:</td>
<td></td>
</tr>
<tr>
<td>Vital signs:</td>
<td></td>
</tr>
<tr>
<td>Question:</td>
<td></td>
</tr>
<tr>
<td>Answer</td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td>Signature</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

Medical Supplies procurement system for Pharmaceutical Surgical & Laboratory Consumables is the major determinant of medical supplies availability and total expenditure. Medical supplies purchases represent the single largest health expenditure after the personnel in most of health system settings.

Considering the impact of procurement of medical supplies on the operation and effectiveness of health services provided, implementation of centrally managed procurement system is of great value in ensuring regular supply of good quality products at reasonable cost.

Medical supplies procurement is a complex process which involves many steps, ministries, departments, logistics and reliable suppliers/manufacturers relationship. The most important considerations for procurement is the establishment of appropriate and reliable funding for public medical supplies procurement as a high priority.

2.0 SCOPE

Procurement of medical supplies (pharmaceutical, surgical and laboratory consumables) to meet the requirements of MOH Healthcare institutions.

3.0 PURPOSE

To ensure a consistent availability of medical supplies of good quality, efficacy & safety at reasonable cost.

4.0 DEFINITION

Procurement: Is defined as the process of acquiring supplies and services which ideally are cost effective and provide the best quality outcomes for service users.

5.0 POLICY

5.1 Medical supplies procurement is a specialized professional activity that requires a combination of knowledge, skills and experience. It is essential that the procurement activities be performed by competent staff using efficient procedures and working with access to reliable inventory and consumption information.

5.2 Procurement should be planned properly and procurement performance should be monitored regularly; monitoring should include an annual internal and external audits.

5.3 Procurement should be limited to the MOH list of approved drugs and medical consumables, as one of the most effective methods to ensure regular availability of life saving/essential products of priority and control of the expenditure.
5.4 Procurement of Non-Approved Drugs shall be restricted to life saving / vital drugs requested for individual cases only when alternative drug is not available or available but could not be used for a certain reason. Request for purchase of non-approved drugs (Form-A) should be filled by the prescribing consultant/ senior specialist or specialist for a specified period of time and approved by the Head of the Medical Unit. Please refer to DGMS policy titled “Handling Non-Formulary Drug Requests (MOH-DGMS-PH-28)”.

5.5 Direct procurement of medical supplies by hospitals or other health institutions in the Ministry is not allowed, to avoid high acquisition cost, wastage and to ensure proper inventory management.

5.6 DGMS shall develop reasonable defined steps to follow when attempting to resolve shortages of vital/essential medical supplies due to delay in supplies or unexpected increases in utilization of medical supplies.

5.7 DGMS must have a contingency plan in place for appropriate management of medical supplies during emergency and crisis situations. This include:

- Efficient management of Strategic Reserve Stock at Bausher,
- Maintaining suitable level of safety stocks at the central and regional stores.
- Identifying the alternative source for supply of vital and essential items of higher priority.
- Logistic arrangement and enhance intra-collaboration with other concerned emergency management departments.

5.8 Mechanisms should be put in place to ensure reliable financing for procurement of medical supplies to meet the actual needs and satisfactorily operating the health care services in MOH. Good financial management procedures should be followed to maximize the rational use of available scarce financial resources.

5.9 Prospective suppliers should be pre-qualified. Selected suppliers should be monitored through a process which considers product quality, service reliability, delivery time and financial viability.

6.0 PROCEDURE

6.1 The key principles of Good procurement to be followed are:

- Procurement of the right items in the right quantities.
- Arrange timely delivery of supplies to avoid shortage and stock outs.
- Procurement by generic names, avoid tendering by trade names and catalogue numbers.
- Limitation of procurement to the approved drug formulary / regular medical supplies list.
- Procurement in bulk quantities to obtain the lowest possible prices.
- Order quantities based on reliable estimate of actual need.
- Reliable payment and good financial management.
- Transparency and followed written standard procedures.
6.2 Effective health technology procurement practice for medical devices leads to safe and quality health care. Other potential benefits of good procurement include:

- The most economically advantageous terms for the equipment acquired – not necessarily the lowest price obtained through tender, but the best deal for the organization’s needs.
- Timely delivery and handover.
- Satisfactory and well-defined terms for delivery, installation, commissioning, maintenance, training, payment and warranty.
- Satisfactory after-sales service.

6.3 The procurement cycle includes most of decisions and actions that determine the specific quantities purchased, delivery and payment which involves the following:

- Establish the Annual Tenders Schedule considering the lead time needed to complete the procurement cycle, which is 10-11 months for the annual tenders and 6-7 months for supplementary tenders.
- Determine the annual quantities needed.
- Reconcile needs and funds.
- Choose procurement method.
- Locate and select suppliers.
- Specify contract terms.
- Floating and Opening of Tenders.
- Analysis, Selection and Approval of awards by the Competent Authority.
- Dispatch of LPOs with the specified delivery schedules for each item.
- Monitor order status.
- Receive and check quality (QCL) and quantity supplied.
- Finance to make the payment the received quantities.
- Distribute drugs to health units.
- Quality surveillance.

6.4 The following approved selection criteria for pharmaceuticals and medical supplies offered against International and Local Tenders should be considered by the Committee for Study & Analysis of Offers to ensure adherence to standard, transparent, consistent approved guidelines for selection.

- Selection is based on multi-factors including registration of pharmaceutical products, prequalification of the Surgical & Lab manufacturers, compliance with the required quality specifications, previous experience and technical advantages and the suitability of the prices offered.
• The correct cheapest offer received should be compared with the prices awarded in Gulf (GCC Joint Tenders) for the same items and the lowest correct offers to be selected, accordingly.

• If similar prices are quoted for the same item from two different suppliers the preference should be given as follows:
  ✓ To select the item from Gulf Tenders, to share the experience and the quality monitoring reports
  ✓ To select the item from the Research / Internationally reputed manufacturer, if the price is almost similar to the generic version quoted.
  ✓ To give the priority for the products being used before, without any problems.
  ✓ To consider dividing the requirement between two companies if deemed necessary.
  ✓ The Technical advantage of one item over the other to be taken into account.

• For non-registered pharmaceuticals or new surgical & Lab products not used before, selection may be also considered in the following circumstances:
  ✓ It is the only offer, it complies with the required specifications and the samples are acceptable.
  ✓ If the offered price of the regularly used product is shown to be exaggerated in comparison to the other offers.

• It is recommended to deal gradually with the new specialized products when procured for the first time from generic or new companies, by arranging only 30-50% of the requirements for evaluation.

• The prices of the technically linked products should be compiled as a group or set and to select the cheapest total value of the correct offers from the successful company accordingly.

• The cheapest offers may be excluded in case of:
  ✓ Pharmaceuticals not being registered locally or in Central Gulf Registration or in other GCC countries.
  ✓ Pharmaceuticals with the narrow therapeutic index or those requiring advanced manufacturing techniques like Recombinant Products & Insulins offered from the generic manufacturers.
  ✓ Biological products produced from blood derivatives offered from non-internationally reputed manufacturers.
  ✓ Receipt of negative reports on the quality of the products.
  ✓ When tender samples are not as per specification,
  ✓ Repeated non-commitment with the delivery schedules.
  ✓ No samples or catalogues are provided for new medical supplies.
  ✓ Not compatible with the available equipment.
✓ Non acceptable conditions or restrictions stated by the Tenderers in their offer.

• Preference to be given to national manufacturers as per the approved support percentage for the local industry. i.e., 10%.

• To support Ministry of Health policy encouraging procurement of generic products as per Oman National Drug Policy in order to rationalize the use of the available resources.

6.5 MOH should facilitate continuing participation of other health care governmental institutions, (MOD, ROP, SQUH, DIWAN) by including their desired items in the International and Local MOH tenders and Gulf joint Tender to get the benefit of reduced bulky prices selected against these tenders and to unify the specifications and quality of products purchased by all governmental institutions in Oman.

• Quality assurance of medical supplies purchased by Ministry of Health shall follow an undergoing process through many procedures from product selection, receipt, distribution and quality monitoring, which may be illustrated as under:

✓ Careful product & supplier selection.

✓ Registration of manufacturers and their pharmaceutical products.

✓ Prequalification of Manufacturers of Medical and Laboratory items.

✓ Batch certification for each batch supplied.

✓ Post shipment inspection.

✓ Analytical drug testing (QCL).

✓ Proper storage and distribution procedures.

✓ Drugs & Medical Supplies Quality Reporting Programs.

6.6 Emergency purchase from Oman Embassy in UK and India should be considered as important alternative source of urgent supply in case of:

• Non approved items requested urgently for hospitals or for patients treated abroad through Local Purchase Request/Form-A, when they are not available in the local market.

• Shortage in the stock due to delay in medical supplies and non-availability of alternative stock in the local market.

• No offers are received in the tenders due to small quantity requested or small value.

**Exclusion:** Not to be purchased through Oman Embassy in UK and India

- Heavy or Bulky items due to high air freight costs.

- Biological products and vaccines for safety reasons.

- Refrigerated items unless it is required in emergency situations taken into consideration that the appropriate cold packaging is maintained during shipments and accompanied with data loggers.

- Inflammable and restricted chemical items for safety reasons.
6.7 The below mentioned Procurement Performance Indicators should be monitored quarterly by DGMS, analyzed, documented and disseminated to the management:

- Percentage availability of Vital Medicines (target ≥95%)
- Percentage availability of Vital Surgical & Lab items (target ≥95%)
- Percentage of Procurement through Open Tenders (target ≥95%)
- Percentage of prequalified manufacturers of medical devices (target ≥75%)
- Percentage of Procurement of Formulary Drugs (target ≥ 95%)
- Average Percentage of 40 key drugs with International Price Indicators (target ≥ 75%)
- Percentage of batches passed QCL Analysis (target ≥ 95%)

7.0 RESPONSIBILITY

The Directorate General of Medical Supplies (DGMS):

- Quantification of annual requirements, processing of tenders, receipt, storage, and distribution of the medical supplies to MOH Healthcare units and monitoring the quality of the purchased products.
- Procurement of the urgent and emergency needs.

The Directorate General of Financial Affairs (DGFA):

- Budget allocation, approval and dispatch of LPOs, signing the contracts and making payments, sanctioning the delay penalties in case delay etc.

8.0 RELATED DOCUMENTS

8.1 Royal decree No. 36/2008, Regulating the Execution of Government Tenders
8.2 Managing Medical Supplies Policy (MOH-DGMS-PH-12)
8.3 Response to Out-of-Stock Formulary Medications (MOH-DGMS-PH-13)
8.4 Handling of Non-Formulary Requests (MOH-DGMS-PH-28)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operational principles for good pharmaceutical procurement, WHO</td>
<td>J Rankin, JD Quick, S. Muziki</td>
<td>1999</td>
<td>32</td>
</tr>
<tr>
<td>Procurement process resource guide – WHO Medical device Technical Series</td>
<td>Andrew Gammie</td>
<td>2011</td>
<td>27</td>
</tr>
<tr>
<td>Managing Procurement, Part II Pharmaceutical Management, WHO</td>
<td>Management Sciences for Health</td>
<td>2012</td>
<td>38</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

Ensuring an adequate supply of safe and effective drugs of acceptable quality is an integral part of the MOH healthcare policy. Drugs, surgical and laboratory consumables play a crucial role in diagnostic, preventive and curative healthcare. They are a vital and an expensive component in the provision of health services, they constitute a proportion of more than 10% out of the overall health allocated budget.

To ensure maximum benefit from such investment, it is essential that the medical supplies requirements should be based on realistic estimates. Rational prescribing and efficient drug management with a sense of cost and quality consciousness are equally important.

Central medical supplies operations and distribution system for multiple facilities are better able to improve inventory cost management, standardize formulary, eliminate redundancy, and streamline workflow to improve efficiency, reduce expenses and optimize the medication supply chain.

Inadequate storage space in DGMS and Health Units in MOH due to the growing increase in the consumption of drugs, surgical and laboratory and expansion and accessibility of health services is of great concern. However this is at least managed by requesting multiple delivery lots from the Manufacturer and issue of monthly, bi-monthly or every three months’ supply to the Health Units according to the storage space available in each Health Unit. Bulky supplies like I.V fluids. Inco pads etc. are supplied to some hospitals every two weeks.

2.0 SCOPE

Distribution of medical supplies including, indenting, issue, transportation, receipt and storage of medical supplies.

3.0 PURPOSE

3.1 Describe the general measures considered appropriate for the indenting, issue, receipt, transportation and storage of medical supplies in MOH Healthcare units.

3.2 Ensure that the desired standards of stock management and quality of products are achieved.

4.0 DEFINITION

Drug Distribution System: Refers to the different methods by which the pharmacy receives drug orders, prepares the drug for distribution and in turn, distributes the drug to the patient care area.

An indent: Is an official order or requisition for supply of medical supplies from the medical stores based on estimation and budget availability.
Normal indent: For the regular periodic indenting as per the predetermined delivery schedule.

Supplementary indent: For additional requirement of items that have shown an unexpected increase or unstable consumption.

Urgent Indent: To cover the acute shortage of vital and lifesaving items.

Non-moving item: If its stock remains static for a period exceeding one third of the period of its validity. As example, the items with total validity period of more than 18 months and other surgical items with no validity date are also deemed non-moving if their stock remains static for six months continuously.

Slow-moving item: If they are demanded seldom and remain in stock for long or irregular periods and accordingly less than 50% available stock is issued in the last three months and some amounts are anticipated to remain unused at the time of expiry.

5.0 POLICY

5.1 Medical stores staff must have practical skills in ordering, storage, dispensing as well as in record keeping. They must develop promptness, accuracy in recording and counting the exact amounts and well organized to be able to do the job properly. Personnel employed in storage are should wear suitable protective or working uniform appropriate for the activities they perform.

5.2 At each storage site there should be an adequate number of qualified personnel to achieve quality assurance objectives. Personnel should receive proper training in relation to good stock management practices, regulations, procedures and safety.

5.3 A good stock control system should be strictly followed to prevent under stocking, stock outs, over stocking and products expiring before they can be used and ensures efficient use of financial resources. The stock in the pharmacy & medical stores, wards and other medical departments (unofficial stock) must be considered while indenting and stock checking.

5.4 The Directors of Drug & Medical Stores at DGMS will prepare a predefined agreeable one year planner of indenting Schedule to regulate the issue of supplies to all health units. This annual schedule will be communicated to all health units in the governorates in the month of December of every year for execution from the beginning of January of the next year. Further an updated monthly indenting schedule will be circulated by DGMS to the concerned health units prior to the beginning of each month. However if the submission of the monthly indent from any health unit is delayed beyond the specified month then it will be automatically posted to the next month.

5.5 While processing the normal indents by DGMS, an extra buffer stock quantity will be issued to accommodate any increase in the consumption based on indent issue frequency periods as follows:

- 7 days (23.3%) extra quantity will be issued for monthly indents.
- 10 days (16.6%) extra quantity will be issued for bi-monthly indents.
- 14 days (15.5%) extra quantities will be issued for three-monthly indents.
5.6 The expiry dates of products in DGMS system are be allotted as per the exact expiry details i.e. date, month and year that affixed on the packs by the manufacturers, however when the expiry dates are being affixed by the manufacturers in months and years only e.g. April 2019 the expiry dates will be incorporated in DGMS system at the end of that month e.g. 30 April 2019 based on the expiry dates stated in the certificates of analysis of each batch received or as recommended by the respective manufacturer.

5.7 Direct receipt or distribution of breast milk substitutes by baby milk companies is strictly prohibited as per Omani Code for Marketing of Breast Milk products as it contradict with MOH policy encouraging breast milk feeding. In case of violation, the name of the violating medical representative and his company should be reported.

6.0 PROCEDURE

6.1 Indenting for Medical Supplies:

• The Health Units shall prepare the periodic (normal) indents well in advance so as to reach DGMS at least one week before the specified delivery schedule. Separate indent should be sent for each category i.e. Drugs /surgical/ Lab. to expedite processing by each concerned store. On account of any unexpected national holidays, the rescheduling of the indents will be informed by DGMS.

• The quantities indented should cover monthly, bimonthly or quarterly requirement as per the predetermined delivery frequency taking into consideration the buffer stock required during the lead-time. It is imperative that indents must be prepared correctly including the stock available in the medical stores, pharmacy and medical departments.

• If the requested quantity exceeds the average consumption, the health unit should give justification as a remark in the indent or by separate letter. Acceptance to issue more quantity is subject to availability of sufficient stock in DGMS and validity of the reasons provided and criticality of the item needed.

• Health units that are sending online indents through the system need to confirm with the DGMS for its receipt and also to send a hard copy of the same within the same week.

• Hard copy of the indent to be submitted in the reception in DGMS / Regional Stores for registration and distribution by the Administration Department in DGMS to the concerned stores. Referral forms of specialized drugs (for new cases only) should be submitted with the indent.

• For Narcotics, a complete and clearly hand-written form A, countersigned and stamped by Pharmacist In-charge and Medical Officer In-charge of a hospital/health unit should be delivered along with computer generated indent by fax/in-person.

• For Psychotropic a normal indent, countersigned by pharmacist In-charge to be delivered by fax / in-person.

• Indents for non-approved medicines prescribed for individual cases should be submitted separately along with Form-A. Request for non-approved medicines prescribed by Royal Hospital/ Sultan Qaboos University hospital should be arranged directly by these institutions. Please refer to policy titled “Handling of Non-Formulary requests MOH-DGMS -PH-28”.

85
6.2 Issue of supplies to health units:

- Issue will be based on the stock available in requesting health units and average consumption during the last 12 months, plus the extra buffer quantity as per the approved issue policy and according to stock availability in the Central / Regional Stores in DGMS.

- When the quantity is issued as per the actual average consumption rates plus the extra buffer stock, the supply will be considered as completed irrespective to the non-issued quantity.

- The computer system will only allow the issue according to nearest expiry date i.e. First Expiry First Out (FEFO) unless authorized to issue longer expiry. However in very few circumstances a small quantity may be issued with remaining three month shelf life. While efforts should be made to utilize these items prior its expiry dates to avoid wastage, care shall be taken not to issue these items for a period beyond the course of the treatment period.

- Loose quantities will not be issued, unless it is unavoidable like request for minute quantities less than the full pack. Instead sometimes full pack with extra quantity may be issued with a note in the issue voucher that extra quantity is being issued more than requested to be considered in the next order.

- Supplementary indents will be issued within at least three days. Urgent indents for life saving will be issued on the same day. Pending quantities mentioned in the pending issue report will be sent on receiving the items by DGMS, therefore sending supplementary indents for those pending quantities is not necessary.

- An automatically generated pending issue report from the system will include quantities non-issued fully or partially due to non-availability of stock. If a suitable alternative for the pending item is available, the health unit to be informed to place a separate indent if desired.

- The main reasons in case of not issuing the full quantity requested will be mentioned in the pending issue report as:
  - Stock not available and will be issued when received.
  - Less stock available, the remaining quantity will be issued when received.

- On supply and receipt of pending items at the central or regional stores later on, the computer system to generate a report about the details of health units and the pending quantities to facilitate compiling the pending issue quantities of various health units as ready reference and expediting the issue procedure to each health unit. Any pending quantity will be cancelled if the next periodic order is received and contains the same item(s).

- Very short expiry laboratory items will be issued directly on receipt to the concerned health unit based on a pre-coordinated arrangement.

- Specifically specialized medical supplies like instruments will be issued based on the annual estimation received from the concerned regional hospital.
• Issuing of narcotics will be made after the arrival of the officially delegated pharmacist from the concerned health unit. Printed narcotic issue vouchers and normal issue voucher for psychotropic will be signed by both the issuer and the recipient after careful checking of the issued quantity and accordingly the items will be collected by the pharmacist.

6.3 Dispatch and Transportation

• The packed cartons from each store in DGMS will be numbered serially. The number of cartons to be mentioned against each item in the issue voucher, for tracing purposes later on, if needed. The issue voucher and pending issue reports must be printed and handed over to the driver of the transporting vehicle.

• If loose quantity is issued it will be kept in an envelope or amber glass bottles for the tablets with clear indication of the item description, quantity issued, batch no and expiry dates on the envelopes or the labels of the containers. Loose items to be kept in one carton with affixing a label sticker – LOOSE.

• The total number of cartons from each section to be indicated the attached Medical Supplies Dispatch & Receipt Form Arabic (Annex A). The Dispatch Form, after verification of the total number of carton should be signed and handed over to the driver of the shipping vehicle. The driver name, his mobile number and vehicle number should be mentioned in the dispatch form. Copy of the signed dispatch form should be faxed back to Supply Chain Section, DGMS via Fax 2235 8489 or 2235 8333.

• Products should be transported from DGMS in such a way that their integrity is not impaired and that storage conditions are maintained. Transport road vehicle shall be equipped with A/C. Pending, supplementary, urgent quantities should be collected by health units in A/C vehicle.

• Refrigerated items will be packed appropriately in a cool box with sufficient number of ice bags, as per the packing list. Refrigerated items and the inflammable items will be kept as the last items in the vehicles. These items must be removed immediately first on receipt by the health units and to be kept in the dedicated storage area as required.

• The entire content of cool boxes should evacuated instantly on receipt, to enable returning with the vehicles along with the ice packs and refrigerated packing list being signed indicating the receipt of all fridge items in good storage conditions.

• When appropriate DGMS will keep Data Loggers inside the vehicle/cool boxes for long distance institutions. In such cases the receiving person in the health unit shall state in writing the exact arrival time in the specified format provided with the Data loggers and return the form and data logger with the same driver.

6.4 Receipt at Health Units:

• On arrival of the consignment, the receiving person in the health unit shall sign the dispatch form confirming the receipt of all cartons. Later on, the Health unit should check carefully the items received against the issue voucher and sign on the green copy and send it back to the central stores within a week’s time confirming the receipt of full quantities. If the copy is not sent back the consignment will considered as completely received.
6.4.1 Settlement of discrepancy in issues / receipt

Discrepancy in issue or receipt of any item in the health unit should be dealt with as per the approved procedure regarding the settlement of quantities received as excess or less as under:

- If variation between the quantity or batches indicated in the issue voucher and the actual received quantity has been observed, the stock taking of the item and other look alike items should be checked again. If discrepancy is confirmed the health unit should fill the attached Receipt Discrepancy Form (Annex B) and send the same with a covering letter to the Head of follow up Office of Director General of Medical Supplies, Fax No. 2235 8333 within a week’s time maximum.

- Accordingly DGMS independent stock verification committee will conduct a physical stock checking of the item and take the following steps based on the findings:
  - If the Excess quantity is reported by the health tally with the less quantity observed in DGMS, the health unit will be informed officially to return the excess quantity if it exceeds more than average two months consumption of the health units. However the health unit is not required to return the excess quantity of less than two months consumption and instead an issue voucher will be issued from the DGMS to facilitate receiving the excess quantity in the inventory of health units. For excess quantity settlement the health unit should issue a Receipt Voucher (Form No. 2/1 – Medical Stores) as per the regulation in force.
  - If less quantity reported by the health unit tally with excess stock found in DGMS the health units will be informed to collect the less quantity from DGMS.
  - If less reported quantity is not found in DGMS, the concerned store will verify with all health unit being issued at the same day. If it is confirmed also that no excess stock is supplied to them, then the health unit will be notified to fill the adjustment Form of Excess or Less stock (Form no: 11 Stores) with the details of less quantity and to process an issue voucher (Form No.5 - Medical Stores) to settle the difference in less quantity, on approval by the Director of the hospital / health unit, as per regulation in force.

6.5 Storage at Health Units

6.5.1 General

- Storage areas should be of sufficient capacity to allow the orderly storage of the various categories of medical supplies, products in quarantine, and returned or recalled products. Precautions must be taken to prevent unauthorized persons from entering storage areas.

- Storage areas should be designed or adapted to ensure good storage conditions. In particular, they should be clean, dry and free from accumulated waste and vermin, and maintained within required temperature limits and adequate lighting. Products should be stored off the floor and suitably spaced to permit cleaning and inspection. For more general storage guidelines please refer to MOH policy titled “Pharmacy departmental safety policy (MOH-DGMS-PH-06)”.
• A sanitation contract should be available indicating the frequency of cleaning and the methods to be used to clean the premises and storage areas. There should be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination.

• There should also be a written programmed contract for pest control. The pest-control agents used should be safe, and there should be no risk of contamination of the materials and pharmaceutical products.

• Physical segregation quarantine area should be provided away from shelves for the storage of rejected, expired, recalled or returned products. The products, and areas concerned should be appropriately identified. The cartons of such products should carry a labelling sticker “Expired or Recalled not for use”.

• Highly active and radioactive materials, narcotics, psychotropic and other hazardous, sensitive and/or dangerous materials and pharmaceutical products, as well as substances presenting special risks of abuse, fire or explosion, (e.g. combustible liquids and solids and pressurized gases) should be stored in a dedicated area that is subject to appropriate additional safety and security measures.

• Medical Supplies should be stored in conditions which assure that their quality is maintained, and stock should be appropriately rotated. The “First Expired/First Out” (FEFO) principle should be followed.

6.5.2 Cold chain management

• Cold rooms in hospitals shall be equipped with alarm system connected with maintenance department for 24 hours surveillance.

• Temperature of cold rooms and refrigerators must be monitored and recorded twice daily on the specified temperature monitoring chart (Annex C) including holidays and weekends.

• Household-style refrigerators are acceptable if they have been independently tested and found to comply with the temperature control requirements of a recognized standard for medical refrigerators.

• Generator back up in health unit must be available with adequate fuel tank capacity and sufficient fuel to cover a prolonged power outage.

• While carrying out dispensing, cold room power supply should not be switched off and the door must be closed.

• For Personnel safety to minimise the risks associated with cold stress and potential hypothermia:
  ✓ Protective clothing and equipment i.e., coats, gloves etc. should be used.
  ✓ Maximum time a staff staying in the cold room should not exceed 30 minutes at a time, with minimum of 15 minutes break.
  ✓ Cold room doors should be opening freely from inside.
  ✓ Before entering & after leaving the cold room, another staff should be informed.
• Recorded temperature monitoring data should be available for review. The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained.

• Temperature mapping should show uniformity of the temperature across the storage facility. It is recommended that temperature monitors be located in areas that are most likely to show fluctuations.

• Equipment used for monitoring should also be calibrated at defined intervals.

• In case of any shutdown or power outages, please report to DGMS within 24 hours with complete details of items (item name, code, quantity, batch no, manufacturer) and the excursion temperature & duration, for further study about the suitability of use based on the respective manufacturer recommendation.

6.5.3 Non-Moving, Slow Moving:

• Medical stores in health units should check quarterly and define the non-moving or slow-moving items. A statement indicating the available stock non/slow-moving items, its expiry date, last receipt and issues and review reasons.

• The Health Unit should verify the possibilities of its use in other health units in the Governorate. However, rotation of stock of Narcotics & Psychotropics between health units shall be subject to prior official written approval from DGMS.

• Only limited quantities shall be requested for vital, but slow-moving items. What remains in stock in the health unit may be replaced before being expired according to procedures stated in provision 1 above.

6.5.4 Dealing with expired and items not suitable for use:

• Upon expiry of any item, or availability of item not suitable for use or spoiled, the in charge of medical stores in the health unit should immediately remove the item from shelves and keep it in an isolated place away from the issue areas at the store/pharmacy. The quantity removed shall be deducted from the balance stock recorded in the registers and entered in the Format of Sale and Condemnation of items (Form no. 12 Stores) with indication of the reasons and involved value.

• The above said form should be forwarded for approval of HE The Under Secretary for Admin & Finance.

• Upon approval by the matter to be referred to the Sale & Condemnation Committee the concerned health unit for verification and safe disposal of the items, in coordination with Oman Environmental Services Holding Company S.A.O.C “be’ah”.

• The above procedure does not apply to expired/ spoiled controlled narcotics and psychotropic drugs which should be dealt with Director General of Pharmaceutical Affairs & Drug Control (DGPA&DC) as per the regulation in force.

6.5.5 Return of items from Health Units

Return of items to DGMS should be against the Material Return Voucher (Form No. 15 -Stores) for the following four types;
• Slow and non-moving items: Health units to send a letter requesting for return of slow moving, or item approaching expiry for DGMS. Only on receipt of official approval from DGMS the item should be returned.

• Replacement against guarantee letter: In case of replacement of expired batches received earlier against guarantee letter the Director of the Drug / Medical Stores in DGMS will inform the concerned health units to return the available stock, if any.

• Recalled quantities (for quality reasons only) the involved batches shall be removed from the stock and returned to DGMS within a week's time of initiation of Recall by DGMS

• Return on request by DGMS: This include the request from DGMS for return of items for rotation to other Health units or quantities issued by mistake.

The returned quantity from each Health Unit to be deducted in the in DGMS Inventory Management System from the issued quantity to reflect in the real consumption of that health unit.

6.5.6 Inventory management

• Periodic random and annual stock reconciliation (stock checking) should be performed by comparing the actual and recorded stocks. All significant stock discrepancies should be investigated as a check against inadvertent mix-ups and/or incorrect issue. Amendments of discrepancy of the stock should be entered in the Form of Excess or Less stock (Form no: 11 Stores) and approved by the Director of the Hospital /Health unit or Director General as applicable and amended in the system by only the Information Technology Department.

• The following reports should be retrieved from the inventory system in each health unit for study and appropriate action.

  ✓ Monthly report of expired/spoiled list of items.
  ✓ Monthly report on near expiry items.
  ✓ Monthly report on items available for less than 1 month.
  ✓ Quarterly report for stock available for more than 4 months.

7.0 RESPONSIBILITY

Directorate General of Medical Supplies:

• Maintaining sufficient regular stock of good quality at reasonable cost to meet the requirements of health units in timely manner.

Pharmacy and Medical Stores in Healthcare units:

• Maintain sufficient stock based on realistic needs.

• Monitor the physical stock, consumption patterns and the quality of products in the pharmacy, medical stores and floor stock in all medical units.
8.0 RELATED DOCUMENTS
8.1 Pharmacy Departmental Safety Policy (MOH-DGMS -PH- 06)
8.2 Procurement of medical supplies (MOH-DGMS -PH- 11)
8.3 Response to Out-of-Stock Formulary Medications (MOH-DGMS -PH- 13)
8.4 Handling of Non-Formulary requests (MOH-DGMS -PH- 28)
8.5 Handling Drug Recalls (MOH-DGMS -PH- 38)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/journal/articles/Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical supplies and equipment for Primary Health Care, ECHO Intl Health Services</td>
<td>Manjit Kaur &amp; Sarah Hall</td>
<td>2001</td>
<td>192</td>
</tr>
<tr>
<td>Guidance for Storage &amp; Transport of time and temperature-sensitive pharmaceutical products</td>
<td>WHO TaskForce</td>
<td>2011</td>
<td>49</td>
</tr>
<tr>
<td>Centralizing Drug Distribution for Health System Pharmacies</td>
<td>Barbara Giacomelli</td>
<td>2016</td>
<td>3</td>
</tr>
<tr>
<td>Temperature Management of Medicines Storage and Transport, S. Health, NHS</td>
<td>Steve Mennear</td>
<td>2017</td>
<td>18</td>
</tr>
</tbody>
</table>
التاريخ : / / م   وقت المغادرة : .................................

جهة التحميل
المؤسسة الصحية
المحافظة : اسم الموظف / السائق
رقم البطاقة / الرخصة : وزن الشاحنة : ( ) طن
نوع الحمولة : ( )
رقم الهيكل : توقيع السائق
توقيع الامام المخزن

<table>
<thead>
<tr>
<th>الأقسام</th>
<th>عدد الكراتين</th>
<th>عدد الألواح</th>
<th>توقيع أمين المخزن</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cool Box</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>مخزن الحقن</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Misc</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>مخزن الأدوية المتنوعة</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tablet</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>مخزن الأقراص</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Syrup</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>مخزن الأشربة</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Instruments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>مخزن الآلات والأدوات المتخصصة</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surg. (store 5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>مخزن المضادات والأربطة الجراحية</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Misc. (store)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>مخزن المواد المتنوعة</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disposable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>مخزن المواد ذات الاستعمال المفرد</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>مخزن المواد المختبرية</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spare parts</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>مخزن قطع غيار الأجهزة الطبية</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flammable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>المواد قابلة للإشعال</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>المجموع</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

توقيع سلسلة الإمداد : .................................................................

يعتمد : ...........................................................................................................

مدير دائرة مستودعات الأدوية/مدير دائرة مستودعات المواد الطبية
( يعني هذا الجزء من قبل الوحدة الصحية )

 توقيع : .................................................................
التاريخ : .................................................................
الوقت الوصول : .................................................................
الختم : .................................................................

ملاحظة : تعاد هذه الإمارة ( فور إستلام المواد ) إلى المديرية العامة للإسعاف الطبي بالفاكس رقم : ( 22358489 أو 22358332 )
Annex B

RECEIPT DISCREPANCY REPORT

To,

The Head of Coordination & Follow up,
DG Office, DGMS, Muscat.

Fax: 2235 8333

STORE : ...........................................................................................................................................................................................................

<table>
<thead>
<tr>
<th>Sr</th>
<th>Item code</th>
<th>Description</th>
<th>SIVM no: &amp; Date</th>
<th>Qty as per Issue Voucher</th>
<th>Batch &amp; Expiry</th>
<th>Qty received physically</th>
<th>Batch &amp; Expiry</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Receiving Staff name: ........................................................................................................ Signature: .........................................................................................................................

Head of Pharmacy & Medical Stores: ................................................................. Signature: .........................................................................................................................

Health unit name: ......................................................................................................... Governorate: ........................................................................................................... Health Unit Stamp
### Annex C

**COLD ROOM & FRIDGE TEMPERATURE MONITORING CHART**

| Date | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
|      |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
|      |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| **Record max temp (°C)** | +14 | +13 | +11 | +10 | +9 | +8 | +7 | +6 | +5 | +4 | +3 | +2 | +1 | 0 | -1 | -2 | -3 | -4 | -5 | -6 | -7 | -8 | -9 | -10 | -11 | -12 | -13 | -14 | -15 | -16 | -17 | -18 | -19 | -20 | -21 | -22 | -23 | -24 | -25 | -26 | -27 | -28 | -29 | -30 | -31 |
| **Record min temp (°C)** |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| **Initials** |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| **Comments** |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |

**Note:** ✓ When checked, STRIVE FOR 5°C
1.0 INTRODUCTION

Drug shortages present an ongoing challenge for healthcare providers and health facilities. There are a variety of reasons for drug shortages. According to the ASHP/UUHC drug shortage program, manufacturing problems constitutes (23%), increased supply/demand issues (13%), discontinuation (6%), raw materials (3%) and (55%) for other reasons.

In MOH Oman drug shortage may occur due to several reasons, including:

- Delay in supplies by the manufacturers due to manufacturing problems, raw material shortage or regulatory issues.
- Unexpected increases in utilization of a drug, due to change in treatment protocol, resulting in a temporary shortage.
- Increased number of referral cases on approved specialized medicines from Royal Hospital without prior intimation to DGMS to arrange additional quantities.
- No offers are received from any supplier locally and no other sources are available.
- Voluntary discontinuations or recalls of a product by the manufacturer.
- Withdrawal/recall from the market by Health Authorities/Manufacturers or DGMS for quality problems.
- Increased demand due to emergency situations or infectious disease outbreak like H1N1.

2.0 SCOPE

Shortage in all life-saving and essential medical supplies approved in MOH formulary

3.0 PURPOSE

To establish an acceptable response pattern to be followed in dealing with out-of-stock situations of the approved drugs in MOH Healthcare Units.

4.0 DEFINITION

4.1 Critical, Life-Saving Item - Any drug that is required to be given within 24 hours for a life-threatening situation, without which the patient would suffer adverse consequences.

4.2 Non Critical Item – A drug that can be safely withheld for a period of time. Their availability is preferred but not crucial.

5.0 POLICY

5.1 Directorate General of Medical Supplies (DGMS) shall develop reasonable defined steps to follow when attempting to resolve pharmaceutical stock shortages.

5.2 This policy applies to all out-of-stock approved lifesaving/essential medicines; the response will differ based on the severity of the situation
6.0 PROCEDURE

6.1 General strategies for managing shortages:
- Validate drug shortage.
- Follow good inventory management practices.
- Identify alternative drugs or therapeutic equivalents.
- Prioritize patients to receive drugs in short supply.
- Modify Approved Drug Lists, Clinical guidelines & other policies for discontinued products.
- Establish contact with other sites of Health Systems.
- Advance information from the suppliers about the anticipated drug shortage to address the issue proactively.

6.2 Health systems should refrain from stock piling which causes two distinct problems:
- Increased inventory is costly and may not be absorbed by normal usage if shortages do not occur as anticipated.
- Stockpiling can cause artificial shortages when health systems drain the supply chain and exceed ordering capacities.

6.3 Directorate General of Medical Supplies (DGMS) should follow the below procedure in case of drug shortage:
- The Drug Stores Department will liaise with the Department of Specifications & Supplies to determine the expected due date of delivery of the item, from the respective supplier.
- If the final determination is that there is no supply of the item at the stores within a week’s time, and if the same item is available in other dosage strength, the quantity of that item may be considered for increase.
- Attempts should be made to procure a suitable quantity from the local market to cover the shortage. However if not available in the market, to arrange a loan from the Strategic Reserve Stores.
- If the item is not available in Strategic Reserve Stores also, arrangements should be made to obtain an Emergency Purchase through Oman Embassy UK or India.
- If small quantity is required consider taking as a loan from other governmental institutions.
- If there is no supply anticipated and no offers are received, The Drug Stores Department should inform the Health Units about the shortage, for intimation to the end users.
- For items discontinued by the manufacturers, and when no other sources are available, the matter to be referred to the Central Drug Committee (CDC) for omission of the item from MOH Formulary and approval of a suitable alternative if any.
- The Department of Specifications & Supplies should review on monthly basis the list of items not sufficient for one month / non-available drugs / Overdue supplies and follow up vigorously with suppliers to expedite the supply.

6.4 The Pharmacy & Medical Stores at Health Units should follow the below procedure in case of shortage:
- The pharmacist in the Pharmacy/Medical Stores, shall first determine that the medicine is in fact out-of-stock.
• If no stock can be located, the Medical Stores Department will send an Urgent Demand to the Central Drug Stores DGMS / Regional Medical Stores to deal with the situation.

• If the final determination is that there is no supply of the item will be received soon from the Central Drug Stores / Regional Medical Stores, the pharmacist will suggest to the prescribing physician, if possible, the substitution of a therapeutically equivalent item from the MOH approved formulary, as the below suggested actions:-

  Action 1: Use interchangeable product if medication is unavailable.
  Action 2: Switch to an alternative drug within class.
  Action 3: Switch to alternative drug class to ensure continued therapy for the disease.

• In emergency situations the pharmacist on duty will attempt to arrange a loan of the item from the nearest MOH Health facility.

• What other medicines the patient is taking and also whether the patient should remain on the current medication or to switch back to the original when received these are considerations need to be addressed with the prescriber when discontinuing temporarily the original medication.

7.0 RESPONSIBILITY

Directorate General of Medical Supplies (DGMS):
• Maintain sufficient stock for vital and essential medical supplies as applicable.
• Follow vigorously with the Suppliers to ensure the delivery of orders as per the specified delivery schedules,
• Arrange alternative stock of critical items through emergency purchase in case of shortage.

Pharmacy & Medical Stores Departments in Healthcare Units:
• Appropriate indenting of the Health Unit’s requirements.
• Follow good storage and dispensing guidelines.
• Rationalize the use of available stock and encourage using the available cost effective alternatives in case of shortage.

8.0 RELATED DOCUMENTS
- Procurement of Medical Supplies (MH-DGMS-PH-11)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidelines for managing Drug Shortage in Hospitals &amp; Health System</td>
<td>American Society for Health System Pharmacists</td>
<td>2009</td>
<td>7</td>
</tr>
<tr>
<td>Drug Shortages – A Guide for Assessment and Patient Management</td>
<td>Canadian Pharmacists Association</td>
<td>2010</td>
<td>12</td>
</tr>
<tr>
<td>Medicine Shortage Information – General Information</td>
<td>Dept of Health Australian Govt</td>
<td>2016</td>
<td>7</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

Unused medications can pose a significant health, safety and environmental hazard when improperly stored or disposed of. Many countries have established “Medication Return Programs” to allow the public to return (at no charge) unused or expired medications to the participating pharmacies in the provinces.

Due to improper disposal of these drugs, there are traces of pharmaceuticals in the environment—in the soil and in the water. Concentration levels of these products may be very low, but they may be enough to have adverse effects on the environment and on human health. Effects can also build up over time.

Expired and unused prescription medications are often left lying in medicine cabinets and cupboards at homes, which may lead to their potential misuse and abuse. Among the factors that contribute to excessive medicines in patient’s storage are as follow:

- Change of treatment regimen.
- Cessation of treatment regimen.
- Non-compliance to their medications.
- Patient has passed away.
- Medicines obtained from various sources (Polypharmacy).

2.0 SCOPE

Unused, spoiled, expired medication returned to MOH institutions by the public or patients.

3.0 PURPOSE

3.1 Promote the opportunity for the public to return the unwanted/expired medications to MOH Healthcare units for safe disposal in environmentally-friendly manner.

3.2 Reduce the risk of exposing the public to unwanted medicines and accidental poisoning at home.

4.0 DEFINITION

Medications Returned by patients: All unused or expired medications brought from home into the Health Units by the public or patients.

5.0 POLICY

5.1 All medications brought from home shall be handed over to the Pharmacy & Medical Stores Department in the Health Unit preferably during the normal duty hours.

5.2 The medications returned by patients shall not be entered to the regular stock as there is no assurance of their strength, quality, purity or identity.
5.3 Narcotic / Psychotropic or Controlled medications brought from home should be entered in the Medication Return Form and sent directly to Directorate General of Pharmaceutical Affairs & Drug Control (DGPA& DC) as per the current regulations.

5.4 Recalled items returned by patients should be sent to DGMS as per Drug Recall Policy (MOH-DGMS-PH-37) for compiling in quarantine and returning back to supplier for destruction and replacement with fresh stock of good quality.

5.5 Public are to be encouraged through campaigns and educations programs to return back the unused or expired medications from home for safe disposal and not to flush medicines down the toilet or sink.

5.6 Medications returned by patients shall not be thrown in the garbage or given away and shall be kept in dedicated containers for disposal in coordination with Oman Environmental Services Holding Company S.A.O.C “be’ah”.

5.7 A pharmaceutical destruction form should be submitted to be’ah including code number, item descriptions, trade names, generic names, dosage forms, pack size, packaging materials (blisters, glass bottles, ampoules etc. pharmacology group, batch number, expiry date, quantities, weight in Kg, total weight & remarks (expired, spoiled)

6.0 PROCEDURE

6.1 The Pharmacist shall identify the unwanted medications brought from home to be returned to the Pharmacy and fill out appropriately the Medication Return Form (Annex A) with the following details.

- Patient name (optional except for controlled drugs).
- Reason for return.
- Medication name and dosage form.
- Quantity returned and expiry date.
- Dispensed by (MOH / Private / Others).

6.2 In pharmacy area, the returned medications shall be sorted out by the following categories and put in the assigned boxes indicating the total weight in kilogram accordingly, in quarantine away from shelves:

- Non-cytotoxic medications returned from home.
- Cytotoxic materials returned from home.
- Narcotic & controlled Medications returned from home.

6.3 Medications issued by health unit and returned by patients within 24 hours to the same health unit due to dispensing error or they are not needed should be verified and approved by the Head of Pharmacy & Medical Stores for reuse and entry in the system, except if the one of the following conditions exists :

- Medication has been used, opened or loose tablets.
- Medications that require refrigeration.
- Medications that are expired.
- Medication is a compound drug.
6.4 Returned medications should be separated as solid medicines, ampoules/vials, liquids, and aerosols and kept in the quarantine.

6.5 The Quality Management, Medication Safety Officer and Head of Pharmacy & Medical Stores shall inspect regularly the medication return area to ensure that no return medications are being accumulated.

6.6 Copies of Medication Return Forms and disposal documentation should be kept in the Pharmacy & Medical Stores Department.

7.0 RESPONSIBILITY

Pharmacy & Medical Stores, in MOH Healthcare Units:
- Receive and safely dispose the patient’s returned medications through the proper channels (be‘ah) to provide a safe method for disposing of unwanted medicines.

8.0 RELATED DOCUMENTS

N/A

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disposal of unwanted medicines</td>
<td>NHS Community Pharmacy</td>
<td>2004</td>
<td>2</td>
</tr>
<tr>
<td>National Return and Disposal of Unwanted Medicines</td>
<td>Dept of Health, Australia</td>
<td>2008</td>
<td>3</td>
</tr>
<tr>
<td>Safe disposal of prescription drugs, Government of Canada</td>
<td>Health Canada</td>
<td>2016</td>
<td>3</td>
</tr>
<tr>
<td>Program Plan for Medication Return</td>
<td>Manitoba Pharmaceutical Association</td>
<td>2016</td>
<td>30</td>
</tr>
</tbody>
</table>
Sultanate of Oman
Ministry of Health

Governorate: ......................................................... Date: ........................................
Name of Hospital/EHC/HC: ..............................................................

**MEDICATION RETURNED BY PATIENT**

Name of the Patient/Person: ..............................................................
(Optional, Except for controlled drugs)

<table>
<thead>
<tr>
<th>Sr</th>
<th>Item</th>
<th>Dosage form</th>
<th>Qty</th>
<th>B.No: &amp; Expiry</th>
<th>Reasons for return</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Dispensed by: [ ] MOH Unit     [ ] Private Pharmacy     [ ] Others

Received by:
Name: ..................................................................................................
Designation: ..........................................................Signature: ....................

**Comments of the Head of Pharmacy & Medical Stores**

- [ ] To be used
- [ ] Not to be used
- [ ] To be destroyed by be’ah
- [ ] To be referred to DGPA&DC (Controlled items)

( ) Appropriate columns

Head of Pharmacy & Medical Stores........................................Signature:............

Note:
- Controlled drugs must be returned to DGPA&DC for destruction
1.0 INTRODUCTION

Floor stock systems increased the amount of human error involved with dispensing drugs, because they bypassed the pharmacist, who would have been aware of issues related to good dispensing practices and other drugs the patient may have been taking, according to knowledge source.

Floor stock system provides many advantages that include;

a) Ready availability of the required drugs at patient care area,

b) Elimination of drug returns,

c) Reduction in the number of drug order transcriptions for the pharmacy and

d) Reduction in the number of pharmacy personnel required.

On the other hand there are many disadvantages of floor stock system which include;

a) Potential for increased medication errors because the review of medication orders is eliminated,

b) Increased drug inventory,

c) Greater opportunity for pilferage and

d) Increased hazards associated with drug deterioration.

2.0 SCOPE

Floor stock medications maintained in the nursing areas at MOH hospitals.

3.0 PURPOSE

To ensure timely availability of necessary medications for urgent/emergent administration and efficient management of all medications maintained as floor stock in patient care areas.

4.0 DEFINITION

4.1 Floor Stock Medications: Are medications stored in the specialized nursing areas based on an approved list that is customized to meet the urgent need of the medical unit concerned.

4.2 Types of Floor Stock Medications:

4.2.1 Controlled medications.

4.2.2 Regular medications:

- Medications used in emergency situations (Stat).
- Routinely used medications that do not need pharmacy intervention (PRN).
5.0 POLICY

5.1 The inpatient pharmacy/medical department in coordination with the concerned physicians and the nursing units in the wards/clinics will develop a list of drugs to be supplied to each ward or clinic as floor stocks, including the minimum and maximum levels of floor stock supply of each item.

5.2 Floor stock should be minimized particularly in hospitals implementing Unit Dose System for 24 hours.

5.3 High-Alert medications (including concentrated electrolytes) are not allowed as Floor Stocks except in critical care areas (ICU, OR, ED etc.) or as part of Crash Cart medications.

5.4 Concentrated electrolyte products shall be stored separately from one another and segregated from other products containing potassium or sodium. Appropriate independent double check shall be carried out during dispensing and administering.

5.5 Any further addition or deletion in the floor stock’s list needs approval from the In-charge of the nursing unit and inpatient pharmacy.

5.6 Each nursing unit should have its approved list, posted on all floor stocks cabinets. It is also the responsibility of the individual nursing unit staff to maintain the specified stock levels to minimize wastage.

5.7 Floor stock medications should be properly labeled and stored separately in locked cabinets under proper storage conditions in a clean and organized area with proper temperature and light protection, and should not be accessible to patients or visitors.

6.0 PROCEDURE

6.1 The pharmacy shall maintain a master list of allowable floor stock medications which shall include maximum quantities to be stocked as floor stock in each nursing unit.

6.2 The type of medications supplied to the wards or clinics as floor stocks may differ from ward/clinic to another as per specialty, patient and service needs.

6.3 Concerning Narcotic and Controlled Drugs’ stocks the following has to be adhered to:
   - All Narcotic and Psychotropic drugs should be stored only in the approved Narcotic Cabinet. The key must be kept in custody with the nurse in-charge.
   - Narcotic and Psychotropic drugs should be prescribed, issued and recorded as per the approved controlled drugs regulations.
   - The stocks should be audited every shift with proper documentation of handing over.

6.4 Nursing units (the stock-able locations) should replenish the floor stock medications directly from the inpatient pharmacy or medical stores (whatever applicable), through a computerized request weekly or when needed on topping-up system basis.

6.5 External preparations, disinfectants, oral preparations, otic and ophthalmic preparations should be stored separately from injectable medicines.

6.6 Drugs requiring refrigeration should be stored in the refrigerator 2-8°C with proper temperature monitoring twice daily.
6.7 It is the head nurse’s responsibility that all discontinued or left over medications are returned after patient goes home, to the inpatient pharmacy and should not remain as floor stock.

6.8 Items not included on the floor stock list are not authorized to be issued through floor stock request;

6.9 No medications should be stocked in the nursing unit except those approved in the unit’s “Floor Stock list”. All non-approved floor stock medications will be collected during the periodic nursing-unit inspection.

6.10 Any expired medications or medications whose expiration date will fall before the time of the next inspection must be removed by the nursing unit and returned to the inpatient pharmacy.

6.11 It is the pharmacy’s responsibility to inspect all nursing care areas on a monthly basis to ensure that all medications are not over-stocked, well separated, properly labeled, and no expired medications are available.

7.0 RESPONSIBILITY

Pharmacy & Medical Stores Departments in Healthcare Units:

- Inpatient Pharmacy staff to ensure regular availability of the allowable floor stock medications in coordination with the incharge nurse and monitor regularly their quality, expiry and storage conditions.

8.0 RELATED DOCUMENTS

8.1 High Alert Medications Policy (MH-DGMS-PH-35)

8.2 Look Alike and Sound Alike Medication Policy (MH-DGMS-PH-36)

8.3 Managing Medical Supplies (MH-DGMS-PH-12)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control of concentrated electrolyte solutions</td>
<td>JCI, WHO</td>
<td>2007</td>
<td>3</td>
</tr>
<tr>
<td>Drug Dispensing Errors in A ward Stock System</td>
<td>Stig E. Anderson, Dept. of Clinical Pharmacy, Denmark</td>
<td>2009</td>
<td>5</td>
</tr>
<tr>
<td>Guidelines for Inpatient Pharmacy Practice – Floor Medications</td>
<td>Pharmaceutical Services, MOH Malaysia</td>
<td>2010</td>
<td>68</td>
</tr>
<tr>
<td>Floor Stock Orders</td>
<td>California Health Care Services</td>
<td>2012</td>
<td>1</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION
Patients should actively be encouraged to bring their own medications (POMs) with them during an inpatient stay to assist the treating doctors and pharmacists to take the best possible medication history and reconcile medications, initiated or ceased during an admission and at the point of discharge. POMs remain the property of the patient but, for safety purposes, must be managed appropriately by nursing unit staff during an inpatient admission. POMs must be stored in accordance with the storage conditions recommended on the packaging of the products by the respective manufacturer, and, where appropriate, returned to the patient upon discharge.

2.0 SCOPE
Patient’s own medication brought at the time of admission or consultation.

3.0 PURPOSE
3.1 Promote a safe and consistent approach to the management and use of Patient’s Own Medications (POMs).
3.2 Optimize patient care by ensuring that POMs are only administered to patients where it is safe and appropriate.

4.0 DEFINITION
Patient’s Own Medications (POMs): Are medications the patient is using before his admission to the hospital or attending any health unit to treat either the same disease or for other diseases.

5.0 POLICY
5.1 It is important that health unit staff have access to information pertaining to patients’ current medications to ensure a safe and consistent approach to the use of POMs during their hospital admission or attending any health unit, and promote continuity and quality in the management and administration of medications within MOH Health Units.

5.2 The patient’s own medications should be checked, appropriately stored, labeled and shall be re-dispensed and administered to the same patient only against physician’s order, or returned to the patient or disposed of with his consent.

6.0 PROCEDURE
6.1 Upon Admission :

6.1.1 When a patient arrives at the nursing unit, the admitting staff should ask patients to make their medications which they are actively taking available for documentation of medication history to be used for medication reconciliation and review before initiation of the treatment.
6.1.2 The in-charge nurse must inform the attending physician about the patient’s own medications for review and decide whether to be included or excluded from the treatment plan.

6.1.3 Nursing staff should place patient’s own medications in a plastic bag and complete the Patient’s Own Medication details with the patient’s addressograph and send the medications to the inpatient pharmacy for verification of the quantity, expiry dates integrity, clearness and its safety.

6.1.4 The pharmacist should sort POM from non-medications, identify the actual medication’s name, dosage, strength, and quantity and expiration date of each medication.

6.1.5 POMs to be used (administered) during the patient’s admitted episode, must be carefully assessed to ensure they meet the following requirements
- Loose medications (i.e. mixed supply contained in a bottle or blister pack) should not to be used unless they can be positively identified.
- The condition of the medication and the container must be of good quality i.e. clean, dry, with no sign of tampering, damage or contamination.
- Medication with specific storage instructions or short expiry once opened may only be used if clearly unopened and stored correctly (e.g. fridge items, eye drops).

6.1.6 The physician will assess the appropriateness and effectiveness of current patient’s own medications with particular consideration of any problems associated with current drug therapy and current medical condition and write to continue medications into the patient’s medication plan (discontinued medications should also be noted and reviewed at discharge).

6.1.7 If the Physician recommends using these medications, the bag containing Patient’s Own Medications that approved by the physician will be kept in the ward in a separate drawer labeled with patient’s name and file no.

6.1.8 Expired medications shall be placed in a plastic bag with expired medication sticker “expired” and stapled. A note to be added beside the medication name with the Patient’s Own Medication details.

6.1.9 Medications with unknown expiration date shall be kept in a plastic bag, with sticker bearing a note “unknown expiration date” and stapled. A note to be added beside the medication name as “unknown expiration date” with the Patient’s Own Medication details.

6.1.10 Narcotic and Controlled POMs: shall be sorted and kept in a zip lock plastic and a designated sticker to be affixed on the Patient’s Own Medication details, and to be kept in the ward Narcotic & Controlled drugs cabinet separately from the regular stock medications as per the approved Narcotic and Psychotropic Substance regulations.

6.1.11 Nursing staff will be responsible for the administration of the POMs to the patient.
6.1.12 If the patient’s home medications are not permitted, the patient to be informed and the nurse will send the medications of the admitted patient to the pharmacy department.

6.1.13 Home medications which are essential to the patient and not included in the hospital formulary (Non-Formulary Drug), will continue to be arranged by the patient themselves.

6.2 Patient’s Transfer:
When transferring a patient to another nursing unit in the hospital or another hospital the staff should place all POMs (including new medications issued by the hospital) and a copy of the patient’s current medication chart into POMs bag for transferal with the patient.

6.3 Upon patient’s discharge:

6.3.1 Nursing staff will sign the original Patient’s Own Medication list and return all patients’ own substances to the patient.

6.3.2 The patient shall be informed about the new medication regimen that the attending physician has prescribed for him. If the discharge regimen contains continuation of a Non-Formulary drug that’s found in the patient’s own medication, the pharmacist will dispense only the approved available medication and direct the patient to arrange the non-approved product(s).

6.3.3 For controlled drugs the nursing staff will bring Patients Own Medication Form and retrieve the narcotic or/and controlled POMs, and handed over to the patient or caregivers as deemed necessary.

6.4 Medications disposal:

6.4.1 The pharmacist will inspect Patient’s Own Medications and if it is determined that the medications are not clean, expired, or not properly labeled, the medication shall be disposed of, and patient will be informed of the action taken.

6.4.2 Medications still in pharmacy from discharged/deceased patients should be reviewed and disposed of at the hospital (pharmacy department) discretion and recorded.

7.0 RESPONSIBILITY
The pharmacist in-charge
• Review and assess appropriately the medications brought by the patient, for suitability before initiation of the treatment regimen by the Physician.
• Dispose the medications which are not properly labeled or expired, with the patient consent.

8.0 RELATED DOCUMENTS
Medication Reconciliation Policy (MOH-DGMS-PH-17)
### 9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of Patient’s Own Medications in Canadian Hospitals – A National Survey</td>
<td>Heather Lummis Ingrid Sketris, CJHP Volume 61</td>
<td>2008</td>
<td>9</td>
</tr>
<tr>
<td>Patients taking their own medications while in the Hospital</td>
<td>Mathew Grissinger, Pennsylvania, Patient Safety Advisory</td>
<td>2012</td>
<td>9</td>
</tr>
<tr>
<td>Guideline Patients’ Own Medications S. Australia Health</td>
<td>Public Health and Clinical Systems Division</td>
<td>2013</td>
<td>14</td>
</tr>
<tr>
<td>Handling and Storage of Patient’s Own Medicines on Inpatient Wards (S.O.P)</td>
<td>Cathy Riley, NHS UK</td>
<td>2015</td>
<td>6</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION
Medication reconciliation (MR) is a patient safety intervention that was introduced to improve communication about patients’ medication information during transition through the healthcare system. It is targeted at both the patient and the patient’s healthcare providers and is designed to help prevent adverse drug events. The need for effective (MR) processes has been well established. Without effective processes in place, failures in communication about a patient’s medications can result in harm to the patient, can unnecessarily burden the healthcare system, and can affect society at large. To achieve the overarching goal of (MR) in preventing adverse drug events from occurring is by collecting an accurate and comprehensive medication list and using this list to make appropriate prescribing decisions for a patient.

Medication reconciliation processes should be implemented within each healthcare sector, but for such intervention to be most effective, linkages across sectors are needed. The primary care sector has a pivotal role in creating these linkages with hospitals.

2.0 SCOPE
Reconciliation of all medications the patient is taking before admission or during transition.

3.0 PURPOSE
3.1 Reduce errors of omission, interactions or duplications in therapy and potential adverse drug reactions and to ensure that the medicines the patient was taking before admission or transfer are appropriate for the current status of the patient.

3.2 Obtain and maintain a complete and accurate list of the medications that a patient is taking, to optimize safe, effective, and appropriate drug therapy across continuum of care.

4.0 DEFINITION
Medication Reconciliation (MR): Is a formal process of obtaining and verifying a complete and accurate list of each patient’s current medicines.

5.0 POLICY
5.1 A medication history must be obtained for all patients on admission by collecting and documenting an accurate and up-to-date medications list.

5.2 The medication list should cover all types of medications that the patient is taking, including prescription medications, non-prescription medications, vitamins and supplements, natural and herbal products.

5.3 Medication reconciliation process shall be followed at the time of admission, transfer and discharge.
5.4 The Physician must review all the medications listed at the time of admission and then should decide to continue or discontinue the medications based on the patient status.

6.0 PROCEDURE

6.1 Admission

- For any admitted patient to MOH Health Units, all medications taken prior to admission, should be listed within twenty-four (24) hours of admission and documented on patient medication history. The patients must be identified and their names and other demographics to be recorded on documentation (if not already noted).

- The Physician will ask the patient about all his/her current medications they are currently taking including multivitamins and herbals and history of drug allergies or Adverse Drug Reactions (ADRs) and document all required information (drug name, strength, dose, route, formulation, frequency) on patient medication history. If the patient’s own drugs are available the strength and other information may be obtained from these drugs.

- If the patient is unable to recall his/her medications, other sources of information shall be consulted (e.g., caregiver recall, patient’s medication profile, patient’s primary care provider) to get all kind of information regarding patient case.

- There may be enough information gained from the patient and patient’s own drugs -as mentioned above- to create an accurate drug history. If at least two sources of information are available, they should be used to create an accurate drug history. Medications for the treatment of addiction must be preferably verified by someone other than the patient.

- The medication history must be signed and dated by the professional staff who is completing it.

- The Pharmacist will compare the initial medication order with the list of identifiable medications taken prior to admission and dispense the medication accordingly based on the physician order.

6.2 Patient Transfer/ Discharge:

- When patient is going for surgery or transfer to/from critical patient units, all medications should be discontinued, then the required final medication order must be written by the physician.

- When care is transferred a current and accurate list of medicines, including reasons for change is provided to the person taking over the patient’s care. Points of transition that require special attention are:
  - Admission to hospital.
  - Transfer from Emergency Department to other care areas (Wards, Intensive Care or Home).
  - Transfer from the Intensive Care Unit to the ward.
  - From the hospital to home, or to another hospital or to Primary Healthcare facility.
• Upon patient discharge from the Hospital to home, the prescriber shall list all medications to be continued by the patient on the Patient Discharge Plan.

7.0 RESPONSIBILITY

Pharmacy Department in Healthcare Units:
• The Pharmacist shall review the medication history taken at the time of admission by the Physician / Nurse and issue the medications prescribed at the time of admission and discharge, as required.

8.0 RELATED DOCUMENTS
- Patient’s own medications policy (MOH-DGMS-PH-16)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication Reconciliation</td>
<td>Australian commission on Safety and Quality in health care</td>
<td>2014</td>
<td>4</td>
</tr>
<tr>
<td>Assuring Medication Accuracy at Transition in care: Medication Reconciliation</td>
<td>JCI, WHO</td>
<td>2014</td>
<td>36</td>
</tr>
<tr>
<td>Medication Reconciliation Guide, ISMP, Ontario</td>
<td>IMPR Canada</td>
<td>2015</td>
<td>65</td>
</tr>
<tr>
<td>Medicines Reconciliation Policy, NHS Trust, UK</td>
<td>Gareth Fenn, NHS</td>
<td>2015</td>
<td>27</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

Medication order review is one of the important aspects of pharmacist patient care. All health-system pharmacies have an obligation to provide a review of medication orders that ensures safe medication use. Medication order review is ‘the systematic appraisal of all aspects of a patient’s medication management to optimize patient outcomes.’ It covers the review of all inpatient medication charts, ideally on a daily basis, medication reconciliation on admission ideally within 24 hours of admission for high-risk patients and during discharge process as well as outpatient prescriptions.

Medication order review is a composite of multiple tasks, including verifying information, applying critical thinking skills, and making appropriate decisions. The effective interprofessional collaboration allows pharmacists to make all necessary interventions in the medication-use process to identify and solve medication issues and increase patient safety.

2.0 SCOPE

Review of all medications orders, including but not limited to:

- Outpatient, inpatient, patient transfer and discharge prescriptions.
- Parenteral fluids and parenteral nutrition orders.

3.0 PURPOSE

To ensure that the medications prescribed are evaluated and monitored and the medication therapy is appropriate and thereby reducing the potential for preventable medication errors or adverse events.

4.0 DEFINITION

A medication Order: Is written directions provided by a prescribing practitioner for a specific medication to be administered to an individual. The prescribing practitioner may also give a medication order verbally in emergency situations.

Medication Order Review Is a multistep process in which pharmacists evaluate orders (prescriptions) for safety, efficacy, and appropriateness by examining drug- and patient-related factors.

5.0 POLICY

5.1 All patient information, including the patient’s name, medical record number, birth date, sex, pertinent problems/diagnosis, lab values, height, weight, pregnancy/lactation status, allergies, and sensitivities shall be available to all appropriate healthcare providers, including pharmacists.
5.2 The Pharmacy shall dispense medications only upon the receipt of complete, appropriate medication orders entered by authorized members of the medical staff. The order to be completed must include complete drug information, complete patient specific information, and complete prescriber information.

5.3 The pharmacy will review medication orders for availability, dose, route, frequency, drugs are prescribed and dispensed for their approved indications, or any other incomplete/incorrect prescribing information.

5.4 It is within acceptable professional pharmacy practice for pharmacist not to dispense medication based on clinical scientific knowledge and/or standards or practice until the matter is verified, provided that the physician and the immediate pharmacy supervisor involved in the care of the patient, are informed.

5.5 The pharmacist intervention made seeking verification of physician’s order should be activated and documented in the patient’s file in Al Shifa system.

5.6 Verbal orders for any medication are not acceptable, except under critical circumstances such as emergent care and life-threatening situation.

5.7 Where such verbal orders are necessary, the nurse, or other qualified practitioner, must repeat the verbal order back to the prescriber for verification. The prescribing physician will countersign the medication order before leaving the patient care area.

5.8 Telephone orders for medications are allowable if the prescriber cannot reasonably attend the patient care area to write the order (or enter using an offsite electronic method) within an appropriate time frame for care.

5.9 Where such telephone orders are necessary, the nurse, or other qualified practitioner, must repeat the medication order back to the prescriber for verification, unless the situation urgency does not allow for such verification. The physician, or designated replacement physician, will sign the telephone order as soon as possible, and in all circumstances within 24 hours of the order time.

5.10 Prescribing specialized medications beyond own specialty is not allowed as per the Central Drug Committee decisions and approved protocols, prescribing to be restricted for each item based on the allowed Specialty and Health care level.

5.11 Prescriptions for medications prescribed by doctors for themselves is permitted only in certain occasions i.e., to save a life or to avoid serious deterioration in health, where no other person with legal right to prescribe.

5.12 For high risk medications and high-risk patients (pediatric, geriatric or patients with renal or hepatic impairment) there should be systems in place to minimize adverse drug events.

6.0 PROCEDURE

6.1 The pharmacist reviews the order for completeness and appropriateness. If the order is complete and appropriate, the pharmacist will process the order.

6.2 Orders which are unclear, lacking the necessary elements of a medication order, or not appropriate for the patient the pharmacist should consult with a more senior pharmacist for a second opinion, where possible to discuss the concerns. If the order is still not acceptable, the pharmacist should call the physician who is responsible for the care of the patient for clarification.
6.3 In the event of conflict between the prescriber and the pharmacist, the issue shall be escalated to the pharmacy supervisor.

6.4 If the pharmacy supervisor feels it is not appropriate to dispense the order after discussions with the prescribing and/or staff physician in charge, he should contact the appropriate consultant physician to discuss the situation and take the next step in the process.

6.5 The pharmacist will review and monitor medication orders for the following:
- Patient allergies and sensitivities.
- Approved indications for use.
- Prescriber authority for restricted drugs.
- Therapeutic duplications.
- Any serious or potential Drug-Drug interactions and Drug-Food interactions that might affect the patient drug therapy outcome.
- Appropriateness of the medication dose, frequency, and route of administration.
- Contraindications.

6.6 For newly admitted patients, the pharmacist will compare the initial medication order with the list of medication taken prior to admission as per “Medication Reconciliation Policy” (MOH-DGMS-PH-17)

6.7 The Pharmacy department should have a multidisciplinary program system (Al Shifa system) whereby significant drug interactions are identified, resolved and communicated to physicians, nurses and/or dietitians, and patient’s caregivers, thereby providing a mechanism for effective drug-drug and drug food interaction management.

6.8 Medication orders for pediatric and neonatal patients should have normalized doses (e.g. Doses written as mg/kg where appropriate. The final dose should be calculated and provided on the order form). The weight of the patient should be on the order form or entered in the patient’s electronic medical record.

7.0 RESPONSIBILITY
Pharmacists, Assistant Pharmacists in Healthcare Units:
- Appropriately review the medication order, intervene with the prescriber when deemed necessary, entry of medication order, dispensing, counseling documenting and monitoring.

8.0 RELATED DOCUMENTS
8.1 Medication Reconciliation policy (MOH-DGMS-PH-17)
8.2 Discharge Medication Order (MOH-DGMS-PH-20)
8.3 Medicines Dispensing Guidelines (MOH-DGMS-PH-21)
## 9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical Review Policy, Office of Safety and Quality, Department of Health, W. Australia</td>
<td>Office of Safety and Quality, Department of Health, W. Australia</td>
<td>2007</td>
<td>30</td>
</tr>
<tr>
<td>Medication Order &amp; Administration UNM Health Science center, University of New Mexico</td>
<td>Medication Safety Committee, University of New Mexico</td>
<td>2012</td>
<td>15</td>
</tr>
<tr>
<td>Medication Order Requirements, Health Service Authority - Vancouver, USA</td>
<td>Health Service Authority - Vancouver, USA</td>
<td>2016</td>
<td>9</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

When Required Medications (PRN) medications are usually prescribed to treat short term or intermittent medical conditions i.e. it is not to be taken regularly. Medicines used to treat pain, nausea or vomiting as examples are often taken by people who are experiencing symptoms irregularly. In such circumstances the person may not need the medication every day.

Excessive issue of PRN medications may lead to unwanted adverse drug reactions, accumulation and wastage of medications. i.e., Paracetamol in MOH is a good example for such over use, where the annual consumption in the ministry has exceeded forty two million tablets.

PRN medication(s) may fall into any drug classification, and may include but are not limited to:

- Analgesics (medications used for pain) e.g. Paracetamol tablet and suppository etc.
- Anti-inflammatory drugs (medications used for inflammation & pain) e.g. Ibuprofen, diclofenac etc.
- Gastrointestinal tract drugs (medications used for heartburn, constipation, etc) e.g. Hyoscine N-Butyl tablets. Glycerin suppository, Lactulose syrup, Antacids etc.
- Sedatives or hypnotic (medications used for sleep) e.g. Diazepam etc.

2.0 SCOPE

Prescribed PRN medication orders.

3.0 PURPOSE

3.1 Provide guidelines for handling and support to ensure safe and effective management, and dispensing of when required (PRN) medications ordered by the physicians.

3.2 To reduce waste and unnecessarily accumulation of medicines with patients.

4.0 DEFINITION

“When required” (PRN) medication: PRN Abbreviation means as necessary/as required (from the Latin “pro re nata”), for an occasion that has arisen, as circumstances require.

It is prescribed when the patient presents with a defined intermittent or short-term condition, signs or symptoms and not given as a regular daily dose or at specific times.

5.0 POLICY

5.1 Inpatient medications prescribed as PRN must be dispensed in quantities sufficient for 24 hours (according to frequency) unless the prescriber determine otherwise, to ensure continuity of care and prevents patient suffering.

5.2 If when required medication (PRN) is given regularly then a referral to the prescriber should be considered for a review as the medical condition may have changed and the treatment required may need altering.
6.0 PROCEDURE

6.1 PRN medications must be administered strictly in accordance with the written instruction of the physician who has prescribed it. This instruction must include the purpose of the PRN medication and the circumstances when it must be used. The dosage to be administered initially, the frequency of the repeat dosage and the maximum dosage in 24 hours and the action that must be taken if the symptoms persist after the medication has been administered if necessary.

6.2 The Prescriber must check what regular medication the patient may be taking daily before prescribing PRN medication, to safeguard from receiving excessive amounts of other drug with similar therapeutic effect or a combination of medications that are contra-indicated.

6.3 Where PRN psychotropic medications are used they must be part of the patient’s agreed pro-active strategy in the management of escalating deterioration of mental health, in accordance with instructions from a psychiatrist.

6.4 When the uses of PRN medications are considered, as a part of the patient integrated care plan the outcomes should be evaluated on an on-going basis.

6.5 PRN orders must be entered in the computer system by the treating physician and shall be dispensed from the ward’s floor stock or through Unit Dose System. The total daily dose of PRN medication, shall not to exceed the maximum recommended dose in 24 hours.

6.6 PRN medication should be supplied in its original package, blisters or appropriately labeled repacked containers as this enables to maintain manufacturer’s expiry date and reduces unnecessary medication waste.

6.7 On discontinuation of ‘PRN’ medication any remaining medication should be safely disposed of, and the patient should be monitored in case symptoms re-occur and requires further review from the prescriber.

7.0 RESPONSIBILITY

Pharmacy & Medical Stores Departments in Healthcare Units:

- The dispensing pharmacist should review and issue appropriately the PRN prescription to the nursing care unit and to communicate with the prescriber if necessary.

8.0 RELATED DOCUMENTS

N/A

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/journal/articles/Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRN – As required medications, SOP’s</td>
<td>Webstercare, Australia</td>
<td>2012</td>
<td>3</td>
</tr>
<tr>
<td>Good Practice guidance medication prescribed to be taken ‘when required’ (PRN) in care homes</td>
<td>Effective prescribing and Performance Committee, Berkshire East, NHS</td>
<td>2013</td>
<td>3</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

The main reasons why errors occur with patient’s medication, include poor communication at key ‘transition points’, when the responsibility for a patient’s care is transferred from one place to another; a lack of suitable monitoring and review of treatment; or patients not taking their medicines as agreed. Therefore, when a patient is admitted to and discharged from hospital and their medication is changed, good communication between the hospital and referred back institution, and good monitoring and review, are extremely important.

During a patient’s stay in hospital, their medication may be changed. To ensure that ongoing care is consistent with any new regimen that is introduced in the hospital, good information on medication changes should be sent to the referred back institution when a patient is discharged, however problems may arise when discharge information is either late or incomplete.

2.0 SCOPE

Admitted to and being discharged / transferred cases from Hospitals.

3.0 PURPOSE

To provide a medicines management framework to safely discharge the admitted patients on medicines with clear guidance on what medication patients need to take home.

4.0 DEFINITION

Discharge Medications Order: Is an order written by a physician for the patient including all the medications prescribed in the hospital at discharge.

5.0 POLICY

5.1 Whenever possible, discharge prescriptions should be entered in the Health Information System (Al Shifa) ideally twenty four (24) hours prior to discharge day, to prevent delayed discharges.

5.2 If a patient’s discharge is delayed and their prescription changes, the relevant changes must be made to the discharge order. All staff must be proactive in order to ensure that preventable delays in discharge do not occur.

5.3 Discharge medications shall be ordered during the pharmacy working hours. If discharge is required beyond the regular working hours, then the discharge order to be supplied by the Emergency Pharmacy through the “discharge location inventory” in the system.

5.4 Physician discharge medication sheet/referal form shall be legible, clear, complete, and shall include the following:

- Patient name medical record number / patient’s information sticker.
• Diagnosis.
• Name of medications.
• Dose, frequency and duration.
• Date and time.
• Name of the authorized Physician.

5.5 When medicines are given to patients at discharge it is the responsibility of the pharmacist to ensure that the patient has the correct medicines and understands how to take them as the final check point of discharge.

5.6 Should the patient have questions or problems with their medicines, the pharmacist should answer the questions using their professional knowledge.

5.7 Discharge of patients on IV Antibiotics to be administered in the nearest PHC institutions is not recommended as per the recommendation of Directorate General of Primary Health Care due to concerns related to safety of IV Cannula, administration frequency and non-availability of some Antibiotics in the PHC setting.

5.8 Discharge medication orders written by the physician for the patients to take home and discharge medication profile shall be maintained for all patients in the system.

6.0 PROCEDURE

6.1 The Pharmacist / Assistant Pharmacist in the inpatient pharmacy will review the discharge order in the system, prepare the medicines, generate the labels and the order shall be doubled checked by another pharmacy staff.

6.2 The supply issued shall be determined based on a maximum thirty (30) days supply. A refill for additional two months, if needed will be recorded in the system, and to be collected by the end of each month until the next clinical visit.

6.3 A reduced supply will usually be made for medicines which have a specific short course length or when the patient confirmed that the stock is available at home.

6.4 Insulins quantity should be issued as per the calculated units needed for one month. If any quantity exceeds one month, the same should be considered in the calculation of the following month.

6.5 The discharge medication will be collected by the patient/caregiver otherwise, in certain situations where the patient need special counselling, the medication can be picked-up by the Nursing Staff after calling the pharmacy and confirming that the medications are ready for pick-up.

6.6 For discharge prescription containing new medications or high risk’ medicines like Warfarin and prophylactic (LMW) Heparin or Insulin, the patients should be counselled satisfactorily on how to use these products and must be to ensured also that the patient is competent to administer the S.C. injections themselves or otherwise a provisions is in place for somebody to administer it for them.

6.7 The Pharmacy staff shall carefully review the multiple medications (Polypharmacy) prescriptions and to counsel the patient appropriately to avoid risks often associated with multiple medication use such as adverse effects, drug/drug interactions, drug/disease interactions, and inappropriate dosing.
6.8 All discharge medications that require refrigeration must be kept in the fridge and patients must be informed to keep appropriately in the household fridge.

6.9 Controlled medications must be kept in double locked cabinet in the ward and dispensed on discharge as per controlled drugs regulations.

6.10 Unused medication by a patient must be returned to the pharmacy along with a Nursing Communication slip indicating the reason of the returned medication, i.e. discharge plan is changed, medication is cancelled, patient passed away and others.

6.11 On discharge, the patient should be provided with a copy of the discharge summary.

7.0 RESPONSIBILITY

The Pharmacists and Assistant Pharmacists in Hospitals:

- Review the discharge medications, report /prescription, counsel the patient and dispense the medicines as per the approved dispensing procedures.

8.0 RELATED DOCUMENTS

8.1 Medications Dispensing Guidelines (MH-DGMS-PH-21)

8.2 Medication Order Review (MH-DGMS-PH-18)

8.3 Medication Reconciliation Policy. (MH-DGMS-PH-17)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/journal/articles/Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Managing patient after discharge from Hospital</td>
<td>Care Quality Commission</td>
<td>2009</td>
<td>56</td>
</tr>
<tr>
<td>Best Possible Medication Discharge Plan-Patient Interview Guide</td>
<td>ISMP Canada</td>
<td>2011</td>
<td>1</td>
</tr>
<tr>
<td>Issuing of Discharge Medicines to In-Patients, Mid Essex Hospital, NHS</td>
<td>Jane Giles</td>
<td>2014</td>
<td>5</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

The following guidelines have been developed to set down general standards for good dispensing practices, to provide guidance to the Pharmacists and Assistant Pharmacists in the Ministry of Health Institutions, in relation to their professional practice, and should be considered as integral part of their job description and responsibilities.

Medication errors are a leading cause of mortality in the United States. Dispensing errors account for about 21% of all medication errors. In addition to causing serious morbidity and mortality, dispensing errors increase the economic burden on society by adding to health care costs. Faulty dispensing may also result in litigation, which can be expensive and lead to increased costs for professional liability. Dispensing in error is traumatic for the pharmacist as well as the patient; therefore, the goal of every pharmacy is to reduce the amount of dispensing errors.

Dispensing errors include any inconsistencies or deviations from the prescription order, such as dispensing the incorrect drug, dose, dosage form, wrong quantity, or inappropriate, incorrect, or inadequate labeling. Also, confusing or inadequate directions for use, incorrect or inappropriate preparation, packaging, or storage of medication prior to dispensing are considered to be errors.

Dispensing errors committed by individuals are often the result of error-prone systems and processes. Therefore, the main strategy to reduce dispensing errors is to implement a system oriented approach rather than a punitive approach targeted at an individual.

2.0 SCOPE

Dispensing of medicines in MOH Health Units.

3.0 PURPOSE

Safe dispensing and labelling of medicines to ensure treatment compliance and patient safety.

4.0 DEFINITION

The dispensing process: Is the review of a prescription and the preparation, packaging, labelling, dispensing, counselling and record keeping.

5.0 POLICY

5.1 Dispensing Pharmacists and Assistant Pharmacists are accountable for the whole dispensing process. As part of this accountability, they must ensure that dispensing tasks are delegated to persons trained and competent to perform them.

5.2 The pharmacist/assistant pharmacist should ensure that the prescription is valid, that the medicine is clinically appropriate for the patient, and that information is provided to ensure safe and appropriate use of the medicine.
5.3 Pharmacists should take all reasonable steps to minimize the occurrence of medications and dispensing errors. Good practice dictates there should be a systematic approach in dealing with errors and near misses and corrective action taken.

5.4 In presence of sufficient number of pharmacists and assistant pharmacists, the assistant pharmacists shall assist the pharmacists in the dispensing process by carrying out the functions of data entry and assembling medicines. However, the pharmacist is responsible for cross-checking, dispensing the medicine and counseling the patient. If no pharmacist is available a senior experienced assistant pharmacist will review, cross check, dispense and provide counseling.

5.5 Where there is any doubt about the authenticity of a prescription, the pharmacist/assistant pharmacist should contact the prescriber for confirmation. Dispensing without a prescription or from an unauthorized prescriber is strictly prohibited.

5.6 Prescriptions from private health care establishments – even those endorsed with stamps of three private pharmacies stating non availability- must not be dispensed. Prescriptions from MOH Health Institution shall be dispensed only from same health unit where it is prescribed.

5.7 Dispensing staff should ensure that all pharmacy services are provided in a manner that respects the patient’s privacy requirements & confidentiality.

5.8 Life-saving drugs must be made available in sufficient quantities, and the pharmacist/assistant pharmacist should consider the medical consequences of not supplying such medicines in an emergency.

5.9 Pharmacy department should arrange to accept from the public unwanted medicines for safe disposal as outlined in the policy “Medications Returned by Patients (MOH-DGMS-PH-14)”

5.10 The prescription issued shall be determined based on a maximum ninety (90) days supply, a refill shall cover maximum 30 days to be collected by the end of each month until the next clinical visit. Dispensing for more than one month is not allowed even to cover annual vacations, travel period or during the study period abroad to avoid shortage to other patients.

5.11 In case of delay in collection of the medication, the computer will allow dispensing for the remaining days only.

5.12 A reduced supply will usually be made for medicines which have a specific short course length and supply shall not to be made if pharmacy have confirmed with patient that supplies are available with him at home.

5.13 Insulins quantity should be issued as per the calculated units needed for one month. If any quantity exceeds one month, the same should be considered in the calculation of the following month.

5.14 Prescribing specialized medications beyond own specialty is not allowed as per the Central Drug Committee (CDC) decisions and approved protocols. As such prescribing has to be restricted for each item based on the specialty and Health care level.

5.15 Prescriptions for medications prescribed by doctors for themselves is permitted only in certain occasions i.e., to save a life or to avoid serious deterioration in health, where no other person with legal right to prescribe.
6.0 **PROCEDURE**

6.1 Appropriate dispensing practice should be followed to ensure that:

- The right patient is served,
- A desired dosage form of the correct drug is given,
- The prescribed dosage and quantity are given,
- The right container that maintains the potency of the drugs is used,
- The container is appropriately labelled,
- Clear instructions are delivered verbally to the patient.

6.2 The process of dispensing includes:

- Receiving a prescription,
- Ascertaining the authority of the prescriber to prescribe,
- Ensure that the patient to be properly identified so the medicine is dispensed to the person for whom it is intended,
- Determining the prescriber’s intentions as to the patient’s medicine, including the dosing instructions,
- Reviewing the medication history and other relevant patient information,
- Entering the prescription details in the pharmacy computer,
- Generating a label for the dispensed medicine,
- Selecting or preparing the product intended by the prescriber,
- Print the dispensing sheet, that to be signed by the staff who prepared the medicines and cross checked, dispensed and countersigned by a more senior staff,
- Clearly labelling the container of the medicine with the directions for its use as intended by the prescriber,
- Scanning of the product barcode towards the end of the dispensing process (when such facility, is provided) to provide more effective method in minimizing selection errors,
- Carefully checking and re-checking all dispensing for accuracy and completeness,
- Counseling the patient, or the patient’s agent,
- Ensuring that the entire dispensing process has been carried out according to good pharmacy practice.

6.3 Handling and Dispensing of Controlled Drugs (Narcotics / Psychotropic) must be strictly adhered to, as per the stipulation of the Law of Combat of Narcotics and Psychotropic Substances and its related Ministerial Decisions.

6.4 Sufficient personnel must be available to perform dispensing tasks adequately. Policies and procedures should ensure that reasonable workload levels and working hours are established and rarely exceeded.

6.5 All staff that have access to the computer system should have an individual password and should dispense using their own password.
6.6 If a pharmacist/assistant pharmacist received an incomplete prescription, or in case of any errors regarding the dose, strength, duration or drug interaction, he should contact the prescriber before dispensing the items, who should subsequently arrange for necessary amendment where applicable, and the same to be inserted by the prescriber in the system. In case of manual prescriptions, the amendments should be made and signed by the prescriber. Such interventions should be documented.

6.7 When handling chemical or biological materials particular attention should be given to the possibility of allergy, fire, explosion, radiation, or poisoning. Substances including corticosteroids, some antimicrobials, phenothiazines and many cytotoxics are irritant or very potant and should be handled with caution. Contact with the skin and inhalation of dust should be avoided.

6.8 Certain technically difficult or high risk preparations should not be prepared extemporaneously in the Pharmacy as per policy “Extemporaneous Pharmaceutical Preparations” (MOH-DGMS-PH-39)

6.9 Except in emergency situations, all sterile and non-sterile drug products should be dispensed from the pharmacy department for individual patients. The storage of nonemergency floor stock medications on the nursing units or in patient-care areas should be minimized. Particular caution should be exercised with respect to drug products that have commonly been involved in serious medication errors or whose margin of safety is narrow, such as concentrated forms of drug products that are intended to be diluted into larger volumes (e.g., concentrated lidocaine and potassium chloride injection).

6.10 Fingers should not be used to count tablets, a spoon to be used to put tablets and capsules onto a counting tray to avoid contamination of drugs.

6.11 Medication errors. Near miss and incidents occurring during the dispensing process, i.e. all errors identified, not just those that reach the patient and regardless of how serious the incident may appear should be identified and documented and their causes studied in order to develop systems that minimize recurrence. The record should be kept for three years.

6.12 For all drugs particularly high risk drug products, all work should be checked by a second individual (preferably, another pharmacist) to ascertain that the drug, labelling, packaging, quantity, dose, and instructions are accurate.

6.13 In the handwritten prescription the following should be intimated to the prescriber if observed:

- The unnecessary use of decimal points, e.g. 3 mg, not 3.0 mg. Quantities of 1 gram or more should be written as 1 g etc. Quantities less than 1 gm should be in milligrams, e.g. 500 mg, not 0.5 g. Quantities less than 1 mg should be in micrograms, e.g. 100 micrograms, not 0.1 mg. When decimals are unavoidable a zero should be in front of the decimal point where there is no other figure, e.g. 0.5 ml not .5 ml. Use of the decimal point is acceptable to express a range e.g. 0.5 to 1g.

- Micrograms, ‘nanograms’ and ‘units’ should not be abbreviated.

- The term ‘milliliter’ (ml / mL) is used in volumes, and not as c.c, or cm3.
6.14 The requirements for a valid non controlled drugs prescription includes:

- Should be written in indelible ink by MOH medical doctors or dentists and must be signed in indelible ink by the practitioner using his own name (if handwritten).
- Should state the name, the age or date of birth of the patient if under the age of 12 years.
- Should state of the name of the doctor and his specialty.
- Should be dated, stamped by doctor seal and issued once in original.
- Handwritten prescription In addition to the above said requirements of non-controlled drugs, the valid controlled drug prescription must:
  - Be prescribed in the officially specified prescription pads and stamped by the concerned MOH Authority, computer generated prescription is unacceptable.
  - State the dose to be taken in the prescribers own handwriting.
  - State the form and strength of the preparation, total quantity of the preparation or the number of dose units, in both words and figures, to be supplied, written in the prescriber’s own handwriting.
  - State the quantity in words and figures when prescribing drugs prone to abuse; this is obligatory for controlled drugs.

6.15 The prescriptions or dispensing sheet for non-controlled drugs are to be kept in the pharmacy for a minimum retention period of three months for reference and auditing.

6.16 All drugs should be packed in suitable and appropriately labelled containers to ensure correct use, maintain potency & quality during the period of use.

6.17 The label on the container/envelop of dispensed drugs should contain the following in order to promote patient compliance:

- Drug name (use generic name),
- Strength (usually in mg),
- Quantity dispensed,
- Expiry date
- Clear instructions for use in a familiar language,
- Cautionary label (e.g. “Keep out of reach of children”),
- Name of the patient,
- Name of the health facility,
- Date of dispensing.

6.18 Patient counselling is the final checking process to ensure the correct medicine is supplied to the correct patient. The pharmacist / assistant pharmacist should make every effort to counsel, or to offer to counsel, the patient whenever a medicine is supplied to verify that patient understand why a medication was prescribed and dispensed, its intended use, dosage, duration of treatment and special precautions etc. The patient consultation area must be a designated area. Please refer to “Patient Counseling policy (MOH-DGMS-PH-22)"
6.19 Dividing & Repacking of Syrups in solution forms particularly if the duration of treatment is for three days or less, should consider the following:

- For less expensive drugs: It is no longer recommended to divide any syrup with pack size 100ml or less. The entire bottle to be provided with proper counselling to the patient ‘not to use the remaining portion without medical advice’ (e.g. Chlorpheniramine, Paracetamol, Antihistaminic & Decongestant syrup etc.)

- For more Expensive drugs: supplied in pack of 200-500ml, to be repacked in glass bottles (E.g,. Lactulose, Phenobarbitone, Phenytoin, Benzoin Tincture, Chloral hydrate, Potassium Chloride, Leviracetam, Baclofen, Isoniazid etc.). However if the duration for long time beyond one month for chronic diseases, then full bottle should be supplied and the remaining portion should be considered during next issue after verification with the patient.

- Preparation area: Should have adequate space for repacking. It should be maintained in clean, orderly and sanitary condition.

- Suspensions: Particularly those with narrow therapeutic index should not be divided for safety reasons (lack of homogeneity).

- Labelling: Should state clearly the generic name of the product, daily dose, batch/lot no., manufacturing, expiry and repacking dates.

6.20 For storage conditions of certain group of medicines after opening please refer to the Good Practices Guidelines on expiry dates after opening, Issued by Berkshire, NHS attaching the detailed list and expiry date recommendation for each formulation type. (Annex A)

7.0 RESPONSIBILITY

Pharmacists and Assistant pharmacists in Healthcare Units:

- Review the prescription carefully, cross check, intervene if necessary, label, dispense the medicines and counsel the patient appropriately.

- Ensure that the medicines are issued correctly to the right patient and medication errors, near miss and incidents that may occur during the dispensing process are identified and documented.

8.0 RELATED DOCUMENTS

8.1 Pharmacy Duty Rostering Policy (MOH-DGMS-PH-08)
8.2 Response to Out-of-Stock Medication (MOH-DGMS-PH-13)
8.3 Medication Reconciliation Policy (MOH-DGMS-PH-17)
8.4 Medication Order Review (MOH-DGMS-PH-18)
8.5 Discharge Medication Order (MOH-DGMS-PH-20)
8.6 Patient counselling (MOH-DGMS-PH-22)
8.7 Drug Food Interactions (MOH-DGMS-PH-31)
8.8 Drug-Drug Interactions (MOH-DGMS-PH-32)
8.9 High Alert Medications (MOH-DGMS-PH-35)
8.10 Look-Alike/ Sound-Alike Medications (MOH-DGMS-PH-36)
9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidelines for preventing medication errors in Hospitals - ASHP</td>
<td>ASHP</td>
<td>1993</td>
<td>9</td>
</tr>
<tr>
<td>10 Strategies for Minimizing Dispensing Errors - Pharmacy Times Newsletter</td>
<td>Rama P. Nair, Daya Kappil, and Tonja M. Woods.</td>
<td>2010</td>
<td>2</td>
</tr>
<tr>
<td>Guidelines of Dispensing of Medicines – Pharmacy Board of Australia</td>
<td>Pharmacy Board of Australia</td>
<td>2015</td>
<td>17</td>
</tr>
<tr>
<td>Polypharmacy Guidance</td>
<td>NHS, Scotland</td>
<td>2015</td>
<td>65</td>
</tr>
</tbody>
</table>
### Annex A

**Good practices guidelines on expiry dates after opening**

<table>
<thead>
<tr>
<th>Formulation type</th>
<th>Expiry details</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablets &amp; capsules in original blister strips or container with printed expiry date</td>
<td>Manufacturer’s expiry date as printed on original box or individual foils (check patient information leaflet)</td>
<td>PRN (when required) medication, wherever possible, should be used from the manufacturer’s original pack. (The expiry date is printed on each strip). Medicines kept for use in next month should be recorded in the ‘carried forward’ section of the MAR chart.</td>
</tr>
<tr>
<td>Tablets &amp; capsules stored in dispensing bottles from pharmacy</td>
<td>6 months from date of dispensing unless otherwise informed by Community pharmacist</td>
<td></td>
</tr>
<tr>
<td>Aspirin Dispersible tablets stored in dispensing bottles from pharmacy</td>
<td>1 months from date of dispensing</td>
<td></td>
</tr>
<tr>
<td>Tablets/Capsules stored in pharmacy packed blisters - Monitored Dosage System (MDS)</td>
<td>8 weeks from date of dispensing</td>
<td></td>
</tr>
<tr>
<td>Oral liquids (in original manufacturer’s packaging or amber bottles)</td>
<td>6 months from date of opening or follow manufacturer’s guidance e.g. for specially manufactured items or expiry date on packaging. For antibiotics, check with community pharmacist if not clear from label.</td>
<td>Estimate the amount of any liquids carried over. Medicines retained for use should be recorded in the ‘carried forward’ section of the MAR chart.</td>
</tr>
<tr>
<td>External liquids (e.g. Lotions, shampoos &amp; bath oils)</td>
<td>6 months from opening or manufacturer’s recommendation where shorter</td>
<td></td>
</tr>
<tr>
<td>Formulation type</td>
<td>Expiry details</td>
<td>Comments</td>
</tr>
<tr>
<td>------------------</td>
<td>----------------</td>
<td>----------</td>
</tr>
<tr>
<td>Creams in tubes or pump dispensers</td>
<td>3 months from date of opening or manufacturer’s recommendations if shorter</td>
<td>Write the DATE and initial when opened on the dispensing Label for audit trail purposes.</td>
</tr>
<tr>
<td>Creams in pots, tubs or jars.</td>
<td>1 months from date of opening</td>
<td></td>
</tr>
<tr>
<td>Ointments in tubes or pump dispensers</td>
<td>6 months from date of opening or manufacturer’s recommendations if shorter</td>
<td></td>
</tr>
<tr>
<td>Ointments in pots, tubs or jars.</td>
<td>3 months from date of opening or manufacturers recommendations if shorter</td>
<td></td>
</tr>
<tr>
<td>Sterile Eye/Ear/Nose drops/ Ointments</td>
<td>28 days from date of opening</td>
<td></td>
</tr>
<tr>
<td>Rectal Diazepam</td>
<td>Individual foil wrapped tubules Manufacturer’s expiry date</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Non-foil wrapped 6 months from date of opening</td>
<td></td>
</tr>
<tr>
<td>SIP Feeds/ oral supplementary nutrition</td>
<td>Unopened, follow Manufacturer’s expiry date. Follow manufacturer’s guidance once opened (most keep for 24 hours in fridge)</td>
<td>Calogen will last 14 days after opening. Tube feeds like Nutrison will last 24 hours (stored in fridge) from opening and supplements such as Complan Shake will last 24 hours (stored in fridge) once prepared.</td>
</tr>
<tr>
<td>Inhalers</td>
<td>Manufacturer’s expiry date</td>
<td>If inhalers / sprays are used on a PRN basis, keep for on-going use; do not routinely re-order each month. Write details on current MAR chart.</td>
</tr>
<tr>
<td>Glyceryl trinitrate sprays</td>
<td>Manufacturer’s expiry date</td>
<td></td>
</tr>
<tr>
<td>Insulin</td>
<td>Unopened: Manufacturer’s expiry date when stored in a fridge at temperature between 2°C and 8°C. Once opened: 4 weeks for insulin vials and pens unless otherwise stated. When in use can be kept at normal room temperature (i.e. less than 25°C).</td>
<td>One pen/ cartridge will often be sufficient per month. (A box of 5 will rarely be needed every month). Ask the G.P to prescribe the nearest number of pens/ cartridges needed per month to reduce stock piling.</td>
</tr>
<tr>
<td>Product</td>
<td>Expiry Date Details</td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Persantin Retard (Dipyridamole SR)</td>
<td>6 weeks after opening original dispensing container. Once capsules are packed down into another container then 4 weeks expiry</td>
<td></td>
</tr>
<tr>
<td>Glyceryl Trinitrate tablets</td>
<td>8 weeks after opening</td>
<td></td>
</tr>
<tr>
<td>Madopar capsules and tablets</td>
<td>2 weeks when dispensed into another container</td>
<td></td>
</tr>
<tr>
<td>Nicorandil</td>
<td>Manufacturer recommendation, then once opened each blister has a 30-day expiry. Use each blister strip at a time before opening the next. The blister strip contains a drying agent to protect the tablets from moisture which should NOT be removed or swallowed.</td>
<td></td>
</tr>
<tr>
<td>Asasantin Retard Capsules</td>
<td>6 weeks after opening original dispensing container. Once capsules are packed down into another container then 4 weeks expiry</td>
<td></td>
</tr>
<tr>
<td>Chlorpromazine Syrup 25mg/5ml &amp; 100mg/5ml (Rosemont)</td>
<td>6 months after opening</td>
<td></td>
</tr>
<tr>
<td>Gastrocote Liquid</td>
<td>1 month after opening</td>
<td></td>
</tr>
<tr>
<td>Largactil Syrup</td>
<td>1 month after opening</td>
<td></td>
</tr>
<tr>
<td>Oramorph 10mg/5ml Liquid</td>
<td>90 days after opening</td>
<td></td>
</tr>
<tr>
<td>Risperdal 1mg/ml Liquid</td>
<td>3 months after opening</td>
<td></td>
</tr>
</tbody>
</table>

References used:

- Continuing Professional Pharmacy Education (CPPE) Supporting Care Homes in Medicines Management April 2007
1.0 INTRODUCTION

Patient counseling is a key competency element of the Pharmaceutical Care process. It is vital that pharmacists/asst. pharmacists are in a position to give appropriate, reliable and trustworthy information to patients regarding their usage of prescribed medicinal products.

Patient counseling involves the pharmacist/asst. pharmacist communicating the correct information and advice to patients regarding their medicine therapy. The counseling process if properly implemented and consistently maintained should result in the safe supply of prescribed medicinal products and ensure that they are used rationally and appropriately. The pharmacist/asst. pharmacist must offer to discuss with the patient or their representative all such matters in the exercise of his/her professional judgment, and must be satisfied that the patient has sufficient information to take their medicinal product safely and as prescribed, and that they know how to store the medicinal product.

2.0 SCOPE

Counseling required to be provided by pharmacy staff depending on the patient’s individual needs.

3.0 PURPOSE

The main aim of effective patient counseling is to enable and encourage the safe and proper use of medications by patients in order to achieve the required therapeutic outcomes.

Benefits of medication counseling include:

- Active participation by the patient in disease management.
- Increased compliance with medication therapy regimens.
- Avoidance or minimization of adverse effects.
- Fewer complications.
- Improved therapeutic outcomes.

4.0 DEFINITION

Counseling may be defined as: a one-to-one interaction between a pharmacist/asst. pharmacist and a patient or caregiver. It is interactive in nature. It should include an assessment of whether or not the information was received as intended and that the patient understands how to use the information to improve the probability of positive therapeutic outcomes.

5.0 POLICY

5.1 Pharmacist/asst. pharmacists, in their role as custodians of medicinal products, should ensure that the review of medicinal therapy and patient counseling is consistent with the needs and safety of the patient.
5.2 Pharmacist must implement robust systems in the pharmacy, reflecting good dispensing practices, and support also the patient in their knowledge and use of their prescribed medicinal products and in this way; empower the patient to make informed decisions regarding their own healthcare needs.

5.3 The pharmacist/ asst. pharmacist should ascertain that the patient has sufficient understanding of the indication of the medicinal product and is aware of how to use their medicinal product safely.

5.4 Pharmacist/ asst. pharmacists should do their utmost to ensure that the person they are providing counseling to is in fact the patient themselves, or an approved representative of the patient to avoid any unintentional breaches of patient confidentiality.

5.5 The patient consultation area must be a designated area and, therefore, used solely for the purpose of patients consultation and counseling. The area should not be used for other purposes, e.g. the storage of medicines or excess stock. The area must be constructed so as to ensure a reasonable level of privacy for the patient, i.e. any discussion with the patient, when speaking at a normal volume, should not be overheard by others.

6.0 PROCEDURE

6.1 Amount and type of counseling required to be provided to the patients varies depending on the patient’s individual needs, and the individual situation in question.

6.2 When a medicinal product is substituted with a new generic of the same composition from other manufacturer, the pharmacist/ asst. pharmacist must take the necessary steps to ensure that the patient is aware of the substitution from the previous one is with the same specifications and quality, and they only differ in the trade names and the packaging designs.

6.3 If the product is replaced in the prescription care should be taken to explain which medicinal product has been replaced, to ensure that the risk of duplication of therapy is avoided.

6.4 Counseling may be conducted via oral, written, or technology-based (e.g., videotapes, audiotapes, and interactive computer software) communication. In general, the most effective method of communication is oral counseling combined with written instructions. There are many types of printed counseling materials including leaflets, pamphlets, and wallet cards.

6.5 Routinely, effectively and, appropriately the patients should be educated on the following when dispensing outpatient prescriptions or discharge medications, or when providing recommendations about management of specific drug related problems:

- Name and class of the drug (e.g. antibiotic, pain reliever).
- Directions for use like how take/administer it and duration of treatment and including education about drug devices.
- Special storage requirements.
- Common or important drug-drug or drug-food interactions.
• Common or important potential side effects and associated time frames.
• Instructions for what to do with any previously dispensed medicinal product(s), no longer required (i.e. safe disposal of medicinal product).
• Instructions for what to do when a dose is missed.
• Special directions for preparation, such as reconstitution of powders and “shake well” for suspensions.
• Precautions to be observed (e.g., care in driving, avoidance of alcohol, and avoidance of sun exposure).
• Prescription refill information, including when the patient is due for the next refill.

6.6 The Pharmacy staff shall carefully review the multiple medications (Polypharmacy) prescriptions and to counsel the patient appropriately to avoid risks often associated with multiple medication use such as adverse effects, drug/drug interactions, drug/disease interactions, and inappropriate dosing.

6.7 Patients and caregivers who should always be counseled:
• Confused patients.
• Patients who are sight or hearing impaired.
• Patients with poor literacy.
• Patients whose profile shows a change in medications or dosing.
• New patients or those receiving a medication for the first time (transfer prescription).
• Children and parents receiving medication.
• Patients receiving medication with special storage requirements, complicated directions, significant side effects.

6.8 Patients and caregivers who should be counseled at certain intervals:
• Asthmatic patients.
• Diabetic patients.
• Patients taking four or more prescribed medication (Polypharmacy).
• Patients who are mentally ill.
• Patients using appliances.
• Epileptic patients.
• Patients with skin complaints.
• Patients misusing drugs.
• Patients who are terminally ill.

6.9 Medicines that may prompt the need for counseling include:
• Medicines with high potential for interactions with other medicines, supplements, herbal products and food, e.g., warfarin.
• Medicines with common or significant side effects which can affect adherence or treatment continuation, e.g., amino salicylates associated with blood disorders and ACE inhibitors associated with dry cough.
• Medicines with complex administration requirements.
• Medicines with special storage requirements.
• Medicines where adherence is key , e.g., narrow therapeutic index drugs, anti-tuberculosis drugs

6.10 The following guidelines will help the healthcare professional develop an appropriate approach to counseling patients:
• Review the patient record prior to counseling to obtain relevant patient-related information as necessary.
• Identify yourself at the beginning of counseling and address the patient by name.
• Use open-ended questions (i.e., questions requiring more than a yes or no answer) to assess the patient’s understanding of the medication therapy, problems and concerns, and adherence to the medication therapy regimen. Examples of open-ended questions are as follows:
  - What did your doctor tell you this medication is for?
  - How did your doctor tell you to take this medication?
  - What bad effects did the doctor say to watch for?
  - What kind of problems are you having with this medication?
• Avoid the use of overly technical medical terms.
• Present information precisely and in a logical order. Give the patient information in manageable amounts. Avoid overwhelming the patient with large amounts of information at one time.
• Demonstrate special administration techniques (e.g., inhalers and eye preparations) using models, illustrations, and diagrams. Allow the patient an opportunity to practice the technique.
• Be understanding, attentive, nonjudgmental, and empathetic.
• Display positive nonverbal behaviors, such as appropriate eye contact, body language, physical distance from the patient, tone of voice, and pace of speech.
• Provide the patient an opportunity to provide feedback regarding problems and concerns, information needs, medication effects, and adherence.
• Identify medication therapy problems by using active listening techniques and observing verbal and nonverbal clues.
• Assist the patient in developing solutions to actual or potential problems.
• Plan follow-up with the patient, as necessary. This is particularly important for patients receiving long-term medication therapy.
• Summarize information at the end of the counseling session, emphasizing important key points. Verify the patient’s understanding of the proper use of the medication(s).

• Document all counseling activities in the patient’s record. This will provide information for future interactions with the patient and ensure consistency in the continuum of care.

6.11 Techniques for assessing effectiveness include the following:

• Stop frequently during the session and ask the patient questions to verify understanding of information as it is presented.

• Use open-ended questions (i.e., questions requiring more than a yes or no answer).

• Ask the patient to repeat instructions.

• Ask the patient to demonstrate any special administration or monitoring techniques (e.g., inhalers or blood glucose meters).

• Provide the patient an opportunity to ask questions and voice concerns.

7.0 RESPONSIBILITY

Pharmacists and Assistant Pharmacists in Healthcare Units:

• Provide correct information and clear instructions to the patient or caregivers about the use, precautions and storage of the prescribed medications.

• Provide effective patient counseling particularly on medicines that may prompt the need for counselling based on patient’s individual needs.

8.0 RELATED DOCUMENTS

Medication Dispensing Guidelines, (MOH-DGMS-PH-21)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Counseling patients on medicines, Royal Pharmaceutical Society</td>
<td>Royal Pharm Society, UK</td>
<td>2011</td>
<td>2</td>
</tr>
<tr>
<td>Practice Direction -Patient Counselling</td>
<td>College of Pharmacists Manitoba, Canada</td>
<td>2014</td>
<td>4</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

The fundamental difference between the Unit Dose System (UDS) and the older drug dispensing methods, it provides more active role of the pharmacist in the medication cycle and permit the nurse be dedicated to the nursing care responsibilities. The fully automated dispensing systems (not yet being implemented in MOH) have the advantage of providing information on patient pharmacotherapy, and decreasing the amount of time taken up by unit-dose cart filling, however the high cost of these systems as well as increased workload in some areas of the pharmacy department are the main disadvantages.

Perhaps the most profound alteration produced by the unit-dose system is that pharmacists now review a copy of all medication orders written by physicians before dispensing medications. This single feature has triggered the success of the unit-dose system and has given birth to clinical pharmacy practice.

With sincere efforts and enthusiasm Ibra Regional Hospital lead the implementing of UDS in the Ministry since 1996 followed by Sur hospital in 2000, Nizwa Hospital in 2002, Al Nahdha Hospital in 2004, Sohar Hospital in 2008, and later SQH-Salah, Al Masarrah Hospitals. Some other local hospitals like Sinaw, Sumail etc. has also implemented UDS in the beginning of 2000.

MOH plan is aiming to shift all hospitals currently using the conventional dispensing system to Unit Dose System and to resolve any space problems in the Central Unit Dose dispensing unit in the future.

2.0 SCOPE

MOH hospitals implementing Unit dose Distribution System.

3.0 PURPOSE

TO OUTLINE GENERAL GUIDELINES FOR IMPLEMENTING OF AN EFFICIENT DISPENSING SYSTEM WITH THE AVAILABLE RESOURCES FOR INPATIENTS WHICH CAN:

- Reduce incidence of medications errors,
- Decrease in the overall cost of medications,
- More efficient usage of pharmacy and nursing personnel, allowing for more direct patient-care involvement by pharmacists and nurses.
- Improved overall drug control and drug use monitoring,
- More accurate patient billing for drugs (Insurance reimbursement, expatriates),
- Reduce pilferage of drug from patient care area,
- Greater control over pharmacy workload & scheduling of personnel,
• Reduce drug inventories throughout the institution,
• Greater adaptability to computerized and automated procedures.

4.0 DEFINITION

Unit Drug Distribution System: Is defined as a set of procedures or methodologies by which drugs are converted or dispensed by the pharmacy service from manufacturer’s original pack to patient-oriented and labelled dosage forms transported to patient location where they may be stored, monitored and administered.

There are two basic types of Unit Dose System designs; a Centralized Unit Dose services which are generally provided from a single self-contained location in the hospital and a Decentralized which operates from two or more dispensing locations, commonly called pharmacy satellite.

5.0 POLICY

5.1 Medications must be provided in an identified dosage unit ready for administration. Whenever possible, sterile product should be provided in a single use container. However packaged medication shall be protected from contamination, moisture, light and excessive temperature.

5.2 Dispensing shall be restricted with trained pharmacist and assistant pharmacists. Items dispensed must be verified for accuracy prior to issue. This must include checking for identity, dose, expiry date, appropriateness, and drug interactions.

5.3 It is reasonable that individual medication orders for hospital inpatients should be processed, dispensed and delivered in a timely manner way as per the predetermined delivery schedules, before the next scheduled administration time. Dispensing through unit dose system will provide 24 hours supply of medication to admitted patients.

5.4 The pharmacist shall exercise a professional judgment at completion of dispensing procedure to ensure the right medication is dispensed for administration to the right patients, in the right dose, via the right route at the right time.

5.5 The nursing staff shall recheck all trolley prior to receiving to ensure that all medications are prepared according to prescriptions made by the prescriber. The trolley will be under the nursing staff responsibility after the signature by the dispensing pharmacy staff and the receiving nurse in the assigned sheet or register.

5.6 It is the pharmacy responsibility to inspect all wards covered by the unit dose pharmacy on a regular time-table basis to ensure that all medications are not over-stocked, well separated and properly labelled and no expired medications are available.

5.7 Risk Management system should be in place to ensure dispensing errors are minimized.

6.0 PROCEDURE

6.1 Preparation and dispensing processes:
• During the physician’s round, the medications prescribed for each admitted patient will be entered in the system by the physician.
• The prescription after authorized by the physician will be received through the system in the in-patient pharmacy.
• Unit dose medication trolleys shall be used as medication storage facilities in the ward. Each particular tray in the trolley is for a specific patient and shall be labelled with patient bed number. Also each medication trolley shall be labelled with the ward name.

• The nursing staff should send the medication trolleys to the unit dose pharmacy after completion of rounds based on the prescriptions for all admitted patients in the ward.

• The Unit Dose Dispensing is intended to be run ideally on three shifts basis. The morning shift duty time will be (7am-2pm)

• The individual medication doses to be scheduled, prepared, distributed and administered on a timely basis.

• The pharmacist checks the prescriptions in the system and verifies for any errors regarding the dose, frequency or any possible drug interactions. In case of any discrepancies, the pharmacist makes the necessary interventions after consulting the prescriber.

• Medication shall be dispensed in individually labelled containers or envelopes provided by ministry of health.

• The pharmacy staff will print labels for the admitted patients medications with the following information:
  ✓ The patient name and location (Medical record no.).
  ✓ Hospital name and bed no.
  ✓ Generic name and strength of the medication.
  ✓ Dose and frequency.
  ✓ Route of administration.
  ✓ Accessory or cautionary statements as required.
  ✓ Date dispensed.
  ✓ Expiry date of medication.

• Filling of medications is recommended as under:
  ✓ Tablets: Are filled in the envelopes for 24 hours use.
  ✓ Injections: Small ampoules are supplied in labelled envelopes, big vials will be supplied with the label applied on original packs.
  ✓ Oral Liquids: The required doses to be measured for 24 hours and dispensed in an amber bottle. (Note: antibiotic powder suspensions should be dispensed as full bottle)
  ✓ Skin, ENT, Eye Medications and Inhalers: Full packs to be dispensed after discharge if required to complete course of therapy.
  ✓ Multi-dose Parenteral Preparations (Heparin, Insulin, Etc.), IV Fluids: Will be issued from medical store in their weekly/biweekly indents or by patient’s name. However, insulin cartridges and disposable insulin pens are dispensed from unit dose pharmacy.
• After labelling, filling of all required medications for each patient is completed and the medications are placed in the respective drawers of the concerned ward unit dose system trolley.

• Once the unit dose system trolley is filled for all patients, the pharmacist checks the trolleys for all medications, quantity and volume before dispatching the trolley to the wards.

• The pharmacy staff should inform the concerned staff nurse to collect their medication trolleys of their wards.

• The staff nurse along with the pharmacy staff should cross check the medication trolley and acknowledge receipt of medication by signing in the medication trolley register.

• The medication trolleys in each ward should not be accessible to patients or visitors.

• In case there is any change in the dose or frequency, discontinuation of any drug or if any additional medications are required, the prescriber should make the required changes in the computer and the staff nurse will inform the pharmacist who will dispense the same.

• In case of any third group antibiotic, the pharmacy staff should collect the duly filled up forms with the culture sensitivity report and issue antibiotics on 24 hour basis.

• Antibiotics should be dispensed only for (7 days or as needed) in daily divided doses required for treatment. Any further requirement should be forwarded to the pharmacist in the specified form which should be filled by the prescriber for the extended duration. In case of third generation antibiotics, the form should be countersigned by the consultant.

• Human albumin/ Plasma Preparations are to be dispensed on a unit dose basis only after collecting the duly filled up forms.

• Narcotic and Psychotropic medications are not to be kept or dispensed by the unit dose pharmacy.

• Emergency items required by other wards not covered by the unit dose pharmacy will be dispensed only under the request of the shift nurse supervisor and should be replaced by the medical store in the morning shift next working day.

• All activities will be registered in the communication handing over book including handing over keys, medication arrangements, receipts, etc.

• The hospital wards shall request large volume solutions (Normal saline, dextrose, ringer lactate, etc) directly from medical stores.

• No medications dispensed by unit dose pharmacy should be stocked in the wards. All medication should be sent back to the pharmacy.

• The inspection report is kept in ward stock checking file inside the pharmacy and a copy will be sent to the head of pharmacy department and the quality department if required.
• Medications dispensed for patients, but not used, should be returned to the pharmacy. Procedures for returning medications to stock should be supervised. These include the following considerations:
  ✓ Integrity of the medication returned package.
  ✓ Proper storage of medication on the nursing care area.

• The following type of medications should be discarded:
  ✓ Any opened topical medications.
  ✓ Opened multi dose or single dose vials.
  ✓ Any medication handled by the patient.
  ✓ Any medication returned by ambulatory patients.
  ✓ Improperly stored medications.
  ✓ Any opened or used liquid form medications.

6.2 Space Requirement (Inpatient Pharmacy Unit):
• There should be adequate space appropriate to the service provided and activities undertaken.
• The location of the inpatient pharmacy should be chosen to be close to the inpatient area to facilitate flexible drug distribution to wards.
• An area within the inpatient pharmacy should be provided for dispensing and drug distribution. This area should be well-lit, well equipped, and large enough to promote good workflow and separation tasks.
• Sufficient storage area in the inpatient pharmacy is required for an appropriate amount of working stock.
• The ward issue area must contain adequate bench for assembly and packing of stock.
• Appropriate facilities should be provided for drug requiring particular storage & handling e.g. (Cytotoxic, Flammable agents, etc.)

6.3 The main components of Equipment & Materials Required are:
• Picking station.
• Cart 42”X24” Double Wide for transportation with full spine.
• Process table for organizing and r-checking of Medication.
• Trolleys for wards with cassette trays, drawers for IV fluids.
• Extra cassette trays for refilling at pharmacy.
• Machine or manual unit for packaging of tablet & powders (Med dose).
• Containers (Foil or plastic) for packaging of syrups, tablets & powders etc..
• Computers & printers.
7.0 RESPONSIBILITY

Pharmacy and Medical Stores Departments in Hospitals:

- IMPLEMENT AN EFFICIENT UNIT DOSE DISPENSING SYSTEM IN THE HOSPITAL WITH THE AVAILABLE RESOURCES AIMING TO REDUCE INCIDENCE OF MEDICATIONS ERRORS AND DECREASE IN THE OVERALL COST OF MEDICATIONS.

8.0 RELATED DOCUMENTS

N/A

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/journal/articles/Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASHP Statement on Unit Dose Drug Distribution</td>
<td>ASHP</td>
<td>1989</td>
<td>1</td>
</tr>
<tr>
<td>WHO Consultancy assignment report on UDS in MOH Oman</td>
<td>Dr. Ayed Al Shamrani</td>
<td>2006</td>
<td>14</td>
</tr>
<tr>
<td>Guidelines for Inpatient Pharmacy Practice – Unit Dose Dispensing System</td>
<td>Pharmaceutical Services, MOH Malaysia</td>
<td>2010</td>
<td>68</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

Drug utilization review (DUR) is as an authorized, structured, ongoing review of prescribing, dispensing and use of medication. DUR encompasses a drug review against predetermined criteria that results in changes to drug therapy when these criteria are not met. It involves a comprehensive review of patients' prescription and medication data before, during and after dispensing to ensure appropriate medication decision-making and positive patient outcomes. As a quality assurance measure, DUR programs provide corrective action, prescriber feedback and further evaluations.

DUR programs play a key role in helping managed health care systems understand, interpret, evaluate and improve the prescribing, administration and use of medications. Employers and health plans find DUR programs valuable since the results are used to foster more efficient use of scarce health care resources. Pharmacists play a key role in this process because of their expertise in the area of medication therapy management. DUR affords the managed care pharmacist the opportunity to identify trends in prescribing within groups of patients whether by disease-state such as those with asthma, diabetes or high blood pressure, or by drug-specific criteria. Pharmacists can then, in collaboration with prescribers and other members of the health care team, initiate action to improve drug therapy for patients.

2.0 SCOPE

Medicines with the highest potential for problems in order to get the most return on the work involved.

3.0 PURPOSE

The goal of a DUE or MUE is to promote optimal medication therapy and ensure that drug therapy meets current standards of care. Additional objectives may include:

- Creating guidelines (criteria) for appropriate drug utilization.
- Evaluating the effectiveness of medication therapy.
- Enhancing responsibility/accountability in the medicine use process.
- Controlling medicine cost.
- Reducing inappropriate drug use and related hospitalization visits.
- Preventing medication related problems, for example adverse drug reactions, treatment failures, over-use, under-use, incorrect doses and non-formulary medicine use.
- Identifying areas in which further information and education may be needed by health-care providers.
4.0 DEFINITION

Drug Utilization Review (DUR): Is a quality improvement process that serves as a means to enhance the benefits of drug therapy by detecting and correcting deficiencies in the drug use process to ensure safe, rational, and cost-effective drug therapy.

Other terms considered synonymous with Drug Utilization Review (DUR) include Drug Use Evaluation (DUE), Medication Use Evaluation (MUE), and medication use management.

5.0 POLICY

5.1 A nominated Drug Utilization Review Committee should conduct the utilization review as per predefined and approved criteria based on standard treatment guidelines for each items.

5.2 The Drug Utilization Review plan should include:
- A delineation of the responsibilities and authority of those involved in the performance of utilization review activities.
- Conflict of interest statement is applicable to all involved in utilization review activities.

5.3 The DUR selection should concentrate on medicines of the high-priority areas which include:
- High-volume drugs.
- Expensive drugs.
- Drugs with a narrow therapeutic index.
- Drugs with a high incidence of ADRs.
- Critically important therapeutic categories, for example cardiovascular, emergency, toxicology, intravenous drugs, chemotherapy and narcotic analgesics.
- Antimicrobial drugs, prophylactic and therapeutic.
- Drugs undergoing evaluation for addition to the formulary.
- Drugs used for non-labeled indications.
- Drugs used in high-risk patients.
- Common clinical conditions often poorly treated.

6.0 PROCEDURE

6.1 Determines a need for a review, primarily based on the medications of high-priority areas in term of high potential for toxicity or adverse effects, frequency or volume of use and/or cost etc.

6.2 Establishing DUE criteria for the use of any medicine should be made using the hospital’s standard treatment guidelines (STGs). In the absence of hospital STGs, criteria may be based on recommendations from national or other locally available satisfactory drug use protocols, other relevant literature sources, and/or recognized international and local experts.
Components of drug use for DUE criteria include:

- Uses: appropriate indication for drug, absence of contraindications.
- Selection: appropriate drug for clinical condition.
- Preparation: steps involved with preparing a drug for administration.
- Administration: steps involved in administration, quantity dispensed.
- Patient Education: drug and disease-specific instructions given to patients.
- Monitoring: clinical and laboratory.
- Outcome: for example: decreased blood pressure, blood glucose, asthma attacks.

6.3 Reviewing many criteria will make the DUE process more difficult, and may impair successful completion of the review. Therefore the number of criteria established for each medicine is often between 3 and 5.

6.4 Once the criteria are established, thresholds or benchmarks are decided for each criterion in order to define the expectations or goals for compliance with the specified criteria. A threshold of 90-95% compliance may be set, below which they would instigate corrective action.

6.5 Drug utilization review (DUR) may be conducted in any one of the following three categories:

- Prospective DUR: Involves evaluating a patient’s planned drug therapy before a medication is dispensed. This process allows the pharmacist to identify and resolve problems before the patient has received the medication. Issues commonly addressed by Prospective DUR:
  - Clinical abuse/misuse.
  - Drug-disease contraindications (when a prescribed drug should not be used with certain diseases).
  - Drug dosage modification.
  - Drug-drug interactions (when two or more different drugs interact and alter their intended effects, often causing adverse events).
  - Drug-patient precautions (due to age, allergies, gender, pregnancy, etc.).
  - Formulary substitutions (e.g., therapeutic interchange, generic substitution).
  - Inappropriate duration of drug treatment.

- Concurrent DUR: Is performed during the course of treatment and involves the ongoing monitoring of drug therapy to foster positive patient outcomes. It presents pharmacists with the opportunity to alert prescribers to potential problems. As electronic prescribing becomes more widely adopted, the concurrent DUR process may be performed by the prescriber at the time of prescription transmission to the pharmacy, allowing interventions before the drug is dispensed.
Issues Commonly Addressed by Concurrent DUR:
- Drug-disease interactions.
- Drug-drug interactions.
- Drug dosage modifications.
- Drug-patient precautions (age, gender, pregnancy, etc.)
- Over and underutilization.
- Therapeutic Interchange.

- Retrospective DUR: Reviews drug therapy after the patient has received the medication. A retrospective review aims to detect patterns in prescribing, dispensing or administering drugs. Based on current patterns of medication use, prospective standards and target interventions can be developed.

Issues Commonly Addressed by Retrospective DUR:
- Appropriate generic use.
- Clinical abuse/misuse.
- Drug-disease contraindications.
- Drug-drug interactions.
- Inappropriate duration of treatment.
- Incorrect drug dosage.
- Use of formulary medications whenever appropriate.
- Over and underutilization.
- Therapeutic appropriateness and/or duplication.

6.6 Data must be collected from a suitable random sample that collected retrospectively, or prospectively. The treatment of at least 30 patients, or 100 patients for common clinical conditions, should be reviewed per health facility or hospital.

6.7 Sources of data include patient charts, dispensing records, medication administration records, laboratory reports, ADR reports, medication error reports, antimicrobial sensitivity reports, and documented staff and patient complaints.

6.8 Data are tabulated in a form that corresponds to the criteria chosen for the DUE. The percentages of cases that meet the threshold for each criterion should be calculated and summarized. The identified deficiencies and/or problems in compliance to established criteria, if any, should be submitted by the DUR Committee to the requesting authority i.e., CDC, D&TC, Hospital management, Planning Affairs, Research Depts. and Quality Improvement Dept., for review and corrective action as required.

6.9 After information is presented, a conclusion should be developed about the differences between actual and desired results.

6.10 Recommendations should include specific steps to correct any drug use problem that is evident from performing the DUE. Interventions to improve drug use would include feedback to the prescribers and may also include:
• Education, for example letters, in-service education, workshops, newsletters, face-to-face discussions.
• Institution of drug order forms.
• Institution of prescribing restrictions.
• Changing the formulary list and/or manual.
• Changing the standard treatment guidelines.
• Using another DUE or continuing the present one.

6.11 In every DUE conducted, the follow-up is critical to ensure appropriate resolution of any problems.

7.0 RESPONSIBILITY

Pharmacist’s responsibility in Drug Utilization Review Committee includes:
• Participate in developing an operational DUR Plan and setting the suitable criteria for specific medications and to design effective medication use processes.
• Participate in conducting DUR study to ensure optimal medication use therapy.
• Reviewing individual medication orders against medication use criteria and consulting with prescribers and others in the process as needed.
• Collecting analyzing and evaluating patient-specific data to identify, resolve, and prevent medication related problem.

8.0 RELATED DOCUMENTS

N/A

9.0REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASHP Guidelines on Medication-Use Evaluation</td>
<td>ASHP Board of Directors</td>
<td>1996</td>
<td>3</td>
</tr>
<tr>
<td>Drug Utilization Review, Academy of managed care pharmacy, USA</td>
<td>AMCP Board of Directors</td>
<td>2009</td>
<td>7</td>
</tr>
<tr>
<td>Drug Utilization Review</td>
<td>HMSA, USA</td>
<td>2013</td>
<td>2</td>
</tr>
<tr>
<td>Utilization Review Standards</td>
<td>Utah State Hospital</td>
<td>2013</td>
<td>11</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

In hospitals and primary health care settings, a Drug and Therapeutics Committee (D&TC) provides a forum to bring together all the relevant people to work jointly to improve health-care delivery. As such, a D&TC may be regarded as a tool for promoting more efficient and rational use of medicines. D&TC has been shown to be one of the most effective structures in health units able to address drug use problems.

Essential medicines are one of the most cost-effective ways of saving lives and improving health, and constitute around 10% - 20% of health budgets in many developing countries. Increasing costs and lack of resources often result in public health systems being unable to procure sufficient medicines to meet patient needs. The formulary process is the cornerstone of good pharmaceutical management and rational drug use. Choosing the most appropriate therapies and selecting the most cost-effective good-quality drugs by leads to better quality of care and more efficient, equitable use of resources.

D&TC functions and responsibilities can significantly improve drug use and reduce costs in hospitals and other health care facilities in the following ways:

- Advisory committee to medical staff, administration and pharmacy on all aspects of drug management.
- Developing drug policies.
- Evaluating and recommending selection of drugs for the formulary list.
- Review, developing (or adapting) and implementing standard treatment guidelines.
- Assessing drug use to identify problems.
- Conducting effective interventions to improve drug use.
- Managing adverse drug reactions and medication errors.
- Informing all staff members about drug use issues, policies and decisions.

2.0 SCOPE

The role of Pharmacist in Drug & Therapeutic Committees (D&TCs) functions.

3.0 PURPOSE

To provide general guidance to Pharmacy and Medical Store Departments on the activities of the D&TC and the appropriate management of the MOH formulary system.

4.0 DEFINITION

4.1 Drug and Therapeutics Committee (D&TC): or Pharmacy & Therapeutic Committee (P&TC) as referred to in some countries like USA is the committee that evaluates the clinical use of drugs, develops policies for managing drug use and administration, and manages the formulary system.
4.2 Formulary: A list of medicines approved for use in the healthcare system by authorized prescribers.

4.3 Formulary manual: The document that describes medicines that is available for use in a hospital or clinic (i.e., indications, dosage, and length of treatment, interactions, precautions, and contraindications).

4.4 Formulary system: A system of periodically evaluating and selecting medicines for the formulary, maintaining the formulary, and providing information in a suitable manual or list.

5.0 POLICY

5.1 This policy is a supportive guide and not intended to replace any decisions, policies, processes or guidelines issued by the concerned authorities or Central Drug Committee (CDC) regulating the functions or activities of Drug & Therapeutics Committees (D&TCs) in MOH Healthcare Units.

5.2 Recommendation for addition of medicine intended for regular long term use or deletion from the already approved drugs, should be filled in ‘Form B’ (Annex-A) by the requesting doctor/pharmacist and submitted to D&TC. The request should be reviewed carefully by the D&TC prior forwarding to CDC for a suitable decision.

5.3 Pharmacy Department should ensure that MOH Formulary drugs restricted by CDC to use, either by medical service (e.g., a drug restricted to use by the level of specialty of the prescriber), or prescribing criteria (e.g., a drug restricted to use for specific indication), or patient care area (e.g., a drug restricted to use only in tertiary hospitals) are prescribed as per CDC decisions. Please refer to policy titled “Restricted Formulary Medications (MOH-DGMS-PH-27)”

5.4 Pharmacy Departments should verify that request for supply of Non-Approved Drugs against “From-A” are prescribed for a specified period and restricted to Life saving / Vital drugs requested for individual cases only or when alternative drug not available or available but could not be used for a certain reason. In case of repeated prescribing of the item for regular use, the same should be referred to D&TC for appropriate decision. Please refer to policy titled “Handling Non-Formulary Drug Requests (MOH-DGMS-PH-28)”

6.0 PROCEDURE

6.1 The Pharmacist should carefully review and process the requests submitted for inclusion or omission of new drugs in MOH formulary against (Form-B) including indications for which drug is proposed, alternative drug already approved, advantage compared to the existing approved drug, cost effectiveness comparison, number of patients anticipated annually, proposed treatment guidelines and prescribing level etc.

6.2 The following selection criteria of new drugs developed by WHO may be considered while evaluating new requests:

- Only those medicines should be selected for which sound and adequate data on efficacy and safety are available from clinical studies, and for which evidence of performance in general use in a variety of medical settings has been obtained.
• Each selected medicine must be available in a form in which adequate quality, including bioavailability, can be assured; its stability under the anticipated conditions of storage and use must be established.

• When two or more medicines appear to be similar in the above respects, the choice between them should be made on the basis of a careful evaluation of their relative efficacy, safety, quality, price and availability.

• In cost comparison between medicines, the cost of the total treatment, and not only the unit cost of the medicine, must be considered. Where drugs are not entirely similar, selection should be made on the basis of a cost-effectiveness analysis.

• In some cases, the choice may also be influenced by other factors, such as pharmacokinetic properties, or by local considerations such as the availability of facilities for storage or manufacturers.

• Most essential medicines should be formulated as single compounds. Fixed-ratio combination products are acceptable only when the dosage of each ingredient meets the requirements of a defined population and when the combination has a proven advantage over single compounds administered separately in therapeutic effect, safety or compliance.

• Drugs are specified by the international nonproprietary name (INN) or generic name without reference to brand names or specific manufacturers.

6.3 Elements of a Drug-Evaluation Document depend on the needs of the specific health system, but the following elements are essential for D&TC evaluation of all such documents:

• Brand and generic names and synonyms,
• FDA approval information, including date and FDA rating,
• Pharmacology and mechanism of action,
• FDA-approved indications,
• Potential non-FDA-approved (off-label) uses,
• Dosage forms and storage,
• Recommended dosage regimens,
• Pharmacokinetic considerations,
• Use in special populations (e.g., children, elderly, patients with renal or liver failure),
• Pregnancy category and use during breast-feeding,
• Comparisons of the drug’s efficacy, safety, convenience, and costs with those of therapeutic alternatives (with evidence tables when feasible)
• If information on comparative efficacy is minimal or lacking, data on absolute efficacy (i.e., efficacy versus placebo),
• Clinical trial analysis and critique,
• Medication safety assessment and recommendations (adverse drug reactions; drug–drug and drug–food interactions; specific therapy monitoring requirements; unusual administration, storage, or stability issues; and potential for medication errors, such as look-alike or sound-alike issues), and

• Availability of Lab facilities for Drug Use Monitoring.

• Financial analysis, including pharmacoeconomic assessments.

6.4 Consulting part of the following Information Resources is of value in evaluating the request of addition of new drug in the formulary:


• Secondary Literature: Examples, Medical letters, newsletters, or bulletins produced by national bodies that monitor medicine efficacy, safety, and cost, Medical Letter (USA), Drug & Therapeutics Bulletin (UK), The International Society of Drug Bulletins, Peer-reviewed journals, Australian Prescriber, Journal Watch, Electronic databases, MEDLINE and EMBASE abstracts, International pharmaceutical abstracts, Cochrane Library abstracts and evaluations.

• Tertiary Source: Examples, Martindale: The Extra Pharmacopoeia, British National Formulary (BNF), USP DI Drug Information, And American Hospital Formulary Service (AHFS) Drug Information.


6.5 Effective management of hospital/health unit’s formulary by D&TC provide the following benefits:

• Practitioners will have available for use:
  ✓ Only the most effective and safest products.
  ✓ Medicines have been evaluated systematically.

• Approved and efficacious medicines that all:
  ✓ Medicines are chosen and approved to treat the diseases of the region or country.
  ✓ Physicians develop greater experience with fewer medicines.

• Pharmaceutical therapy at lower cost:
  ✓ Ineffective, high-cost medicines will be excluded from system.
  ✓ Availability of most effective medicines leads to fewer visits, improved outcomes.
  ✓ Reduced inventory cost.

• Consistent supply of medicines:
✓ Regulating the number of medicines will improve procurement and inventory management.
✓ Economies of scale will increase availability of essential medicines.
✓ Saving money leads to consistency in purchasing essential medicines which in turn leads to increased availability.

7.0 RESPONSIBILITY
Pharmacists participating in D&TC Committees:
- Promote the use of high quality and cost effective medicines.
- Ensure compliance with the approved standard protocols and guidelines.
- Address medication safety issues e.g., medication error, Adverse Drug Reactions in D&TC meeting.
- Refer aggregate drug consumption data including Category-A for discussion, rationalization and necessary recommendation for better rationalization of resources, by D&TC.

8.0 RELATED DOCUMENTS
N.A

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug and Therapeutic Committees, A Practical Guide WHO, MSH</td>
<td>Kathleen Holloway, Terry Green</td>
<td>2003</td>
<td>155</td>
</tr>
<tr>
<td>Developing and Maintaining a Formulary, D&amp;TC Training Course</td>
<td>WHO, MSH Manual</td>
<td>2007</td>
<td>26</td>
</tr>
<tr>
<td>ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System</td>
<td>ASHP</td>
<td>2012</td>
<td>10</td>
</tr>
<tr>
<td>Pharmacy and Therapeutics Committee Policies and Procedures</td>
<td>HealthPartners Pharmacy Service, Minnesota, USA</td>
<td>2017</td>
<td>19</td>
</tr>
</tbody>
</table>
### ANNEX-A

Sultanate of Oman  
Ministry of Health  
CENTRAL DRUG COMMITTEE

**Form B**

#### Recommendation for Addition / Deletion of a Medicine in MOH Formulary

*This form should be duly filled, and forwarded to the Drug & Therapeutic Committee. After approval by the D&TC it should be approved by the DG/ Director of Hospital and then forward to the Secretary of the Central Drug Committee.*

<table>
<thead>
<tr>
<th>1- Hospital:</th>
<th>2- Department:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3- **Addition**  ○  **Deletion**

<table>
<thead>
<tr>
<th>4- Medicine Information</th>
<th>Generic Name:</th>
<th>Trade Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4- Medicine Information</th>
<th>Dosage Form:</th>
<th>Manufacturer:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4- Medicine Information</th>
<th>Strength:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4- Medicine Information</th>
<th>Dose:</th>
<th>Duration:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5- Therapeutic Class:

6- Indication(s):

   i-  
   ii-  
   iii-  

7- In case of deletion; please indicate by whom it was requested:-

Name of Consultant

   1. Hospital
   2. Hospital

FDA Approval:  ○ Yes  ○ No  
EMA Approval:  ○ Yes  ○ No

Other Health Authority approval:

8 – Alternative medicine(s) already included in the Formulary:

   ■  
   ■

9 - The requested medicine may replace the following similar medicine(s) already included in the formulary:

   ■  
   ■
Sultanate of Oman
Ministry of Health
CENTRAL DRUG COMMITTEE

10 – Advantages of the requested medicine over similar medicines already included in the formulary (N.B. supportive documents should be submitted) :-

<table>
<thead>
<tr>
<th>11 - a – Proposed Guidelines</th>
<th>National / Hospital</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>International Guidelines</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>11 - b – Prescriber level</th>
<th>General practitioner</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Specialist</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consultant</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

12 - State any other restrictions on the use of this medicine:

13- State the anticipated number of patients/year:

14- Justification for requesting deletion of the medicine from the Formulary

<table>
<thead>
<tr>
<th>Requesting Doctor/Pharmacist</th>
<th>Name</th>
<th>Designation</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>DG/Director/Head of Department</td>
<td>Name</td>
<td>Signature</td>
<td>Date</td>
<td></td>
</tr>
</tbody>
</table>
For Drug & Therapeutic Committee Use:

<table>
<thead>
<tr>
<th>D&amp;T recommendation</th>
<th>Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Justification:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Meeting No:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chairperson, D&amp;T</td>
<td>Name:</td>
</tr>
<tr>
<td>Secretary, D&amp;T</td>
<td>Name:</td>
</tr>
<tr>
<td>DG / Director</td>
<td>Name:</td>
</tr>
</tbody>
</table>

For CDC Task Force Use

<table>
<thead>
<tr>
<th>Unit (acquisition) cost</th>
<th>RO</th>
<th>Daily treatment cost:</th>
<th>RO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Availability in SGH Tender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patent expiry date</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Task Force recommendation</td>
<td>Approved</td>
<td>Disapproved</td>
<td></td>
</tr>
<tr>
<td>Pending</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Meeting No:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chairperson</td>
<td>Name:</td>
</tr>
<tr>
<td>Secretary</td>
<td>Name:</td>
</tr>
</tbody>
</table>
Sultanate of Oman  
Ministry of Health  
CENTRAL DRUG COMMITTEE

For Central Drug Committee Use:

<table>
<thead>
<tr>
<th>Received by CDC Secretary on</th>
<th>Sr. No.</th>
<th>Signature:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discussed In Meeting No:</td>
<td>Date:</td>
<td></td>
</tr>
</tbody>
</table>

- ☐ Approved  - ☐ Disapproved  - ☐ Pending

Remarks:

**Condition(s) / Restriction(s):**

- Prescriber level:  ☐ General Practitioner  ☐ Specialist  ☐ Consultant
- Healthcare level:  ☐ Health Centre  ☐ Extended Health Centre  ☐ Hospital  ☐ Tertiary Hospital

**Speciality / Specialities restricted to:**

**NB:**

1. For Medicine requested for deletion please ignore inapplicable points
2. Total number of pages for Form B is 4
1.0 INTRODUCTION

The use of a drug prescribed for an indication not specifically approved by FDA is often referred to as off-label use. Off-label use (unlicensed indication) can include the use of pharmaceuticals outside of specified populations, for different diseases or stages of diseases, or by different routes of administration. Other types of off-label use involve changes to dosing, dosing schedules, chronology or sequence of use. Also when a drug is approved as a capsule, but it is given instead in an oral solution or prepared extemporaneously.

Before considering off-label use, supporting safety and efficacy evidence must be carefully evaluated and a risk-benefit determination made, especially when alternatives with FDA-approved labeling are available for the intended off-label use.

Off-label prescribing is part of medical practice and may be necessary to fulfill the need of individual patients, when it is the only available treatment option for the patient. The level of evidence to prescribe and use a product off-label use may differ. Sometimes, evidence of efficacy and safety is available, but the pharmaceutical company does not take steps to extend the market authorization. This is for example the case with various medicines used in children: information on efficacy and safety is gathered in clinical practice and made available but this evidence does not (always) lead to a formal application to enlarge the age range for the (off-label used) medicinal product.

If an untoward incident occurs with the use of an unlicensed/off-label medicine in an unapproved clinical situation, any liability arising cannot be transferred to the Manufacturer (License Holder). However, if an untoward incident occurs with a licensed medicine, such as a product defect or a problem with its use in an approved clinical situation, any liability arising may in part or whole be transferred to the Manufacturer (License Holder).

According to the American Cancer Society, cancer treatment often involves using certain chemotherapy drugs off-label, because a chemotherapy drug approved for one type of cancer may actually target many different types of tumors. Bevacizumab (Avastin) is another good example. It is approved by FDA to treat metastatic colorectal cancer etc., but Off-label uses include treatment of age-related macular degeneration (AMD) as a first line therapy for several diseases by many retina specialists and these accounts for more than 50% of anti-VEGF administrations in the US.

2.0 SCOPE

Off-label use of MOH approved formulary drugs

3.0 PURPOSE

3.1 To provide systematic procedure for pharmacy staff on dealing with review and dispensing of formulary drugs, when prescribed for Off-label (unlicensed) indications.
3.2 To help detect and prevent diversion of drugs for unauthorized purposes, and assure compliance with applicable MOH policies and regulations.

4.0 DEFINITION

OFF-LABEL USE: The use of a drug in indications, doses, routes of administration or patient group (age related) not approved in the products labeling.

5.0 POLICY

5.1 Authorizing the use of Off-label indication in MOH formulary may be considered by the Central Drug Committee (CDC) for a specific specialty or level of service in situations where the drug is medically necessary to treat the specific medical condition, including life-threatening or sight-threatening conditions due to the absence of suitable, authorized alternatives.

5.2 Off-label prescription should be based on published evidence; patient safety should be the primary consideration. The ultimate responsibility for the safety and efficacy of off-label use resides with the prescribers.

5.3 An unlicensed medicinal product (Off-Label) may only be supplied in order to meet the special needs of an individual patient. An unlicensed medicinal product should not be supplied where an equivalent licensed medicinal product can meet the special needs of the patient.

6.0 PROCEDURE

6.1 The Pharmacist shall carefully review and evaluate any orders prior to dispensing.

6.2 Upon receiving an order for an off-labeled indication that is not approved by CDC, the pharmacist will research and substantiate with the prescriber the unlabeled use in one of the available drug references such as:
   - Micromedex Drugdex Evaluations (Strength of Recommendation is Class I or II a)
   - British National Formulary (BNF)

6.3 If the drug is not clearly stated to be effective for the off-label indication in one of the above references or other international drug references, the requesting prescriber must submit published scientific evidence supporting the use of the drug for the requested off-label indication before processing the order.

6.4 In emergency or critical situations the order should be processed based on the decision and responsibility of the prescribing Consultant.

7.0 RESPONSIBILITY

Pharmacy & Medical Stores Departments in Healthcare Units:

- Upon receipt of a prescription for off label use, outside the indication approved by CDC, the pharmacist should intervene with the prescribing consultant to justify the clinical situation of the patient.

- Document and monitor incidence of off label prescribing and discuss the same in D&TG meeting, for necessary actions to discourage/limit such practice, if repeated.

8.0 RELATED DOCUMENTS

N/A
### 9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASHP Guidelines on P&amp;TC and the Formulary system – Off Label Use</td>
<td>Board of Directors, Council of Pharmacy Practice</td>
<td>2012</td>
<td>10</td>
</tr>
<tr>
<td>Policy &amp; Procedure for the use of unlicensed medications</td>
<td>Unlicensed medicines working group D&amp;TC Lothian NHS</td>
<td>2014</td>
<td>19</td>
</tr>
<tr>
<td>Understanding Unapproved Use of Approved Drugs «Off Label»</td>
<td>FDA, USA</td>
<td>2018</td>
<td>3</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

In health care systems, Formulary Drugs may be restricted to use, either by medical service (e.g., a drug restricted to use by the level of specialty of the prescriber), prescribing criteria (e.g., a drug restricted to use for specific indication), or patient care area (e.g., a drug restricted to use only in tertiary hospitals).

Reasons for the recommended restrictions include: prevention of resistance; safety concerns; expertise management and rationalizing of resources.

In general formulary management practice, Medicines may be included in the formulary with differing levels of prescribing restriction:

- No restriction (prescribable by all prescribers).
- Restricted to primary care prescribing only.
- Restricted to hospital prescribing only.
- Restricted to hospital specialty only.
- Restricted to consultant prescribing (for specific medical unit) only.
- Restricted to specified indication(s).
- Restricted to prescribing following prior approval for named patient(s) only.
- Restricted medicines include those products that fill a particular need by a specialty within the health system.

Some examples of restricted medicines and their applicability include certain antibiotics for infectious diseases (e.g., Ceftriaxone), Antipsychotic medicines for use by mental health professionals (e.g., use of Risperidone can be restricted to psychiatrists), Antineoplastic products for use by physicians with specialized knowledge of these medicines.

2.0 SCOPE

Review and dispensing MOH formulary restricted drugs.

3.0 PURPOSE

To outline the process of dealing with restricted MOH formulary medications.

4.0 DEFINITION

Formulary restriction: The act of limiting the use of specific formulary medications to specific physicians based on areas of expertise or level of healthcare, or for specific indications and / or age group.
5.0 **POLICY**

5.1 Restricted drugs due to their unique nature, high cost, and/or safety concerns, should be prescribed by Consultants / Specialists or by the Specialty Units based on the Central Drug Committee (CDC) decisions.

5.2 Prescribing specialized medications beyond own specialty is not allowed as per the Central Drug Committee (CDC) decisions and approved protocols, prescribing to be restricted for each item based on the Specialty and Health care level.

5.3 Restricted medications should be identified in the MOH Formulary, Primary Healthcare Formulary, and MOH Health Information System. Details of the restriction are to be provided in the restrictions section of the Medication Monograph in MOH Formulary.

5.4 Requests for inclusion of an approved drug in the primary health care list should be forwarded to the ‘PHC Committee for Reviewing & updating Drugs & Medical Items’ in the attached Form (Annex- A)

6.0 **PROCEDURE**

6.1 Before dispensing the restricted medications the pharmacist should verify the prescription carefully, to ensure that it is limited to the specified authorized physician or the indication or the area of care.

6.2 In certain situations, if the authorized physician is not available or cannot be reached, his substitute may prescribe the restricted medication.

6.3 For Outreach clinics & Referral cases the follow up of prescribing the restricted medications can be continued by the delegated physician in the referred back institutions.

7.0 **RESPONSIBILITY**

Pharmacy Departments in Healthcare Units:

- Upon receipt of any medication order, the pharmacy staff shall verify and dispense the restricted medications within the restriction scope been approved by CDC.

8.0 **RELATED DOCUMENTS**

N/A

9.0 **REFERENCES**

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effect of evidence-based Formulary restriction at a Veteran Affairs Medical Center, Oklahoma</td>
<td>Nathan Moore Formulary watch</td>
<td>2006</td>
<td>10</td>
</tr>
<tr>
<td>Developing &amp;Maintaining Formulary, D&amp;TC Training Course</td>
<td>WHO, MSH, USAID</td>
<td>2007</td>
<td>26</td>
</tr>
<tr>
<td>Restricted Drugs Policy</td>
<td>Pharmacy Services, Canada</td>
<td>2015</td>
<td>2</td>
</tr>
<tr>
<td>Medicines Policy Annexe-3 Buckinghamshire Joint Formulary Policy, NHS</td>
<td>Maire Sapleton Sarah Crotty</td>
<td>2015</td>
<td>41</td>
</tr>
</tbody>
</table>
(Annex-A) Sultanate of Oman
Ministry of Health

PHC Committee for Reviewing & updating Drugs & Medical Items Lists
Request Form for Non-approved Drug(s) in Primary Care Health Lists

This Form should be duly filled by the Concerned PHC Practitioner Doctor and approved by the head of the Health unit, and forwarded through the Director of pharmacy at DGHS Governorate to the PHC committee for reviewing & updating Drugs & Medical Items, at Directorate General of Medical Supplies

Drug Generic Name: ........................................ Therapeutic Category: ........................................
Dosage Form & strength: ............................ Proposed Indication: ........................................

1) Should this drug have any approved alternative in PHC list? (please tick appropriate box)
   Yes □ No □
   If yes specify reason for not using or stopping the available alternative drug
   ...........................................................................................................................................................................
   ...........................................................................................................................................................................
   ...........................................................................................................................................................................

2) Should this drug included in treatment protocol manual(s) for PHC institutions level? (please tick appropriate box)
   Yes □ No □
   If yes specify the manual & indication
   ...........................................................................................................................................................................
   ...........................................................................................................................................................................
   ...........................................................................................................................................................................

3) Please explain briefly the rationale for this suggestion, including any cost implication.
   ...........................................................................................................................................................................
   ...........................................................................................................................................................................
   ...........................................................................................................................................................................

Name of clinician (print) .................................................. Date: ..........................
Name of Health Unit: .................................................. Health unit Level: ...............,
Head of the Unit comments (if any): ..........................................................
Head of the Unit name & signature: ..........................................................
Director of Pharmacy Comments: ..........................................................
Director of pharmacy Name & signature: ..................................................
### Handling Non-Formulary Drug Requests

**MOH DGMS - PH/P&P/028/Vers.001**

**Effective date:** 15/01/2019

**Review date:** 14/01/2022

**1.0 INTRODUCTION**

Formulary medicines meet the needs of the vast majority of patients but it is acknowledged that individual patients may have a need for a medicine which is non-formulary. Medicines management processes shall ensure that the place in therapy of non-formulary medicine is established to meet such needs.

MOH Formulary has been established since long time and it is periodically updated to cope with the latest development in the medicines field. The management of medicines relating to the formulary is robust and forms the basis of good prescribing practice. Prescribing from the formulary is consistent with good clinical practice, however it is recognized that there may be occasions when the need to prescribe a non-formulary medicine will however occur.

Regular stock of non-formulary drugs prescribed for individual cases is not maintained in the Ministry and in most cases stock is not be available also in Oman’s local market and need to be imported from UK, India or USA market. The acquisition process of non-formulary drug may take around one month lead time or even more and at very high cost, therefore prescribing of non-formulary drugs should not be encouraged.

**2.0 SCOPE**

Non-Formulary drugs prescribed for individual cases against (Form A).

**3.0 PURPOSE**

To describe the mechanism for handling non-formulary drug request to ensure that individual patient need is met.

**4.0 DEFINITION**

Non-Formulary Medication: Any generic drug, brand name, or dosage form that is not listed in the MOH approved formulary list.

**5.0 POLICY**

5.1 Request for supply of Non-Approved Drugs (Form-A) should be duly filled by the prescribing Consultant/ Sr. Specialist or Specialist for a specified period of time and approved by the Head of the Unit. Copy of “Form-A” is attached.

5.2 Procurement of non-approved drugs should be restricted to the following conditions:

- Life-saving / Vital drugs requested for individual cases only
- Alternative drug not available or available but could not be used for a certain reason.
5.3 Drugs intended for regular long term use; the application “Form-B” should be submitted by the Drug and Therapeutic Committees in Health Units for CDC approval through

5.4 Non-approved drugs prescribed for referral cases by Royal Hospital or Sultan Qaboos University Hospital, should be arranged directly by the prescribing Institution as per the currently followed practice.

5.5 Non-approved drugs for individual cases who started their treatment abroad by themselves should be arranged by those patients themselves, if shifting to the approved alternatives is not recommended or not acceptable to them.

6.0 PROCEDURE

6.1 The pharmacist should review carefully the request for the non-approved drug and provide professional advice regarding any alternative medicines which are approved that may be appropriate for treating the patient. If the non-formulary medicine is seen to be the only alternative, the prescriber should process “Form A”.

6.2 A duly-filled (Form A) along with Local Purchase Request for procurement of a drug not included in the M.O.H. formulary should be forwarded by the Head of Pharmacy / Medical stores to the Medical Stores Department (Royal Hospital) and to the Department of Drug Stores, DGMS for other Health Units.

6.3 The Director of Drug Stores in DGMS / Medical Stores in Royal Hospital should verify and provide the details for the item availability and cost involved and the request to be referred to the respective Director General for approval/disapproval.

6.4 If approved, a Local Purchase Request should be processed and referred to the purchasing department for arranging the item through Direct Purchase Order initially for three months’ supply as maximum based on the specified duration of treatment and the subsequent total value of the order. Very expensive drugs should be arranged against Urgent Tenders if budget is allocated specifically for such items.

6.5 In case of continuation of the treatment beyond three months, the concerned medical department in the health unit should send on every three months basis a new Purchase Request along with new Form-A.

6.6 If the use of the non-formulary drug is discontinued, the Department of Drug Stores, DGMS should be intimated to withhold the processing of the order.

6.7 Non-formulary drugs shall be properly labeled and stocked separately (in drawer) in the pharmacy in Health Units.

6.8 The Pharmacy and Medical Stores Departments should maintain a record of Non-Formulary Drugs requests for proper management and monitoring.

7.0 RESPONSIBILITY

Pharmacy & Medical Stores Departments in Healthcare Units:

- Review the Non-Approved Drug Requests (Form-A) and refer the same to DGMS/Royal Hospital for further actions.
- Monitor the requests for non-approved drugs and refer the same to D&TC, when usage is regular.
Directorate General of Medical Supplies /Directorate General of Royal Hospital:

- Study the request for non-approved drugs and process the order if approved, with feedback to the requesting Department/Health Unit.

8.0 RELATED DOCUMENTS

Procurement of Medical Supplies (MOH-DGMS-PH-11)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principles of a Sound Drug Formulary System</td>
<td>Council of Pharmacy Practice, ASHP</td>
<td>2011</td>
<td>4</td>
</tr>
<tr>
<td>Policy &amp; Procedure for prescribing non-formulary medicines, Lothian, NHS</td>
<td>Anne Gilchrist, Melinda Cuthbert</td>
<td>2013</td>
<td>9</td>
</tr>
<tr>
<td>Non Formulary medication policy</td>
<td>Pharmacy Services, Boston Medical Center</td>
<td>2015</td>
<td>3</td>
</tr>
</tbody>
</table>
**Form-A**

Sultanate of Oman  
Ministry of Health  
CENTRAL DRUG COMMITTEE

**Request for supply of Non-Approved Drug(s)**

This form should be duly filled by Consultants /Sr. Specialist or Specialist and approved by the Head of Unit only, and forwarded through the Pharmacist In charge to Purchasing Section (For Royal Hospital) & to the Directorate General of Medical Supplies (DGMS) for other Hospitals.

**Important Notes:**

This form should be attached to the Local Purchase Request for procurement of a Drug not included in the M.O.H. Formulary and should be restricted to the following conditions:

1. Life saving / vital drugs requested for individual cases only
2. Alternative drug not available or available but could not be used for a certain reason

Drugs intended for regular long term use application must be submitted through form-B to the Drug and Therapeutic Committees in different hospitals.

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Hosp. No.</th>
<th>Dept.:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ward:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sex: Male ☐ Female ☐</th>
<th>Age:</th>
<th>Nationality:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1- Diagnosis</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2- Requested Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic Name:</td>
</tr>
<tr>
<td>Dosage Form &amp; Strength:</td>
</tr>
<tr>
<td>Dose:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3-Alternative Approved Drug</th>
<th>Available: Yes ☐ No ☐</th>
<th>Used: Yes ☐ No ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic Name:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reason For Not Using or Stopping The Available Alternative Drug & Advantages of the requested drug

(Supportive Documents Should Be Submitted)

...........................................................................................................................................................................

...........................................................................................................................................................................
<table>
<thead>
<tr>
<th>4-Prior Experience of the Prescriber</th>
<th>Yes □</th>
<th>No □</th>
</tr>
</thead>
<tbody>
<tr>
<td>Details: ..................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>.................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>.................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>.................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>.................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5- Side Effects &amp; Precautions of the requested drug:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>........................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>........................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>........................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>........................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6- Remarks / Comments (if any):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>........................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>........................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>........................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>........................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7- Comments of Pharmacist In charge:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>........................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>........................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>........................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>........................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Approximate Cost:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital:</td>
<td>Department:</td>
<td></td>
</tr>
<tr>
<td>Doctors Name:</td>
<td>Designation:</td>
<td>Signature:</td>
</tr>
<tr>
<td>Head of Department:</td>
<td>Signature:</td>
<td></td>
</tr>
<tr>
<td>Tel. / Ext.</td>
<td>Pager:</td>
<td></td>
</tr>
<tr>
<td>Director General / MOIC Approval</td>
<td>Approved □</td>
<td>Disapproved □</td>
</tr>
<tr>
<td>Date: -........../........../.........</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

A Crash Cart helped enhance hospital’s efficiency in emergencies by enabling doctors and nurses to save time, thereby increasing the chances of saving a life. The contents of a crash cart vary from hospital to hospital and primary health care settings, but typically contain the tools and drugs needed to treat a person in or near cardiac arrest. These include but are not limited to:

- Monitor/defibrillators, suction devices, and Bag Valve Masks (BVMs) of different sizes.
- Advanced Cardiac Life Support (ACLS) drugs such as epinephrine, atropine, amiodarone, lidocaine, sodium bicarbonate, dopamine, and vasopressin.
- First line drugs for treatment of common problems such as: adenosine, dextrose, diazepam or midazolam, epinephrine for IM use, naloxone, nitroglycerin, and others.
- Drugs for rapid sequence intubation: succinylcholine or another paralytic, and a sedative such as or midazolam, endotracheal tubes and other intubating equipment.
- Drugs for peripheral and central venous access.
- Pediatric equipment (common pediatric drugs, intubation equipment, etc.).
- Other drugs and equipment as chosen by the facility.

2.0 SCOPE

Nursing Units that have emergency “Crash Carts” and defibrillators.

3.0 PURPOSE

3.1 To ensure proper response to medical emergencies by having properly equipped crash carts that are readily accessible to initiate advanced life-support measures and ensure uniformity of emergency carts throughout MOH Healthcare units based on the level of service.

3.2 To assure that an emergency supply cart containing age appropriate drugs, supplies, and monitoring equipment used in the care and initial treatment of cardiopulmonary arrest victims, including emergency airway and defibrillator components are available and ready for use.
4.0 DEFINITION

A crash cart or code cart (crash trolley): is a set of trays/drawers/shelves on wheels used in hospitals for transportation and dispensing of emergency medication/equipment at site of medical/surgical emergency for life support protocols (ACLS/ALS) to potentially save someone’s life. The cart carries instruments for cardiopulmonary resuscitation and other medical supplies while also functioning as a support for the patient.

5.0 POLICY

5.1 A standardized crash cart must be located within each health unit’s medical departments. That crash cart shall contain a full collection of all approved emergency tools and medications.

5.2 Crash Cart medications can only be administered by appropriately authorized and trained health care professionals.

5.3 Crash carts items shall be provided on an “exchange basis” by the Medical Stores/Inpatient pharmacy to the in-charge nurses in all patient care areas to initiate emergency life-support measures.

5.4 The Medical Stores and nursing staff shall be responsible for maintaining the (RED) drug drawer on all crash carts. The earliest expiration date of any medication shall be documented on the front lid of the drawer.

5.5 The fourth drawer of each adult crash cart (BLUE) shall only contain supplies and equipment to initiate pediatric life-support measures.

5.6 Designated nursing staff in the patient care area shall be responsible for verifying regularly the contents of new crash cart and when it has been used and refilling the crash cart from the medical stores/inpatient pharmacy and returning medication to the pharmacy if expiration date is near or exceeded.

5.7 The defibrillator and cardiac monitor shall be checked and appropriately documented for performance on both battery and electrical current once every 24 hours. The defibrillator will remain plugged into an electrical outlet at all times, except during battery testing. The Biomedical Department will be contacted immediately when a defibrillator problem is detected. A loaner defibrillator shall be obtained.

5.8 Laryngoscopes will be checked prior to placement on the cart. Intubation trays are to be provided by central supply on an exchange basis.

5.9 Oxygen cylinders tank content are to be checked and replaced with full tanks from Medical Stores on an exchange basis.

6.0 PROCEDURE

6.1 The In-charge staff of the Medical Stores/Inpatient pharmacy in collaboration with the In-charge nurse in each patient care unit is responsible to maintain the emergency crash cart as per the approved medications list. All units will set up their own carts to include age-appropriate equipment based on the ages of patients to be served.

6.2 The proximity of the crash cart shall be close enough that medical staff can access the cart instantly. The crash carts are each properly locked so as to ensure that supplies and medications are safe and secure.
6.3 Crash cart refilling order should be through separate medication order from the demanding unit. Drugs for non-emergency situations shall be dispensed from the pharmacy department in the usual manner.

6.4 The Pharmacy Department & Medical Stores will be responsible for the following procedures:
   • Initial stocking and replenishment of the drugs required within the approved list of contents.
   • Regular inspection of the crash cart medications to be carried out on monthly basis. Near expiry items should be replaced one month prior to expiry or three months if the item is moving in another area. Sterile items will be checked for package integrity and expiration date.
   • The pharmacy record of inspections will be kept and shall include; unit inspected, medication expiring, quantity expiring, date expiring, the date expiring drugs are replaced, initials of pharmacy staff responsible for inspection and the initials of the In-charge nurse for that area.

6.5 Contributing factors to patient safety events related to crash carts that should be considered include, but are not limited to:
   • Medication errors and mix-ups.
   • Missing, expired, damaged, contaminated, and unavailable equipment or medications.
   • Empty oxygen tanks.
   • Drained batteries on equipment or equipment failure.
   • Unsecured carts or carts that have been tampered with.
   • Carts secured with heavy duty tape and/or padlocks, preventing immediate access.
   • Incorrect size of equipment.
   • Carts not checked or inspected according to policy and procedure.
   • Staff is unable to locate the crash cart, resulting in a delay getting emergency equipment to the bedside.
   • Staff is unfamiliar with the items regularly stored within the crash cart.
   • Staff is unfamiliar with the procedures for using the crash cart when responding to a life-threatening emergency.
   • Staff is unfamiliar with procedures regarding how to stock or restock the crash cart.

Note: Some of these issues may appear minor, but alone or in combination, they may produce delays in providing care, thereby creating a patient safety risk.

7.0 RESPONSIBILITY

Pharmacy & Medical Stores Departments in Healthcare Units:
   • Maintain and replenish the crash cart medications on an exchange basis with the Incharge nurses.
   • Verify periodically the content and expiry of the crash cart medications.
8.0 RELATED DOCUMENTS

N/A

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code Cart- Checking Procedure, Location, Equipment/Supplies and Exchange Responsibilities</td>
<td>St. peter’s Hospital</td>
<td>2013</td>
<td>4</td>
</tr>
<tr>
<td>Crash Cart Supply &amp; Equipment Check List</td>
<td>Judy Haluka ACLS Training Center</td>
<td>2015</td>
<td>5</td>
</tr>
<tr>
<td>Crash- Cart Preparedness</td>
<td>The Joint Commission</td>
<td>2017</td>
<td>3</td>
</tr>
</tbody>
</table>
0.1 INTRODUCTION

All drugs have the potential to cause side effects, also known as ‘adverse drug reactions’; but not all of these are allergic in nature. Other reactions are caused by drug intolerance, idiosyncratic reactions and pseudo-allergic reactions. The British Society for Allergy and Clinical Immunology (BSACI) defines drug allergy as an adverse drug reaction with an established immunological mechanism. The mechanism at presentation may not be apparent from the clinical history and it cannot always be established whether a drug reaction is allergic or non-allergic without investigation.

Any medication - over-the-counter, prescription or herbal - is capable of inducing a drug allergy; however, a drug allergy is more likely to occur with certain medications. The most common signs and symptoms of drug allergy are hives, rash or fever. A drug allergy may cause serious reactions, including anaphylaxis, a life-threatening condition that affects multiple body systems. A drug allergy is not the same as drug side effects which are listed on a drug label as known possible reactions; it is also distinct from drug toxicity caused by an overdose of medication.

A five-year analysis of confirmed drug-related eruptions in UK, showed that 39.8% were caused by antibiotics, 21.2% by anti-inflammatories, 7.6% by contrast media and 31.4% by others (oral antidiabetics, antimycotics, antipsychotics, anti-epileptics and others).

Most cases of allergy resolve without complications and it may take 10-14 days for the rash to disappear, but most seriously Stevens Johnson syndrome has a mortality of around 10% whilst toxic epidermal necrolysis carries a mortality of 50%.

2.0 SCOPE

Management of established drug allergy cases in the health units.

3.0 PURPOSE

To provide guidance for handling drug allergies including identification, documentation, communication of incidences, reporting and allowing for pharmacy intervention when necessary in order to avoid and/or prevent future incidents from occurring.

4.0 DEFINITION

Drug allergy: Is an adverse drug reaction with an established immunological mechanism.

5.0 POLICY

5.1 Physicians and nurses shall identify any drug allergy for the patient by history and monitor patients’ drug administration i.e. test dose. Any discovered drug allergy should be documented in the patient medical record.
5.2 During the Medication order review and counseling process, the clinical pharmacist / pharmacist should review the patient medication profile. If allergic reaction is found to be reported, the prescribed medicine in question should not be dispensed and he should refer back to the physician for appropriate alternative management.

5.3 Patients should be referred immediately to a specialty clinic if they have:

- A suspected anaphylactic reaction or
- A severe non-immediate cutaneous reaction (e.g., Stevens Johnson syndrome, toxic epidermal necrolysis).
- A suspected allergy to beta-lactam antibiotics if they have a condition which can only be treated by a beta-lactam antibiotic or are likely to need beta-lactam antibiotics frequently in the future.

6.0 PROCEDURE

6.1 During medication reconciliation process, the physician shall confirm from the patient the allergy status as soon as possible following admission/ or during consultation in the outpatient clinics, the discovered allergy shall be documented on the patient medication history.

6.2 When a person presents with suspected drug allergy, his/her reaction should be documented in a structured approach that includes:

- The generic and proprietary name of the drugs / herbal remedies taken during the last 14 days.
- A description of the reaction.
- The indication for the drugs being taken (if there is no clinical diagnosis, describe the illness).
- Date and time of the reaction.
- The number of doses taken or number of days on the drug before onset of the reaction.
- The route of administration.
- Which drug or drug classes to avoid in future.

6.3 Most drug eruptions are unpleasant rather than potentially life-threatening, but extensive care shall be taken for management of the below two potentially fatal drug eruptions:

- Stevens-Johnson syndrome: It may be associated with allopurinol, anticonvulsants, aspirin and NSAIDs, carbamazepine, cimetidine, ciprofloxacin, codeine, diltiazem, erythromycin, furosemide, griseofulvin, indinavir, nitrogen mustard, penicillin, phenothiazines, phenytoin, rifampicin, sulfonamides including co-trimoxazole and tetracyclines. Of these, sulfonamides are most often implicated.
- Toxic epidermal necrolysis: Responsible agents include allopurinol, anticonvulsants, aspirin and NSAIDs, isoniazid, penicillins, phenytoin, prazosin, and sulfonamides including co-trimoxazole, tetracyclines and vancomycin. Both Stevens-Johnson syndrome and toxic epidermal necrolysis are often caused by infections, especially herpes simplex virus.
6.4 Allergic patterns identified by the National Institute for Health and Care Excellence (NICE) are:

- Immediate: (developing within an hour) - anaphylaxis, urticaria, exacerbation of asthma (e.g., by exposure to NSAIDs).
- Non-immediate without systemic involvement: (6-10 days after first drug exposure or within three days of second exposure) - widespread red macules or papules (exanthemalike) or fixed drug eruption.
- Nonimmediate reactions with systemic involvement: (2-6 weeks after first drug exposure or within three days of second exposure) - drug reaction with eosinophilia and systemic symptoms or Drug Hypersensitivity Syndrome (DHS). The features are widespread red macules, papules or erythroderma, fever, lymphadenopathy, liver dysfunction and eosinophilia.
- Toxic epidermolysis: (7-14 days after first drug exposure or within three days of second exposure).
- Stevens-Johnson syndrome: (7-14 days after first drug exposure or within three days of second exposure).
- Acute Generalized Exanthemata’s Pustulosis: (AGEP) (3-5 days after first drug exposure) - characterized by widespread pustules, fever, neutrophilia.

7.0 RESPONSIBILITY
Pharmacists and Assistant Pharmacists in Healthcare Units:

- Shall review the patient medication profile, intervene with the physician in case of suspected allergy and document accordingly.

8.0 RELATED DOCUMENTS
8.1 Medication Reconciliation Policy (MOH-DGMS-PH-17)
8.2 Medication Order Review (MOH-DGMS-PH-18)
8.3 Management of Adverse Drug Reaction (MOH-DGMS-PH-33)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>White Book on Allergy</td>
<td>World Allergy Organization (WAO)</td>
<td>2011</td>
<td>238</td>
</tr>
<tr>
<td>Drug Allergy Article based on UK and European guidelines</td>
<td>Dr. Laurence Knott</td>
<td>2014</td>
<td>8</td>
</tr>
<tr>
<td>Drug Allergy, NICE Guideline</td>
<td>NHS, UK</td>
<td>2014</td>
<td>7</td>
</tr>
<tr>
<td>Drug Allergy &amp; Adverse Drug Reactions</td>
<td>Asthma &amp; Allergy Foundation of America</td>
<td>2015</td>
<td>3</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

Interaction between foods and drugs can have profound influence on the success of drug treatment and on the side effect profiles of many drugs. The clinical significance of drug-food interactions can be variable. Some foods greatly affect drug therapy, resulting in serious side effects, toxicity or therapeutic failure. In some instances, the interaction may have a beneficial effect by increasing drug efficacy or diminishing potential side effects.

It is difficult to be precise about the effects of food on drug absorption in individuals. Factors such as gastrointestinal transit time, sex, age, the presence of gastrointestinal disease, and for women, the stage of the menstrual cycle, can influence drug absorption and the effect of food on absorption. In general, however, the traditional recommendation to take medicines with a glass of water on an empty stomach will, in most cases, help to ensure optimal absorption. Water is the best drink to take because other drinks, such as milk, may prejudice the absorption of some medicines. The effect of caffeine-containing drinks, either hot or cold, (e.g., coffee, tea, chocolate, cola) has not been well studied, but there is little evidence that such drinks influence drug absorption except in the case of theophylline. It is preferable to take medicines with cool liquids so as to avoid heat labile drugs being destroyed. Fruit juices may decrease the effectiveness of acid labile drugs like penicillin. Tea decreases the absorption of iron.

When a fast therapeutic effect is required (e.g., analgesia), it is best to take a medicine on an empty stomach. However, some drugs (e.g., aspirin and other non-steroidal anti-inflammatory drugs) cause gastrointestinal irritation and food can be used to counteract this side effect. This can be a snack and need not be a full meal.

2.0 SCOPE

Patient counseling on common Drug-Food interactions.

3.0 PURPOSE

To educate patients and/or their families about potential food-drug interactions in relation to the medicines they are currently using.

4.0 DEFINITION

Drug-Food Interaction: The effect produced when some drugs and certain foods or beverages are taken at the same time. A clinically significant interaction is one that causes a therapeutic failure and/or toxicity in the patient.

5.0 POLICY

5.1 Pharmacists in every practice setting need to be vigilant in monitoring for potential drug-food interactions and advising patients regarding foods or beverages to avoid when taking certain medications.
5.2 It is imperative for pharmacists to keep up to date on potential drug-food interactions of medications, especially today’s new drugs, so that they may counsel properly to the patients.

5.3 A Common Drug-Food & Drug-Drug Interaction Chart listing medications including the name of the drug, type of food, mechanism of interaction, and patient counseling should be posted in all pharmacy sections, Out-patient Clinics, and all Nursing Stations as quick reference. (Annex A).

5.4 Any information about history of food-drug interaction should be incorporated into the patient medication profile and counseling patients on the potential effects of these interactions and how to avoid those.

6.0 PROCEDURE

6.1 The Pharmacy Services, Nursing Services, and Dietary Services Departments will work together to educate patients and/or their families about potential food-drug interactions. Patients who will be discharged on drugs with potentially significant food-drug interactions will receive counseling on dietary restrictions prior to discharge. Using preprinted food-drug literature, Handouts given to patients are helpful.

6.2 The Physicians, pharmacists, and the nurses will monitor for the adverse drug–food interactions and will report any adverse reactions.

6.3 In providing drug information to patients, pharmacists often discuss potential side effects and how the medication should be taken.

6.4 The pharmacist calls the prescriber whenever the potential for a medication-food interaction exists and document the communication and follow-up action on the prescription or order form.

6.5 The following tips to the patients can help you avoid problems with their medication:

- Always carry a list of all your medications and the dosing instructions.
- When your doctor prescribes a new medication, tell him/her all the other drugs you already take. This includes over-the-counter drugs and supplements that you use regularly. Also, remind your doctor about any drug allergies you have.
- If you have any side effects from a medication, contact your doctor or pharmacist immediately. Do not wait until your next appointment. If you are not sure if symptoms are related to your medication, be sure to ask.
- It is usually best to take medication with a full glass of water. This may help to prevent stomach irritation and improve absorption.
- Don’t take medications with soft drinks or grapefruit juice.
- Don’t stir your medication into food or drink unless your doctor or pharmacist tells you to. Certain foods may break down the drug, or limit its absorption and may affect the efficacy of medication.
- Always read the directions and warning labels on your medication bottles and packages. If you don’t understand something, ask your doctor or pharmacist.
- Do not take vitamin pills at the same time you take medication. Vitamins and minerals can interact with some drugs.
• Do not mix medication into hot drinks because the heat from the drink may destroy the effectiveness of the drug.

• During pregnancy and nursing always consult a physician or pharmacist before taking any medication. Drugs taken by the mother may affect the infant.

6.6 Medications with most potential for drug-food interactions, that require nutritional counseling include: Atypical Antipsychotics, Tetracycline, Statins, Isoniazid, Warfarin, Lithium, Iron Supplements, Potassium-Losing Diuretics MAO Inhibitors Cyclosporine, Dexamethasone, Digoxin, and Prednisolone.

6.7 Five Common Food-Drug Interactions to be considered in counseling are:

• Tyramine-Containing Foods: Foods high in tyramine should be avoided by people taking MAO inhibitors.

• Grapefruit Juice: It is recommends avoiding grapefruit juice with taking statins. It’s best to avoid or significantly reduce intake of grapefruit juice when taking antihistamines, blood pressure drugs, thyroid drugs, birth control, stomach acid-blocking drugs.

• Natural Black Licorice (Glycyrrhiza): Glycyrrhiza can deplete the body of potassium while causing an increased retention of sodium, affecting the activity of digoxin as example. Excessive amounts of natural licorice should be avoided when taking all of these medications.

• Green Leafy Vegetables: Blood-thinning drugs such as warfarin interfere with vitamin K-dependent clotting factors. Eating too much green leafy vegetables, which are high in vitamin K, can decrease the ability of blood-thinners to prevent clotting.

• Salt Substitutes: Consumers taking digoxin for heart failure or ACE inhibitors for high blood pressure should be careful with salt substitutes.

7.0 RESPONSIBILITY
Pharmacists and Assistant Pharmacists in Healthcare Units:

• Shall identify potential drug-food interactions, intervene with the prescriber, monitor, and advice the patient, document and report any adverse reactions.

8.0 RELATED DOCUMENTS
Management of Adverse Drug Reaction, (MOH-DGMS-PH-33)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/journal/articles/Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food/Drug And Drug/Nutrient Interactions: University of Florida</td>
<td>Linda B. Bobroff, Ashley Lentz and R. Elaine Turner</td>
<td>2009</td>
<td>10</td>
</tr>
<tr>
<td>Five Common Food-Drug Interactions,</td>
<td>Rachel Begun, Academy of Nutrition &amp; Dietetics</td>
<td>2014</td>
<td>3</td>
</tr>
</tbody>
</table>
**Annex A**

**Common drug interactions**

Medicines can treat and even cure one’s ills, but they must be used correctly and their effects monitored - particularly when one takes more than one prescription or over-the-counter treatment at a time. The following chart lists widely used drugs and their possible interactions with other medications, food and alcohol. The list is by no means comprehensive. Patients should always discuss their treatments with each of their doctors and pharmacists.

### ARTHRITIS AND PAIN RELIEVERS

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>DRUG NAME</th>
<th>FOOD</th>
<th>ALCOHOL</th>
<th>DRUG</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANALGESICS/ANTIPYRETICS</td>
<td>Acetaminophen</td>
<td>Take on an empty stomach.</td>
<td>Increases risk for liver damage or stomach bleeding.</td>
<td></td>
</tr>
<tr>
<td>NONSTEROIDAL ANTI-INFLAMMATORIES (NSAIDS):</td>
<td>Aspirin Ibuprofen Naproxen Ketoprofen Nabumetone</td>
<td>Take with food or milk to decrease stomach irritation.</td>
<td>Increases risk for liver damage or stomach bleeding.</td>
<td>Do not take with other pain relievers.</td>
</tr>
<tr>
<td>CORTICOSTEROIDS</td>
<td>Methyl-Prednisolone prednisolone Cortisone Hydrocortisone acetate Prednisone</td>
<td>Take with food or milk to decrease stomach irritation.</td>
<td></td>
<td>Particularly with certain cholesterol-lowering medications such as cholestyramine; raises blood sugar.</td>
</tr>
<tr>
<td>NARCOTIC (PRESRIPTION) ANALGESICS</td>
<td>Codeine Morphine Oxycodone Meperidine Hydrocodone</td>
<td></td>
<td>Avoid because of sedative effects.</td>
<td>Increases sedative effects of other medications.</td>
</tr>
</tbody>
</table>

### CARDIOVASCULAR

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>DRUG NAME</th>
<th>FOOD</th>
<th>ALCOHOL</th>
<th>DRUG</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIURETICS</td>
<td>Furosemide Triamterene Hydrochlorothia-zide Bumetamide Metolazine Spironolactone</td>
<td>Can cause loss of potassium, calcium and magnesium, or potassium overload.</td>
<td></td>
<td>With cardiovascular and analgesic medications.</td>
</tr>
<tr>
<td>CATEGORY</td>
<td>DRUG NAME</td>
<td>FOOD</td>
<td>ALCOHOL</td>
<td>DRUG</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>----------------------------------</td>
<td>-------------------------------------------</td>
<td>----------------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>ANGIOTENSIN CONVERTING ENZYME(ACE) INHIBITORS</td>
<td>Captopril Enalapril Lisinopril Quinapril Moexipril Benazepril</td>
<td>Some should not be taken with meals; may dangerously increase potassium.</td>
<td>Increases drowsiness.</td>
<td>Do not take with potassium supplements or diuretics, with lithium, tetracycline and many other medications.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BETA BLOCKERS</td>
<td>Atenolol Metoprolol Propranolol Nadolol</td>
<td>Take with or without food.</td>
<td>With propranolol or Inderal, may dangerously lower blood pressure.</td>
<td>With many medications; may cause excessive drowsiness.</td>
</tr>
<tr>
<td>ANGIOTENSIN II RECEPTOR BLOCKERS</td>
<td>Candesartan Irbesartan Losartan Olmesartan Telmisartan Valsartan</td>
<td>Take with or without food; avoid potassium overload.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CALCIUM CHANNEL BLOCKERS (CCBs)</td>
<td>Amlodipine Felodipine Diltiazem Verapamil Nifedipine Isradipine</td>
<td>Do not take with grapefruit or grapefruit juice; take with or without food or milk.</td>
<td>Interferes with effectiveness and creates side effects.</td>
<td>Do not take with other blood pressure medications; with some antibiotics, pain relievers, stomach and antidepressant medications.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HMG-CoA REDUCTASE INHIBITORS (STATINS)</td>
<td>Atorvastatin Fluvastatin Locastatin Pravastatin Simvastatin</td>
<td>Do not take with grapefruit or grapefruit juice.</td>
<td>May increase risk for liver damage.</td>
<td></td>
</tr>
<tr>
<td>NITRATES</td>
<td>Isosorbide dinitrate Isosorbide mononitrate Nitroglycerin</td>
<td>Avoid — may dangerously lower blood pressure.</td>
<td></td>
<td>With Viagra can increase heart rate and prove fatal.</td>
</tr>
<tr>
<td>CATEGORY</td>
<td>DRUG NAME</td>
<td>FOOD</td>
<td>ALCOHOL</td>
<td>DRUG</td>
</tr>
<tr>
<td>------------------</td>
<td>------------</td>
<td>---------------------------------------</td>
<td>----------</td>
<td>-------------------------------------------</td>
</tr>
<tr>
<td>ANTI-COAGULANTS</td>
<td>Warfarin</td>
<td>Monitor consumption of vitamin K foods such as broccoli, spinach or kale to keep drug levels balanced; grapefruit juice and nutrient drinks block or decrease concentrations.</td>
<td>Avoid</td>
<td>Do not take with pain relievers or antibiotics, cholestyramine or amiodarone; many restrictions with other medications.</td>
</tr>
</tbody>
</table>

**DIABETES TYPE 2**

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>DRUG NAME</th>
<th>FOOD</th>
<th>ALCOHOL</th>
<th>DRUG</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIABETES (TYPE 2)</td>
<td>Glimepiride</td>
<td>Take with or without food; often taken at breakfast.</td>
<td>Avoid because of risk of hypoglycemia, or low blood sugar.</td>
<td>With many medications, including over-the-counter remedies with a high sugar (sucrose, glucose) content.</td>
</tr>
</tbody>
</table>

**ANTIBACTERIALS**

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>DRUG NAME</th>
<th>FOOD</th>
<th>ALCOHOL</th>
<th>DRUG</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEPHALOSPORINS</td>
<td>Cefaclor</td>
<td>Take on an empty stomach unless stomach upset ensues.</td>
<td>May lose effectiveness if taken with antacids or antibiotics.</td>
<td></td>
</tr>
</tbody>
</table>

| MACROLIDES       | Azithromycin| Take on an empty stomach unless stomach upset ensues. | Increases sun sensitivity; risk of irregular heartbeat if taken with Propulsid; interacts with anti-arrhythmics and other medications. | |

<p>| NITRO-IMIDAZOLE  | Metronidazole | Avoid for at least three days after prescription; may cause nausea, cramps, headache and flushing. | With warfarin. | |</p>
<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>DRUG NAME</th>
<th>FOOD</th>
<th>ALCOHOL</th>
<th>DRUG</th>
</tr>
</thead>
<tbody>
<tr>
<td>PENICILLIN</td>
<td>PenicillinV Amoxicillin Ampicillin</td>
<td>Take on an empty stomach unless stomach upset ensues.</td>
<td>With many medications.</td>
<td></td>
</tr>
<tr>
<td>QUINOLONES</td>
<td>Ciprofloxacin Levofloxacin Ofloxacin Gatifloxacin Moxifloxacin</td>
<td>Take on an empty stomach or an hour or two after eating. Do not take with calcium-rich foods such as milk or yogurt, iron pills or antacids.</td>
<td>Increases sun sensitivity; with cimetidine, also with blood thinners, pain relievers, diabetes and other medications.</td>
<td></td>
</tr>
<tr>
<td>SULFONAMIDES</td>
<td>Sulfamethoxazole plus trimethoprim</td>
<td>Take on an empty stomach unless stomach upset ensues.</td>
<td>Increases sun sensitivity; with warfarin, anticonvulsants, anti-arrhythmics and other medications.</td>
<td></td>
</tr>
<tr>
<td>TETRACYCLINES</td>
<td>Tetracycline Doxycycline Minocycline</td>
<td>Take on empty stomach unless stomach upset ensues; do not take with dairy products, antacids or iron supplements.</td>
<td>Increases sun sensitivity; with warfarin.</td>
<td></td>
</tr>
</tbody>
</table>

**MOOD DISORDERS**

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>DRUG NAME</th>
<th>FOOD</th>
<th>ALCOHOL</th>
<th>DRUG</th>
</tr>
</thead>
<tbody>
<tr>
<td>BENZODIAZEPINES</td>
<td>Lorazepam Alprazolam Diazepam</td>
<td>Caffeine reduces anti-anxiety effect of medication.</td>
<td>Increases drowsiness and risk of seizures.</td>
<td>With levodopa and oral contraceptives; antacids may reduce concentrations.</td>
</tr>
<tr>
<td>MONOAMINE OXIDASE (MAO) INHIBITORS</td>
<td>Phenelzine Tranlycypromine</td>
<td>Potentially fatal increases in blood pressure if food or alcohol containing tyramine is ingested, found in some cheeses, yogurt, sour cream, liver, cured meats, raisins, soy sauce, avocados, caffeine and more</td>
<td>Potentially fatal increases in blood pressure if food or alcohol containing tyramine is ingested.</td>
<td>With prescribed and over-the-counter medications.</td>
</tr>
<tr>
<td>CATEGORY</td>
<td>DRUG NAME</td>
<td>FOOD</td>
<td>ALCOHOL</td>
<td>DRUG</td>
</tr>
<tr>
<td>---------------------------------------</td>
<td>------------------------</td>
<td>-----------------------------------</td>
<td>----------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRIs)</td>
<td>Citalopram Paroxetine Sertraline Fluoxetine</td>
<td>Take with or without food.</td>
<td>Increases drowsiness and dizziness, feelings of depression.</td>
<td>Never take with Pimozide, Marplan, Nardil, Parnate or other mood disorder medications, which can be fatal; interacts with warfarin, antibiotics, asthma, stomach and other medications.</td>
</tr>
<tr>
<td>TRICYCLIC ANTI-DEPRESSANTS (TCAs)</td>
<td>Desipramine Protriptyline Nortriptyline Clomipramine Amitriptyline Imipramine</td>
<td>Take with or without food; do not take with grapefruit or grapefruit juice.</td>
<td>Avoid. Increases drowsiness.</td>
<td>Increases effects of warfarin; do not take with other antidepressants; can cause toxic concentrations with certain cardiovascular medications; with asthma and other medications.</td>
</tr>
<tr>
<td>STOMACH DISORDER</td>
<td>HISTAMINE BLOCKERS</td>
<td>Cimetidine Famotidine Ranitidine Nizatadine</td>
<td>Take with or without food; caffeine may irritate stomach.</td>
<td>Cimetidine can interact with asthma, blood-thinners, antifungals and seizure medications; do not take with other antacids.</td>
</tr>
<tr>
<td></td>
<td>PROTON PUMP INHIBITORS</td>
<td>Lansoprazole Pantoprazole Omeprazole Esomeprazole Rabeprazole</td>
<td>Take on an empty stomach; caffeine may irritate stomach.</td>
<td>May irritate stomach and make stomach healing more difficult.</td>
</tr>
</tbody>
</table>

1.0 INTRODUCTION

From a population perspective in ambulatory and outpatient settings, 9-70% of patients are exposed to drugs with a risk of drug interactions, 1-23% of these being of major relevance. It is estimated that drug interactions cause up to 2.8% of hospital admissions, and may be especially significant for the Long Term Care population. In theory, drug-drug interactions are preventable in most cases, also therapeutic alternatives usually exist and not all drugs within a drug class are susceptible to the same drug interactions (e.g., statins).

Drug interactions may be pharmacokinetic or pharmacodynamic. A pharmacokinetic interaction arises when one drug alters the absorption, distribution, metabolism, or elimination of another agent. A pharmacodynamic interaction arises when one agent changes the pharmacological response of another agent in an additive, synergistic, or antagonistic way.

Patients are frequently receiving complex drug regimens that can predispose them to significant DDIs. Knowledge of the different mechanisms is paramount to either preemptively identify a possible DDI or to address an interaction in a patient’s drug regimen. A multidisciplinary approach is ideal in developing a pharmaco-therapeutic regimen designed to optimize patient outcomes and minimize any potential DDIs.

2.0 SCOPE

Management of drug-drug interactions in MOH Health Care Settings

3.0 PURPOSE

To outline general guidelines for dealing with Drug-Drug Interaction (DDIs)

4.0 DEFINITION

Drug-Drug Interaction: A pharmacokinetic or pharmacodynamic influence of drugs on each other, which can result, beside desired effects, in reduced effectiveness or increased toxicity.

5.0 POLICY

5.1 The updated list of common Drug-Drug Interaction should be readily available and utilized as a quick source of information for identification before prescribing, dispensing and administering the medications.

5.2 One of the important initiatives in the Multidisciplinary Medication Management is the development and promotion of a list of Top Drug Interactions that are particularly problematic in long-term care settings. Each of these drug interactions involves medications that are commonly has the potential to cause significant harm if not managed appropriately. (Annex A).

5.3 Additional consideration is warranted when medications that have a narrow therapeutic index (i.e., cyclosporine, digoxin, and warfarin) are involved.
6.0 PROCEDURE

6.1 Drug-Drug Interaction (DDI) Identification:

- Not all DDIs are identified by every DDI detection tool. This necessitates that each clinician become familiar with common DDIs in his or her area of practice. Clinical judgment is required when evaluating any information identified on a particular DDI.

- A clinical pharmacist/ pharmacist can assist in the detection and interpretation of DDI data and the development of an alternative pharmacotherapeutic plan.

- Drug-drug interaction support checker integrated in Al Shifa-3 should be utilized as a ready reference while prescribing and dispensing.

- Several electronic databases such as Micromedex and Clinical Pharmacology are useful. Computer decision support systems and computerized physician order entry systems can be designed to alert the prescriber to potential DDIs.

- Several resources can help clinicians identify DDIs. Tertiary references such as Hansten and Horn’s Drug Interaction Analysis and Management, American Hospital Formulary Service, Physician’s Desk Reference, and Lexi-Comp’s Drug Information Handbook are useful for DDI identification.

6.2 Action Steps When a DDI Is Identified:

- It is important that the clinical significance of each identified DDI be assessed under the context of the patient involved.

- The significance, mechanism, and predicted onset should be determined.

- Whether to continue a drug, discontinue it, or substitute another drug is an important decision that needs to be made on a case-by-case basis. The decision is easy if a clear therapeutic alternative exists; however, this may not always be possible.

- A clear plan for monitoring and follow-up is essential to maintain therapeutic effectiveness and avoid toxicity (e.g., drug levels, laboratory values, and electrocardiogram). Good communication among all healthcare providers and the patient is essential.

7.0 RESPONSIBILITY

Pharmacists & Assistant Pharmacists in Healthcare Units:

- Review each medication order for DDIs, intervene, assist in drug selection or substitution, counseling, monitor and report any adverse drug events.

8.0 RELATED DOCUMENTS

Management of Adverse Drug Reactions (MOH-DGMS-PH-33)
## 9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Drug Interaction Pairs Associated with an Increased likelihood of Hospitalization, ISMP</td>
<td>Rojer Cheng, ISMP</td>
<td>2012</td>
<td>34</td>
</tr>
<tr>
<td>Common Drug Interactions Leading to Adverse Drug Events in the ICU (Chapter 27 Drug-Induced Complications in the Critically Ill Patient: A Guide for Recognition and Treatment)</td>
<td>John Papadopoulos &amp; Pamela L. Smithburger</td>
<td>2012</td>
<td>12</td>
</tr>
<tr>
<td>Top 10 Particularly Dangerous Drug Interactions in PA/LTC</td>
<td>The Society for Post-Acute and Long-Term Care Medicine</td>
<td>2018</td>
<td>5</td>
</tr>
</tbody>
</table>
## Annex-A

Top Ten Dangerous Drug Interactions in Long-Term Care

<table>
<thead>
<tr>
<th>SR</th>
<th>DRUGS</th>
<th>IMPACT</th>
<th>MECHANISM OF INTERACTION</th>
<th>PREVENTION:</th>
<th>MANAGEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Warfarin VS NSAIDs</td>
<td>Potential for serious gastrointestinal bleeding</td>
<td>NSAIDs increase gastric irritation and erosion of the protective lining of the stomach, assisting in the formation of a GI bleed. Additionally, NSAIDs decrease the cohesive properties of platelets necessary in clot formation.</td>
<td>Avoid concomitant use of an NSAID</td>
<td>Prothrombin time and INR should be monitored every week with co-administration of warfarin with an NSAID. Signs and symptoms of an active bleed should be monitored with particular attention to the appearance and patterns of bruises.</td>
</tr>
<tr>
<td>2</td>
<td>Warfarin Vs Sulfa Drugs</td>
<td>Increased effects of warfarin, with potential for bleeding</td>
<td>unknown; however, clinicians hypothesize that warfarin’s activity is prolonged due to a decreased production of vitamin K by intestinal flora affected by systemic antibiotic administration.</td>
<td>Avoid concomitant use of a sulfa drug with warfarin, particularly sulfamethoxazole-trimethoprim. If use of a sulfa drug is imperative, then reduce warfarin dose by 50% during antibiotic administration. If sulfamethoxazole-trimethoprim therapy is required, then monitor INR every other day for elevating trends.</td>
<td>Prothrombin time and INR should be monitored every week during co-administration of warfarin with a sulfa drug. Signs and symptoms of an active bleed should be monitored daily with particular attention to the appearance and patterns of bruises. Signs of an active bleed include: coughing up blood in the form of coffee grinds (hemoptysis), gum bleeding, nose bleeds, cola- or tea-colored urine (hematuria), and black, tarry stools (hemoccult positive).</td>
</tr>
<tr>
<td>3</td>
<td>Warfarin vs Macrolides</td>
<td>Increased effects of warfarin, with potential for bleeding</td>
<td>Erythromycin inhibits the metabolism and subsequent clearance of warfarin from the body. The activity of warfarin may also be prolonged due to alterations in the intestinal flora and its production of vitamin K for clotting factor production. The interaction between warfarin and macrolide antibiotics is highly probable and often delayed. Concomitant use of a macrolide with warfarin should be avoided; switch to an alternative antibiotic. Microbial pathogen identification prior to antibiotic initiation will decrease the prevalence of unnecessary drug interaction risk. Consider culture sensitivity screening as research indicates cautious use of any antibiotic with warfarin.</td>
<td>If use of a macrolide is imperative, then monitor INR every other day and adjust warfarin dosing as necessary. Signs and symptoms of an active bleed should be monitored daily with particular attention to the appearance and patterns of bruises. Signs of an active bleed include: coughing up blood in the form of coffee grinds (hemoptysis), gum bleeding, nose bleeds, cola- or tea-colored urine (hematuria), and black, tarry stools (hemoccult positive).</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Erythromycin inhibits the metabolism and subsequent clearance of warfarin from the body.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Warfarin vs Quinolones</td>
<td>Increased effects of warfarin, with potential for bleeding</td>
<td>The exact mechanism for the warfarin-quinolone drug interaction is unknown. Reduction of intestinal flora responsible for vitamin K production by antibiotics is probable as well as decreased metabolism and clearance of warfarin.</td>
<td>Prothrombin time and INR should be monitored during co-administration of warfarin with a quinolone. If use of ciprofloxacin is imperative, then monitor INR every other day and adjust warfarin dose as necessary. Signs and symptoms of an active bleed should be monitored daily with particular attention to the appearance and patterns of bruises. Signs of an active bleed include: coughing up blood in the form of coffee grinds (hemoptysis), gum bleeding, nose bleeds, cola- or tea-colored urine (hematuria), and black, tarry stools (hemoccult positive).</td>
<td>Culture and identify microbial pathogen prior to initiation of antibiotic therapy. Consider culture sensitivity screening. The metabolism of warfarin may be delayed in patients administered enoxacin, ciprofloxacin, norfloxacin, or ofloxacin; thus, quinolone selection should focus on one of the newer agents that has not demonstrated significant impairment of warfarin metabolism. Additionally, microbial pathogen identification and sensitivity prior to antibiotic initiation will decrease the prevalence of unnecessary drug interaction risk.</td>
</tr>
<tr>
<td>5</td>
<td>warfarin vs. phenytoin</td>
<td>Increased effects of warfarin and/or phenytoin</td>
<td>Currently unknown, but one theory suggests a genetic basis involving liver metabolism of warfarin and phenytoin.</td>
<td>Obtain baseline phenytoin levels prior to initiation of warfarin. Monitor INR during coadministration. Target INR should be towards the lower end of the therapeutic range.</td>
<td>Prothrombin time, INR, and phenytoin levels should be monitored during coadministration. Signs and symptoms of an active bleed should be monitored daily with particular attention to the appearance and patterns of bruises. Signs of an active bleed include: coughing up blood in the form of coffee grinds (hemoptysis), gum bleeding, nose bleeds, cola- or tea-colored urine (hematuria), and black, tarry stools (hemoccult positive).</td>
</tr>
<tr>
<td>6</td>
<td>ACE Inhibitors Vs Potassium Supplements</td>
<td>Elevated serum potassium</td>
<td>Inhibition of ACE results in decreased aldosterone production and potentially decreased potassium excretion.</td>
<td>Draw potassium level prior to initiation of ACE-inhibitor in a patient</td>
<td>Potassium levels greater than 5 should be monitored carefully due to risk of severe hyperkalemia and EKG changes. Watch renal function (BUN, SCR) also. Adjust potassium supplementation if levels increase.</td>
</tr>
<tr>
<td>7</td>
<td>ACE Inhibitors Spironolactone</td>
<td>Elevated serum potassium levels</td>
<td>Unknown, possibly an additive effect.</td>
<td>Draw potassium level prior to initiation of spironolactone in a patient</td>
<td>Potassium levels greater than 5 should be monitored carefully due to risk of severe hyperkalemia and EKG changes. Watch renal function (BUN, SCR) also. Avoid potassium supplements in patients taking this combination of medications, unless the need is documented and the patient is monitored closely for hyperkalemia.</td>
</tr>
<tr>
<td>8</td>
<td>Digoxin vs Amiodarone</td>
<td>Digoxin toxicity</td>
<td>Multiple theories exist, but actual mechanism is unknown. Amiodarone may decrease the clearance of digoxin, resulting in prolonged digoxin activity. There may also be an additive effect on the sinus node of the heart.</td>
<td>Obtain digoxin level prior to initiation of amiodarone therapy. Then, decrease dose of digoxin by 50% and monitor digoxin levels once weekly for several weeks.</td>
<td>Maintain digoxin level between 1-2. Monitor for signs and symptoms of digoxin toxicity (abdominal pain, anorexia, bizarre mental symptoms in the elderly, blurred vision, bradycardia, confusion, delirium, depression, diarrhea, disorientation, drowsiness, fatigue, hallucinations, halos around lights, reduction in visual acuity, mydriasis, nausea, neuralgia, nightmares, personality changes, photophobia, restlessness, vertigo, vomiting, and weakness).</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>9</td>
<td>Digoxin Vs Verapamil</td>
<td>Digoxin toxicity</td>
<td>Synergistic effect of slowing impulse conduction and muscle contractility, leading to bradycardia and possible heart block.</td>
<td>Monitor heart rate and EKG–PR interval. Evaluate selection of verapamil and digoxin. If patient has CHF, note that verapamil has no proven benefit in reducing mortality or morbidity; furthermore, digoxin offers no additional benefit in mortality, but does improve symptomatology.</td>
<td>Monitor heart rate and EKG–PR interval. Monitor for signs and symptoms of digoxin toxicity (abdominal pain, anorexia, bizarre mental symptoms in the elderly, blurred vision, bradycardia, confusion, delirium, depression, diarrhea, disorientation, drowsiness, fatigue, hallucinations, halos around lights, reduction in visual acuity, mydriasis, nausea, neuralgia, nightmares, personality changes, photophobia, restlessness, vertigo, vomiting, and weakness). Back</td>
</tr>
<tr>
<td>10</td>
<td>Theophylline vs. Quinolones</td>
<td>Theophylline toxicity</td>
<td>Inhibition of hepatic metabolism of theophylline by the quinolones</td>
<td>Obtain theophylline level prior to initiation of a quinolone. Of the quinolones, enoxacin and ciprofloxacin reduce theophylline clearance by 30-84%. Consider switching to gatifloxacin, levofloxacin, moxifloxacin, or trovafloxacin; these agents appear not to inhibit theophylline metabolism.</td>
<td>Monitor theophylline levels. Maintain level within targeted range of 5-15mcg/mL; however, theophylline toxicity may result even when the level is within the targeted range. Signs and symptoms of theophylline toxicity include seizures, nausea, and vomiting.</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

Adverse Drug Reactions (ADRs) are a leading cause of morbidity and mortality, accounting for up to 30% of hospital admissions in the United States, and costing approximately $170 billion annually. Elderly patients are at highest risk of experiencing ADRs, many of which are preventable. The most commonly-implicated medications include antibiotics, anticoagulants, digoxin, diuretics, hypoglycemics, antineoplastics, and nonsteroidal anti-inflammatory drugs.

Successful management of adverse drug reactions requires early identification and prompt treatment of anaphylaxis, whether due to immunoglobulin Ig E- or non-IgE-mediated mechanisms of mast cell mediator release. Acute therapy is directed toward enhancement of oxygenation and maintenance of normotension. Requisite measures include the use of epinephrine, oxygen, and adequate fluid replacement; in some instances, vaspressors or corticosteroid drug therapy may be warranted.

Good management also requires anticipation of adverse reactions whenever a therapeutic program is instituted. Familiarity with the drug groups most commonly responsible for immunologic reactions is helpful, as is knowledge of satisfactory alternatives for these drugs in the presence of known hypersensitivity.

2.0 SCOPE

Management of identified adverse drug reactions.

3.0 PURPOSE

To establish a mechanism to ensure that adverse drug reactions are systematically identified, reported, monitored, evaluated, and documented in order to prevent future recurrences.

4.0 DEFINITION

4.1 Adverse Drug Reaction (ADR) : Is defined as :

- A response to a drug that is noxious and unintended and occurs at doses normally used for the prophylaxis, diagnosis, or therapy of disease or for modification of physiological function (WHO definition)
- Any unexpected, unintended, undesired, or excessive response to a drug that requires discontinuing the drug (therapeutic or diagnostic), requires changing the drug therapy, requires modifying the dose (except for minor dosage adjustments), necessitates admission to a hospital, prolongs stay in a health care facility, necessitates supportive treatment, significantly complicates diagnosis, negatively affects prognosis, or results in temporary or permanent harm, disability, or death (ASHP definition)

4.2 Dose-related ADRs: Are particularly a concern when drugs have a narrow therapeutic index (e.g., hemorrhage with oral anticoagulants). ADRs may result from decreased drug clearance in patients with impaired renal or hepatic function or from drug-drug interactions.
4.3 Allergic ADRs: are not dose-related and require prior exposure. Allergies develop when a drug acts as an antigen or allergen. After a patient is sensitized, subsequent exposure to the drug produces one of several different types of allergic reaction. Clinical history and appropriate skin tests can sometimes help predict allergic ADRs.

4.4 Idiosyncratic ADRs: are unexpected ADRs that are not dose-related or allergic. They occur in a small percentage of patients given a drug. Idiosyncrasy is an imprecise term that has been defined as a genetically determined abnormal response to a drug, but not all idiosyncratic reactions have a pharmacogenetics cause.

5.0 POLICY

5.1 All healthcare professionals providing patient care, has the responsibility of detecting, monitoring, reporting, documenting and resolving Adverse Drug Reactions that occur within the facility in a consistent and timely manner.

5.2 All suspected ADRs that are serious or result in harm must be reported. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalization, and those that are considered medically significant for any other reason and all suspected ADRs associated with new drugs and vaccines.

6.0 PROCEDURE

6.1 The suspected adverse drug reaction must be reported, managed and documented in medical records by physician / pharmacy staff. The ADRs incidences should be filled in the specified format (Annex A) and submitted to the Pharmacy department (The form is also available electronically in MOH website at https://www.moh.gov.om/en/-22)

6.2 Pharmacy department should review and analysis the report and forward the same to DGPA&DC with copy to Pharmaceutical Care Department, DGMS.

6.3 A significant Adverse Drug Reaction to be given more attention is one that:
   • Requires discontinuing the drug.
   • Requires large, (greater than 50%) dosage decrease.
   • Necessitates admission to an acute care hospital.
   • Delays anticipated discharge from the hospital.
   • Necessitates supportive treatment.
   • Significantly complicates diagnosis.
   • Negatively affects prognosis.
   • Results in temporary or permanent harm, disability, or death.

6.4 The following are some tips of the guidelines provided by (ASHP) emphasizing the role of pharmacists in comprehensive ADR management in coordination with other healthcare professionals:
   • Risk Minimization:
     ✓ Understand patient views about medication therapy.
     ✓ Educate about the benefits of treatment.
     ✓ Inform patients about potential ADRs and management strategies should any occur.
- Ensure an updated and accurate medication list.
- Utilize decision support software, if available to help prevent ADRs.
- Start with low doses and frequencies and slowly titrate as tolerated.
- Initiate less-potent agents, agents with direct mechanisms of action, or alternatives with lower adverse event incidence.
- Avoid or reduce the use of interacting medications.
- Dosage forms with minimal systemic exposure are preferable (e.g. creams, patches).

**Recognition, Detection:**
- Be familiar with known ADRs of the medication as well as the patient’s pre-existing symptoms.
- Evaluate new symptoms as possible ADRs, looking into health conditions, labs, or other factors which may explain the symptoms.
- Consider the temporal relationship between medication initiation and symptom onset.
- Challenge concepts like stopping the medication to see if the symptom subsides in absence of the medication, and restarting to see if symptoms return.
- Utilize lab tests for more evidence to identify an ADR.
- Apply probability tools such as the Naranjo Adverse Drug Reaction Probability Scale (see point 8.6) or 4Ts for heparin induced thrombocytopenia.
- Express empathy and maintain a trusting relationship with the patient.
- Reduce dosing or discontinue the offending medication.
- Switch to another agent or dosage form less likely to cause ADRs.
- Treat side effects when necessary (beware of prescribing cascades).
- Document the ADR in the patient’s medical record.
- If working from a care setting separate from pharmacy, notify the patient’s pharmacy to document the ADR in the pharmacy records.
- Report ADRs through appropriate channels as per Adverse Event Reporting System.
- Track and trend ADRs for ongoing process improvement.

6.5 Adverse drug reactions are usually classified as mild, moderate, severe, or lethal as shown in the table below:

<table>
<thead>
<tr>
<th>Severity</th>
<th>Description</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>No antidote or treatment is required; hospitalization is not prolonged.</td>
<td>Antihistamines (some): Drowsiness Opioids: Constipation</td>
</tr>
<tr>
<td>Moderate</td>
<td>A change in treatment (eg, modified dosage, addition of a drug), but not necessarily discontinuation of the drug, is required; hospitalization may be prolonged, or specific treatment may be required.</td>
<td>Hormonal contraceptives: Venous thrombosis NSAIDs: Hypertension and edema</td>
</tr>
</tbody>
</table>
An ADR is potentially life threatening and requires discontinuation of the drug and specific treatment of the ADR. ACE inhibitors: Angioedema
Phenothiazines: Abnormal heart rhythm

An ADR directly or indirectly contributes to a patient’s death. Acetaminophen overdose: Liver failure
Anticoagulants

---

### 6.6 Type of Reactions

<table>
<thead>
<tr>
<th>Type of Reaction</th>
<th>Features</th>
<th>Examples</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A: Dose related (Augmented)</strong></td>
<td>Common Related to the pharmacologic action of the drug – exaggerated pharmacologic response</td>
<td>Dry mouth with tricyclic antidepressants, respiratory depression with opioids, bleeding with warfarin, serotonin syndrome with SSRIs, digoxin toxicity</td>
<td>Reduce dose or withhold drug. Consider effects of concomitant therapy</td>
</tr>
<tr>
<td><strong>B: Non–dose related (Abnormal)</strong></td>
<td>Uncommon Not related to the pharmacologic action of the drug</td>
<td>Immunologic reactions: anaphylaxis to penicillin</td>
<td>Withhold and avoid in future</td>
</tr>
<tr>
<td><strong>C: Dose related and time related (Chronic)</strong></td>
<td>Uncommon Related to the cumulative dose</td>
<td>Hypothalamic-pituitary-adrenal axis suppression by corticosteroids, osteonecrosis of the jaw with bisphosphonates</td>
<td>Reduce dose or withhold; withdrawal may have to be prolonged</td>
</tr>
<tr>
<td><strong>D: Time related (Delayed)</strong></td>
<td>Uncommon Usually dose related Occurs or becomes apparent sometime after use of the drug</td>
<td>Carcinogenesis Tardive dyskinesia Teratogenesis Leucopenia with lomustine</td>
<td>Often intractable</td>
</tr>
<tr>
<td><strong>E: Withdrawal (End of use)</strong></td>
<td>Uncommon Occurs soon after withdrawal of the drug</td>
<td>Withdrawal syndrome with opiates or benzodiazepines (e.g., insomnia, anxiety)</td>
<td>Reintroduce drug and withdraw slowly</td>
</tr>
<tr>
<td><strong>F: Unexpected failure of therapy (Failure)</strong></td>
<td>Common Dose related Often caused by drug interactions</td>
<td>Inadequate dosage of an oral contraceptive when used with an enzyme inducer. Resistance to antimicrobial agents</td>
<td>Increase dosage. Consider effects of concomitant therapy</td>
</tr>
</tbody>
</table>
6.7 Naranjo algorithm for assessing the causality of an ADR:

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Do not know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are there previous conclusive reports on this reaction?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Did the adverse event appear after the suspected drug was administered?</td>
<td>+2</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td>Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Did the adverse reaction reappear when the drug was re-administered?</td>
<td>+2</td>
<td>-1</td>
<td>0</td>
</tr>
<tr>
<td>Are there alternative causes (other than the drug) that could solely have caused the reaction?</td>
<td>-1</td>
<td>+2</td>
<td>0</td>
</tr>
<tr>
<td>Was the drug detected in the blood (or other fluids) in a concentration known to be toxic?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Did the patient have a similar reaction to the same or similar drugs in any previous exposure?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Was the adverse event confirmed by objective evidence?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total score</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total score categories are defined as follows: ADR is: certain > 9; probable 5-8; possible 1-4; unlikely 0.

7.0 RESPONSIBILITY

Pharmacists & Assistant Pharmacists in Healthcare Units:
- Detect, monitor, analyze and process the ADR forms and to refer the suspected serious ADR's reported by the healthcare professionals in the health units to the Pharmacovigilance Dept. in DGPA&DC with copy to Pharmaceutical Care Dept, in DGMS, for the items purchased by MOH.

8.0 RELATED DOCUMENTS

Handling Patient Drug Allergy (MOH-DGMS-PH-30)
High Alert Medications (MOH-DGMS-PH-35)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/journal/articles/Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASHP guidelines on ADR monitoring and reporting</td>
<td>ASHP</td>
<td>1995</td>
<td>3</td>
</tr>
<tr>
<td>Adverse Drug Reactions – PSAP CNS/Pharmacy Practice</td>
<td>Stephanie N Schatz &amp; Rober J Weber</td>
<td>2015</td>
<td>22</td>
</tr>
<tr>
<td>Tips for Managing Adverse Drug Reactions, Pharmacy Times, USA</td>
<td>Jennifer Kim &amp; Amanda D'Ostroph</td>
<td>2017</td>
<td>2</td>
</tr>
</tbody>
</table>
MOH PHARMAcEUTICAL care POLICIES & PROCEDURES

SULTANATE OF OMAN
MINISTRY OF HEALTH

Directorate General of Pharmaceutical Affairs & Drug Control
Pharmacovigilance & Drug Information Department

CONFIDENTIAL

Suspected Adverse Drug Reactions (ADRs) & Drug Related Problems Reporting Form
Drugs/ Herbal Medicines/ Health Products/ Biological Products

<table>
<thead>
<tr>
<th>1. Patient Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient initial(s):</td>
</tr>
<tr>
<td>Weight (Kg):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Suspected Medicine/ Herbal/ Health Product/ Biological</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Name</td>
</tr>
<tr>
<td>Trade</td>
</tr>
<tr>
<td>Suspected</td>
</tr>
<tr>
<td>Concomitant</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Suspected Reactions(s)/ Quality Problem(s)/ Medication Error(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of reaction(s)/ Quality Problem(s)/ Medication Error(s):</td>
</tr>
<tr>
<td>Date of Onset: / / 20</td>
</tr>
<tr>
<td>Date Stopped: / / 20</td>
</tr>
<tr>
<td>Outcome of Reaction:</td>
</tr>
<tr>
<td>Recovered □ Recovering □ No improvement □ Fatal □ Unknown □</td>
</tr>
<tr>
<td>Seriousness of Reaction:</td>
</tr>
<tr>
<td>Patient died □ Life-threatening □ Permanent Disability □</td>
</tr>
<tr>
<td>Hospitalization □ Congenital Abnormality □</td>
</tr>
<tr>
<td>Other □ .................................................................</td>
</tr>
<tr>
<td>Additional Notes (Medical history, test results, allergies, dechallenge, rechallenge, pregnancy etc. Attach papers if necessary)</td>
</tr>
</tbody>
</table>
4. Reporter Details

<table>
<thead>
<tr>
<th>Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Profession: □ Physician □ Pharmacist □ Nurse □ Dentist □ Other HCP</td>
</tr>
<tr>
<td>Address: Institution:</td>
</tr>
<tr>
<td>Governorate:</td>
</tr>
<tr>
<td>Wilayat:</td>
</tr>
<tr>
<td>Tel No:</td>
</tr>
<tr>
<td>Email:</td>
</tr>
<tr>
<td>Signature:</td>
</tr>
<tr>
<td>Date:</td>
</tr>
</tbody>
</table>

Kindly submit the report to:
Department of Pharmacovigilance & Drug Information,
Directorate General of Pharmaceutical Affairs & Drug Control, Ministry of Health
P.O. BOX: 393, Muscat, PC: 100, Sultanate of Oman.
Phone: 22357688 /22357687/ 22357686 Fax: 22358489
Email: mohphar@omantel.net.om
1.0 INTRODUCTION

Medication errors compromise patient confidence in the health-care system and increase health-care costs. The problems and sources of medication errors are multidisciplinary and multifactorial. Errors occur from lack of knowledge, substandard performance and mental lapses, or defects or failures in systems. Medication errors may be committed by both experienced and inexperienced staff, including pharmacists, physicians, nurses, supportive person.

2.0 SCOPE

All identified medication errors.

3.0 PURPOSE

3.1 To outline the role of pharmacists/asst. pharmacists in identifying and handling medication errors and initiating appropriate corrective and preventive measures.

3.2 To describe the mechanism for multi-disciplinary review to allow appropriate implementation and follow-up of changes to prevent future medication errors.

4.0 DEFINITION

4.1 Medication Error: Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient. Such events may be related to professional practice, healthcare products, procedures and systems, including: prescribing, order communication, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.

4.2 Near Miss: Any process variation that did not affect an outcome but for which a recurrence carries a significant chance of a serious adverse outcome.

4.3 Significant Medication Error: Any medication error that if not prevented may cause significant harm to the patient (i.e. permanent harm or death).

4.4 Sentinel Event: Any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not related to the natural course of the patient’s illness.

5.0 POLICY

5.1 The Pharmacy Department has an effective and consistent policy on how to handle medication errors, give appropriate instructions and precautions on how to identify, report, intervene and analyze medication errors, and have a system in place for monitoring and preventing future incidences.

5.2 The Medication Safety Officer / Pharmacy Quality Management Coordinator will monitor the finding of medication errors particularly those related to dispensing errors on regular basis.
5.3 Confidentiality of medication error report will be maintained at all times. However, for officially approved designated studies and statistical reports, the same may be provided.

5.4 The following actions are recommended upon error detection:

- Any necessary corrective and supportive therapy should be provided to the patient.
- The error should be documented and reported immediately after discovery, in accordance with written procedures. For clinically significant errors, an immediate oral notice should be provided to the concerned physicians, nurses, and pharmacists. A written medication error report should follow promptly.
- For clinically significant errors, fact gathering and investigation should be initiated immediately, determined.
- Reports of clinically significant errors and the associated corrective activities should be reviewed by the supervisor and department head of the area(s) involved.
- When appropriate, the supervisor and the staff members who were involved in the error should confer on how the error occurred and how its recurrence can be prevented. Medication errors often result from problems in systems rather than exclusively from staff performance or environmental factors; thus, error reports should not be used for punitive purposes but to achieve correction or change.
- Information gained from medication error reports and other means that demonstrates continued failure of individual professionals to avoid preventable medication errors should serve as an effective management and educational tool in staff development.
- Department managers and D&TC should periodically review error reports and determine causes of errors and develop actions to prevent their recurrence.
- Medication errors should be reported to the national monitoring program (i.e., Pharmacovigilance committee/Medication Safety Advisory committee) so that the shared experiences of pharmacists, nurses, physicians, and patients can contribute to improved patient safety.

6.0 PROCEDURE

6.1 Medication errors are identified and reported immediately (within the same shift in which the incident occurred or was discovered) by health care providers via Medication Error Reporting Form (Annex-A).

6.2 All medication errors will be forwarded to the head of the department (Medical, Nursing, Pharmacy) for appropriate management and corrective actions in a timely manner.

6.3 The below-mentioned guidelines are recommended by ASHP for pharmacists for preventing medication errors in hospitals:

- Pharmacists should participate in drug therapy monitoring when indicated for the assessment of therapeutic appropriateness, possible duplicate therapies; possible interactions.
- Pharmacists should stay abreast of the current state of knowledge through familiarity with literature, consultation with colleagues and other health-care providers, participation in continuing professional education programs, and other means.
• Pharmacists should make themselves available to prescribers and nurses to offer
  information and advice about therapeutic drug regimens and the correct use of
  medications.

• Pharmacists should be familiar with the medication ordering system and drug
  distribution policies and procedures established.

• Pharmacists should never assume or guess the intent of confusing medication
  orders. If there are any questions, the prescriber should be contacted prior to
  dispensing.

• When preparing drugs, pharmacists should maintain orderliness and cleanliness in
  the work area and perform one procedure at a time with as few interruptions as
  possible.

• Before dispensing a medication in nonemergency situations, the pharmacist
  should review the printed medication order. For high risk drug products, all work
  should be checked by a second pharmacist.

• Pharmacists should dispense medications in ready- to-administer dosage forms
  whenever possible. The unit dose system is strongly recommended as the
  preferred method of drug distribution.

• Pharmacists should review the use of auxiliary labels and use the labels prudently
  when it is clear that such use may prevent errors.

• Pharmacists should ensure that medications are delivered to the patient-care area
  in a timely fashion after receipt of orders.

• Pharmacists should observe how medications are actually being used in patient-
  care areas to ensure that dispensing and storage procedures are followed.

• Pharmacy staff should review medications that are returned to the department.
  Such review processes may reveal system breakdowns or problems that resulted
  in medication errors (e.g., omitted doses and unauthorized drugs).

• When dispensing medications to ambulatory patients (e.g., at discharge),
  pharmacists should counsel patients or caregivers and verify that they understand
  why a medication was prescribed and dispensed, its intended use, any special
  precautions that might be observed, and other needed information. For inpatients,
  pharmacists should make their services available to counsel patients, families, or
  other caregivers when appropriate.

6.4 Medication mishaps can occur anywhere in the distribution system:

• Prescribing,

• Repackaging,

• Dispensing,

• Administering, or

• Monitoring.

6.5 Common causes of such medication errors include:

• Poor communication,
6.6 Factors that may influence medication errors include:

6.6.1 Factors associated with health care professionals.
- Lack of therapeutic training.
- Inadequate drug knowledge and experience.
- Inadequate knowledge of the patient.
- Inadequate perception of risk.
- Overworked or fatigued health care professionals.
- Physical and emotional health issues.
- Poor communication between health care professional and with patients.

6.6.2 Factors associated with patients:
- Patient characteristics (e.g., personality, literacy and language barriers).
- Complexity of clinical case, including multiple health conditions, polypharmacy and high-risk medications.

6.6.3 Factors associated with the work environment:
- Workload and time pressures.
- Distractions and interruptions (by both primary care staff and patients).
- Lack of standardized protocols and procedures.
- Insufficient resources.
- Issues with the physical work environment (e.g., lighting, temperature and ventilation).

6.6.4 Factors associated with medicines:
- Naming of medicines.
- Labeling and packaging.

6.6.5 Factors associated with tasks:
- Repetitive systems for ordering, processing and authorization.
- Patient monitoring (dependent on practice, patient, other health care settings, prescriber).
6.6.6 Factors associated with computerized information systems:

- Difficult processes for generating first prescriptions (e.g. drug pick lists, default dose regimens and missed alerts).
- Difficult processes for generating correct repeat prescriptions.
- Lack of accuracy of patient records.
- Inadequate design that allows for human error.

6.6.7 Primary, secondary and tertiary care interface:

- Limited quality of communication with secondary and tertiary care.
- Little justification of secondary and tertiary care recommendations.

7.0 RESPONSIBILITY

Pharmacists and Assistant Pharmacists in Healthcare Units:

- Review the medication order carefully and manage report and document any identified medication errors including dispensing errors.
- Counsel the patients satisfactorily to avoid occurrence of factors related to patients.

8.0 RELATED DOCUMENTS

8.1 Medication Reconciliation Policy (MOH-DGMS-PH-17)
8.2 Medication Order Review (MOH-DGMS-PH-18)
8.3 Look Alike/ Sound Alike Policy (MOH-DGMS-PH-30)
8.4 High Alert Medication policy (MOH-DGMS-PH-35)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Society of Health System Pharmacists (ASHP) guidelines on the prevention of medication errors.</td>
<td>ASHP</td>
<td>1993</td>
<td>9</td>
</tr>
<tr>
<td>Good practice guide on risk minimization and prevention of medication errors</td>
<td>Pharmacovigilance Risk Assessment Committee (PRAC) EMA</td>
<td>2015</td>
<td>41</td>
</tr>
<tr>
<td>Medication Error, WHO Manual</td>
<td>WHO</td>
<td>2016</td>
<td>32</td>
</tr>
<tr>
<td>Medication Error Reports FDA,USA</td>
<td>FDA USA</td>
<td>2017</td>
<td>2</td>
</tr>
</tbody>
</table>
### Annex-A

<table>
<thead>
<tr>
<th>Medication Error Report</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Hospital ID/ Sticker:</strong> ..................................</td>
</tr>
<tr>
<td><strong>1. Date of Incident:</strong> ..............................................</td>
</tr>
<tr>
<td><strong>2. Location of Incident:</strong></td>
</tr>
<tr>
<td><strong>Clinic</strong></td>
</tr>
<tr>
<td><strong>3. In which process did the error occur?</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>4. Has the error reach the patient? (taken by the patient)</strong></td>
</tr>
<tr>
<td><strong>5. Error, Harm:</strong></td>
</tr>
<tr>
<td><strong>6. Indicate the possible error cause(s) and contributing factor(s)</strong></td>
</tr>
<tr>
<td><strong>Staff Factors</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Work &amp; Environment...</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Others, please specify</strong></td>
</tr>
<tr>
<td><strong>7. Please describe the error (include discrepancies/sequence of event/work environment)</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>8. What correction measures has been taken</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>9. Recommendations</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Reporter name:</strong></td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION
Medication errors are significant and often preventable healthcare problems. Although many medication errors may not cause grave harm to patients, some medications are known to carry a higher risk of harm than other medications; and errors in the administration of these medications can have catastrophic clinical outcomes. The Joint Commission On Accreditation of Healthcare Organizations (JCAHO) requires, per Medication Management Standard 7.10 health care organizations to identify certain high-risk “High Alert Medications” used within the facility and further to develop specific processes for enhancing patient safety regarding their utilization.

Some medications have a very narrow margin of safety and can cause severe patient harm when implicated in an adverse drug event and hence require heightened vigilance. The consequences of an error associated with use of these medications can result in significant patient injury and special precautions must be employed with their overall management. These medications are identified as High Alert Medications.

The Institute for Safe Medication Practices (ISMP) has 19 categories and 14 specific medications in its list of High Alert Medications. The Institute recommends that High Alert Medications should be packed differently, stored differently, prescribed differently and administered differently than others. This means developing methods and using technology that makes it impossible for the drug to be given in a potentially lethal manner.

High Alert Medications include medications that are involve in a high percentage of errors and/or sentinel events, such as Insulin and Heparin etc. and medication whose names, packaging and labeling, or clinical use, look alike and/or sound alike, such as Amitriptyline and Aminophylline.

A safe medication system involves the collaboration of a wide variety of resources both directly and indirectly involved in patient care: from the processes to manufacturing and packaging, to prescribing and dispensing, and to infusion pumps and other technologies used in administering these High Alert Medications.

2.0 SCOPE
Safe handling of High Alert Medications.

3.0 PURPOSE
3.1 To establish guidelines to identify and standardize the handling and use of High-Alert Medications in patient-care areas, and to outline the steps necessary to increase awareness of these medications to prevent potential errors.

3.2 To provide and maintain an updated list of medications designated as high alert medications used in Ministry of Health units to ensure safe medication practices and eliminate medication errors that cause harm to patients.
4.0 DEFINITION

High Alert Medications: are medications that bear a heightened risk of causing significant patient harm when used in error. Though medication mishaps with high alert medications may or may not be more common than other drugs, the consequences following an error with these drugs can be especially serious to the patients.

5.0 POLICY

5.1 All health care providers involved in the procurement, storage, prescribing, dispensing and administration of High Alert Medications must be aware of the potential risks associated with them.

5.2 Use of high alert medications shall be in accordance with manufacturer’s instructions, MOH medication safety policies and procedures and treatment guidelines when applicable.

5.3 The pharmacy department will provide general guidelines for the proper handling of high Alert Medications including a defined list, in accordance with the FDA and ISMP Standards. (Annex A).

5.4 High-Alert medications must be properly labeled with RED warning sticker “High-Alert” to each designated drawer or cabinet where these medications are stored. Restrict supply of high risk medications to areas of specified use where possible

5.5 Concentrated electrolytes (Potassium & Sodium Phosphate, Potassium Chloride, and Sodium Chloride) are High-Alert Medications and should not be stocked in patient care areas except as part of the crash cart medications. However, some critical care areas (ICU, ED and OR) may stock limited quantities of these concentrated electrolytes in a separate, locked and properly labeled cabinet away from the regular ward stock medications and closely monitored by nursing and pharmacy staff.

5.6 Dextrose 50% may be stocked for dialysis patients to treat sudden hypoglycemia.

5.7 Ensure high risk medicines and risk awareness components for medication management are included in workforce orientation and ongoing education programs on medication safety.

5.8 Remove the need for rapid mathematical calculation and reduce options and choices by standardizing concentrations of medicines in solutions.

5.9 All incidents regarding high-risk medicines must be reported to ensure appropriate implementation of risk management or improvement strategies.

6.0 PROCEDURE

6.1 Managing high alert medications:

- High Alert Medications should have “High-Alert” medication labels on storage shelves and red stickers on the containers, product packages and loose vials or ampoules.

- High Alert Medications must be double checked before they are prepared, dispensed and administered to the patients. All High Alert Medications issued from the pharmacy must be counterchecked and verified by another pharmacy staff prior to dispensing for the purpose of medication safety and accuracy.
• Any changes of brand/color/preparation of High Alert Medications must be informed to the users as soon as possible.
• All equipment or devices used in the preparation and/or administration of medications shall be calibrated and maintained according to Standard Operating Procedure (SOP).
• All staff involved in the handling of High Alert Medications should be educated on management guideline.

6.2 Strategies to avoid errors involving High Alert Medications:

6.2.1 Procurement:
• Limit the drug strengths available in the formulary of each health care facility.
• Avoid frequent changes of brand or color. Notify the end users whenever there are changes.
• Inform all relevant personnel regarding new High Alert Medications listed in the MOH Formulary.
• Encourage the purchase of equipment and consumables with safety features for safe drug administration.

6.2.2 Storage:
• All personnel must read the High Alert Medication labels carefully before storing to ensure medications are kept at the correct place.
• All High Alert Medications should be kept in individual labeled containers. Whenever possible avoid look-alike and sound-alike drugs or different strengths of the same drug from being stored side by side.
• Use TALL-man lettering to emphasize differences in medication names (e.g. DOPamine and DOBUTamine).
• Limit ward’s floor stock drugs to standard requirement. Reduce the quantity and variation of strength/preparation stocked.
• Label all containers used for storing High Alert Medications as “High-Alert” medication.

6.2.3 Prescribing:
• Use standardized forms for written orders of cytotoxic drugs and parenteral nutrition.
• Do not use abbreviations when prescribing High Alert Medications.
• Specify the dose, route and rate of infusion for High Alert Medications prescribed. (e.g.: IV Dopamine 5mcg/kg over 1 minute)
• Prescribe oral liquid medications with the dose specified in milligrams.
• Do not use trailing zero when prescribing. (e.g. 5.0 mg can be mistaken as 50 mg)
• Use computerized prescriber order entry as far as possible, to eliminate illegible handwriting and misinterpretation of verbal orders. Safety features should be incorporated in the computer system for safe medication use.
6.2.4 Dispensing / Supply:
- High Alert Medications must be counter checked before dispensing.
- High Alert Medications shall be checked upon receiving by the healthcare providers.

6.2.5 Administration:
- The following particulars shall be independently double checked against the prescription or medication chart at the bedside by two appropriate persons before administration:
  - Patient’s name and hospital number.
  - Name and strength of medications.
  - Dose.
  - Route and rate (pump setting and line placements when necessary).
  - Expiry date.
- Label the distal ends of all access lines to distinguish IV from epidural lines.
- Ensure no distraction during administration of medications to patients by implementing special measures.
- Return all unused or remaining specially formulated preparations to the pharmacy when no longer required.
- Ensure administration of intrathecal, cytotoxic drugs, epidural analgesics and parenteral nutrition is done by trained personnel.
- Avoid ordering High Alert Medications verbally. In cases of emergency, phone orders have to be repeated and verified.

6.2.6 Monitoring:
- Closely monitor vital signs, laboratory data, patient’s response before and after administration of High Alert Medications.
- Keep antidotes and resuscitation equipment in wards/ units.

6.2.7 Training:
- All personnel shall be trained prior to handling of High Alert Medications and documentation kept. Staff must be trained to prevent potential errors and enable them to respond promptly when mistakes do occur.

6.2.8 Information:
- References or dilution guide should be made available in the wards and pharmacy.

6.2.9 Patient Education
- Educate patient and family members/caregivers on:
  - Name and purpose of medications.
✓ How much and when to take the medications.
✓ How to take their medications
✓ Common side effects

• Encourage patient and family involvement by:
  ✓ Asking what medications are being given and why they are being given
  ✓ Ensuring positive identification before receiving medications
  ✓ Storage of High Alert Medications.
  ✓ Disposal of expired/ unused High Alert Medications.

6.2.10 Evaluation of Action:
• Monitor adverse drug reactions and medication errors related to High Alert Medications.

7.0 RESPONSIBILITY

Pharmacy & Medical Stores Departments in Healthcare Units:
• Effectively implement strategies for safe handling of high alert medications during procurement, storage, labeling, dispensing, administering, monitoring and patient counseling.

8.0 RELATED DOCUMENTS

8.2 Management of Adverse Drug Reactions (MOH-DGMS-PH-33).
8.3 Medication Error Reporting Policy (MOH-DGMS-PH-34)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-Alert Medications and Patient Safety</td>
<td>Joint Commission</td>
<td>1999</td>
<td>3</td>
</tr>
<tr>
<td>Guideline On Safe Use Of High Alert Medications, MOH Malaysia</td>
<td>Pharmaceutical Services Division, MOH, Malaysia</td>
<td>2011</td>
<td>19</td>
</tr>
<tr>
<td>High Alert Medication Policy, Department of Health, WA–Australia</td>
<td></td>
<td>2014</td>
<td>44</td>
</tr>
<tr>
<td>Management of High Alert Medications, Albert Health Services</td>
<td>Alberta Health Services</td>
<td>2015</td>
<td>4</td>
</tr>
<tr>
<td>High-Alert Medications in Community/ Ambulatory Settings</td>
<td>Institute for Safe Medication Practices (ISMP)</td>
<td>2017</td>
<td>3</td>
</tr>
</tbody>
</table>
### Annex-A

**List of High-Alert Medications approved in the Ministry of Health**

<table>
<thead>
<tr>
<th>Classes/ Categories of Medications</th>
<th>Available formulations in the MOH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrenergic agonists, IV:</td>
<td></td>
</tr>
<tr>
<td>Adrenaline (IV and SC)</td>
<td>Adrenaline (1:1000) 1mg/ml  1ml (IM/SC) (IV following dilution)</td>
</tr>
<tr>
<td></td>
<td>Adrenaline 1:10,000 10ml. 1mg/10ml. preloaded syringe</td>
</tr>
<tr>
<td>Noradrenaline acid tartarate</td>
<td>Noradrenaline acid tartarate 2 mg/ml (equivalent to noradrenaline base 1 mg/ml), 2 - 4 ml ampoule</td>
</tr>
<tr>
<td>Phenylephrine</td>
<td>Phenylephrine 1% 1 ml</td>
</tr>
<tr>
<td>Isoproterenol hydrochloride</td>
<td>Isoproterenol hydrochloride injection 0.2 mg/ml</td>
</tr>
<tr>
<td>Adrenergic antagonists, IV:</td>
<td></td>
</tr>
<tr>
<td>Labetalol hydrochloride</td>
<td>Labetalol hydrochloride I/V 5mg/ml 20ml.</td>
</tr>
<tr>
<td>Metoprolol</td>
<td>Metoprolol 1mg/ml IV</td>
</tr>
<tr>
<td>Propranolol</td>
<td>Propranolol hydrochloride 1mg/ml 1ml.</td>
</tr>
<tr>
<td>Phentolamine mesilate</td>
<td>Phentolamine mesilate 10mg/ml, 1ml.</td>
</tr>
<tr>
<td>Antiarrhythmics, IV:</td>
<td></td>
</tr>
<tr>
<td>Verapamil hydrochloride</td>
<td>Verapamil hydrochloride 2.5 mg/ml 2ml.</td>
</tr>
<tr>
<td>Antiretroviral agents</td>
<td>All formulations</td>
</tr>
<tr>
<td>Antithrombotic agents: 1. Anticoagulants: Warfarin</td>
<td>Warfarin sodium 1mg tab</td>
</tr>
<tr>
<td>WARFARIN sodium 2mg tab</td>
<td>Warfarin sodium 5mg tab</td>
</tr>
<tr>
<td>Unfractionated heparin</td>
<td>Heparin 1000 IU/ml 5ml</td>
</tr>
<tr>
<td></td>
<td>Heparin 25000 IU/ml 5ml</td>
</tr>
<tr>
<td></td>
<td>Heparin 5000 IU/ml 5ml</td>
</tr>
<tr>
<td>LMW heparin</td>
<td>Heparin Low Molecular Weight (Enoxaparin, Dalteparin or Tinzaparin ) 20,000-30,000 I.U. Multidose</td>
</tr>
<tr>
<td></td>
<td>Heparin Low Molecular Weight (Enoxaparin, Dalteparin or Tinzaparin) 18,000 I.U</td>
</tr>
<tr>
<td></td>
<td>Heparin Low Molecular Weight (Enoxaparin or Dalteparin) 4,000 - 5,500 I.U</td>
</tr>
<tr>
<td></td>
<td>Heparin Low Molecular Weight, Enoxaparin 6,000 I.U</td>
</tr>
<tr>
<td></td>
<td>Heparin Low Molecular Weight, Enoxaparin 8,000 I.U or Dalteparin 10,000 I.U.</td>
</tr>
</tbody>
</table>

---

208
<table>
<thead>
<tr>
<th>Classes/ Categories of Medications</th>
<th>Available formulations in the MOH</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Factor Xa inhibitors: Fondaparinux</td>
<td>Fondaparinux sodium 5 mg/ml, 0.5 ml (2.5 mg) prefilled syringe</td>
</tr>
<tr>
<td>3. Direct thrombin inhibitors: Argatroban</td>
<td>Argatroban 100mg/ml, 2.5ml</td>
</tr>
<tr>
<td>Dabigatran etexilate</td>
<td>Dabigatran etexilate 110 mg</td>
</tr>
<tr>
<td>4. Thrombolytics: Alteplase</td>
<td>Alteplase 50mg</td>
</tr>
<tr>
<td>Reteplase</td>
<td>Reteplase 10 units 1.16 gm / ml powder for reconstitution pack of 2 vials with diluent</td>
</tr>
<tr>
<td>Cardioplegic solutions</td>
<td>All formulations</td>
</tr>
<tr>
<td>Chemotherapeutic agents, parenteral and oral</td>
<td>All formulations</td>
</tr>
<tr>
<td>Dextrose, hypertonic, 20% or greater</td>
<td>All formulations</td>
</tr>
<tr>
<td>Dialysis solutions (peritoneal, hemodialysis)</td>
<td>All formulations</td>
</tr>
<tr>
<td>Epidural or intrathecal medications</td>
<td>All formulations</td>
</tr>
<tr>
<td>Hypoglycemics, oral</td>
<td>All formulations</td>
</tr>
<tr>
<td>Immunosuppressant agents</td>
<td>All formulations</td>
</tr>
<tr>
<td>Inotropic medications, IV:</td>
<td>Digoxin 0.25 mg/ml 2ml, Digoxin 0.25mg tab, Digoxin 0.0625mg tab</td>
</tr>
<tr>
<td>Digoxin, oral and IV</td>
<td>Milrinone lactate 1 mg/ml, 10 ml</td>
</tr>
<tr>
<td>Milrinone</td>
<td>Dobutamine hydrochloride 250 mg per vial or amp</td>
</tr>
<tr>
<td>Dobutamine</td>
<td>Dopamine hydrochloride 40mg/ml 5ml.</td>
</tr>
<tr>
<td>Dopamine</td>
<td>Insulin, SC and IV</td>
</tr>
<tr>
<td>Insulin, SC and IV</td>
<td>All formulations</td>
</tr>
<tr>
<td>Liposomal forms of drugs</td>
<td>Amphotericin (50mg.) 50000 IU (liposome coated)</td>
</tr>
<tr>
<td></td>
<td>Amphotericin b 100 mg (lipid complex)</td>
</tr>
<tr>
<td></td>
<td>Amphotericin b (sod deoxycholate complex) 50 mg.</td>
</tr>
<tr>
<td></td>
<td>Amphotericin lozenges 10mg.</td>
</tr>
<tr>
<td>Moderate sedation agents, IV:</td>
<td>Midazolam 5mg/ml 3ml.</td>
</tr>
<tr>
<td>Midazolam</td>
<td>Moderate sedation agents, oral. For children: Chloral hydrate syrup</td>
</tr>
<tr>
<td>Moderate sedation agents, oral. For children:</td>
<td>Chloral hydrate 500 mg/5ml, 200 ml.</td>
</tr>
<tr>
<td>Chloral hydrate elixir 150 ml 143.3mg/5 ml</td>
<td></td>
</tr>
<tr>
<td>Classes/ Categories of Medications</td>
<td>Available formulations in the MOH</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Midazolam</td>
<td>Midazolam 2.5mg/ml.100ml</td>
</tr>
<tr>
<td>Narcotics/ opioids, oral, IV and transdermal</td>
<td>Narcotics/ opioids, oral, IV and transdermal</td>
</tr>
<tr>
<td>Neuromuscular blocking agents</td>
<td>Rocuronium 10 mg/ ml, 5 ml inj</td>
</tr>
<tr>
<td>Parenteral nutrition preparations</td>
<td>Parenteral nutrition preparations</td>
</tr>
<tr>
<td>Pregnancy category X drugs</td>
<td>All formulations</td>
</tr>
<tr>
<td>Radiocontrast agents, IV</td>
<td>Radiocontrast agents, IV</td>
</tr>
<tr>
<td>Sterile water for injection, inhalation and irrigation</td>
<td>Sterile water for injection, inhalation and irrigation</td>
</tr>
<tr>
<td>Sodium chloride for injection, hypertonic, greater than 0.9% concentration</td>
<td>All formulations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specific medications</th>
<th>Available formulations in the MOH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbamazepine</td>
<td>Carbamazepine CR 100 mg tab, Carbamazepine CR 200 mg tab, Carbamazepine CR 400 mg tab, Carbamazepine 100mg tab, Carbamazepine 200mg tab, Carbamazepine liquid 100 mg/ 5 ml. (2%) 100 ml.</td>
</tr>
<tr>
<td>Magnesium sulphate</td>
<td>Magnesium sulphate (50 %) 1 gm - 2 ml Magnesium sulphate (50 %) 5 gm - 10 ml Magnesium sulphate (50 %) 2.5 gm- 5 ml.</td>
</tr>
<tr>
<td>Metformin</td>
<td>Metformin Hcl. 500mg. tab</td>
</tr>
<tr>
<td>Methotrexate oral</td>
<td>Methotrexate 2.5mg tab, Methotrexate suspension</td>
</tr>
<tr>
<td>Oxytocin</td>
<td>Oxytocin synthetic 10 IU Oxytocin 5IU/ml Ergometrine maleate 500 mcg/ml, 1 ml.</td>
</tr>
<tr>
<td>Potassium phosphate injection</td>
<td>Potassium phosphate USP 5 -10 ml.</td>
</tr>
<tr>
<td>Potassium chloride for injection</td>
<td>Potassium chloride 15% 10ml</td>
</tr>
<tr>
<td>Promethazine IV</td>
<td>Promethazine hydrochloride 25mg/ml 1ml. Promethazine hydrochloride 50 mg, 1-2 ml.</td>
</tr>
<tr>
<td>Propylthiouracil</td>
<td>Propylthiouracil 50 mg tab</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

Confusing drug names is a common system failure that may lead to potentially harmful medications. Confusing drugs with similar names accounts for about 10 percent of all medication errors, according to the FDA. Job stress, unfamiliarity with drug names and confusing, unclear orders, among other thing, creates ample opportunity for confusion, throughout the medication process, from ordering to administration.

Common Risk Factors associated with Look-Alike / Sound-Alike Medications (LASA) include:

- Illegible handwriting.
- Incomplete knowledge of drug names.
- Newly available products.
- Similar packaging or labeling.
- Similar strengths, dosage forms or frequency of administration.
- Similar clinical use.

2.0 SCOPE

Handling Look Alike and Sound Alike (LASA) medications available in MOH Health Units.

3.0 PURPOSE

To prevent potentially harmful medication errors that may result from confusing look-alike, sound-alike medication names, and similar packaging.

4.0 DEFINITION

Look-Alike and Sound-Alike (LASA) Medications: Are medications which are visually similar in physical appearance, packaging or with generic or brand names that have spelling similarities and/or similar phonetics.

5.0 POLICY

5.1 Pharmacy & Medical Stores Departments in the Health Units shall keep an up-to-date list of LASA medications available in stock and to be posted in each designated patient care area for staff awareness.

5.2 LASA medications must be identified in the storage areas including Pharmacy, Nursing Units, and Crash Cart/Trolley and in any other areas where medication is stored and should be physically segregated from their LASA pair.

5.3 Medications identified as LASA must be affixed with LASA warning “Yellow Label” in storage location and medications storage bins.
5.4 Double checking should be carried out during prescribing, dispensing and administration processes.

5.5 Tallman lettering should be implemented for FDA Recommended Tall Man letter list of Look Alike Drug names (Annex-A) that approved in MOH with in labeling and supported by the Health Information System (HIS) as additional safe guards to avoid errors with LASA medications.

5.6 All staff are encouraged to report errors and potentially hazardous conditions with LASA medication names to DGMS through Drug Quality Reporting Program.

6.0 PROCEDURE

6.1 Procedures & Strategies: The below mentioned procedures and strategies should be considered to avoid errors with Look-Alike and Sound-Alike Medications which may occur during any of the following processes:

6.1.1 Procurement:
   a. Minimize the availability of multiple medicines strengths.
   b. Whenever possible, avoid purchase of medicines with similar packaging and appearance.
   c. As new products or packages are introduced, compare them with the existing packaging.

6.1.2 Storage:
   a. Use Tall Man lettering to emphasize differences in medications with sound-alike names. Tall Man lettering (or Tall man lettering) is the practice of writing part of a medicines name in upper case letters to help distinguish sound-alike/look-alike medications from one another to avoid medication errors. Examples of Tall Man lettering are DOBUTamine and DOPamine.
   b. Use additional warning labels for look-alike medicines. Warning labels should be uniform throughout the respective facility to facilitate identification (Yellow color labels).
   c. Place LASA medications in locations separate from each other or in non-alphabetical order.

6.1.3 Prescribing:
   a. Prescription should specify clearly the generic name of medication, dosage form, dose and complete direction for use.
   b. Write the diagnosis or medication’s indication for use. This information helps to differentiate possible choices in illegible orders.
   c. Whenever possible, drug names in computerized prescriber order entry (CPOE) should incorporate Tall Man lettering.
   d. Communicate clearly. Take your time in pronouncing the drug name whenever an oral order has to be made. Ask that the recipient of the oral communication repeat the medication name and dose. However such verbal and telephonic orders should be avoided, except in emergency situation.
6.1.4 Dispensing /Supply:
   a. Identify medicines based on its name and strength and not by its appearance
      or location.
   b. Check the purpose of the medication and the dose for the medicines dispensed.
   c. Read medication labels carefully at all dispensing stages and perform triangle
      check. Triangle check is to check actual medicines against the medicines’ labels
      and against the prescription.
   d. Double checking should be conducted during the dispensing and supply
      process.
   e. Highlight changes in medication appearances to patients upon dispensing.
   f. Ensure the availability of LASA warning sticker before dispensing.

6.1.5 Administration:
   a. Read carefully the label each time a medication is accessed, and/or prior to
      administration.
   b. Check the purpose of the medication and the dose prior to administration.
   c. Double checking should be conducted before administration.

6.1.6 Monitoring:
   a. Monitor new drugs added to the formulary as they are released and provide
      guidelines to these new drugs.
   b. A monthly inspection will be conducted by the pharmacy staff to assess
      compliance with the safe storage of LASA medications.
   c. Monitor patients who may have received wrong medications, as result of LASA
      medication error, if any.

6.1.7 Information:
   a. Update healthcare professionals of changes on the list of LASA and confusing
      drug names.
   b. Provide education on LASA medications to healthcare professionals at
      orientation and as part of continuing education.

6.1.8 Patient Education:
   a. Inform patients on changes in medication appearances.
   b. Educate patients and their caregivers to alert healthcare providers whenever a
      medication appears to vary from what is usually taken or administered.
   c. Encourage patients and their caregivers to learn the names of their medication.

7.0 RESPONSIBILITY

Directorate General of Medical Supplies:

- Avoid whenever possible, purchase of medicines of similar packaging and
  appearance.
• To incorporate Tall man lettering in DGMS and Al Shifa system in collaboration with DGIT.

Pharmacy & Medical Stores Depts. in Healthcare Units
• Store LASA in location separate with each other with identifiable labeling and to educate the patients in case of similarities.
• Review carefully the medication order to avoid the potential mix up and confusion while dispensing LASA medications.
• Update periodically healthcare professionals of changes on the list of LASA and confusing drug names.

8.0 RELATED DOCUMENTS
8.1 Dispensing Guidelines (MH-DGMS-PH-20)
8.2 High Alert/High Risk Medication Policy (MH-DGMS-PH-33)
8.3 Drug Quality Surveillance and Reporting Program (MH-DGMS-PH-42)
8.4 Medication Error Reporting (MH-DGMS-PH-34)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Look- Alike Sound- Alike Medications Names</td>
<td>The Joint Commission &amp; WHO</td>
<td>2007</td>
<td>4</td>
</tr>
<tr>
<td>Guide on handling Lookalike, Sound alike medications – Ministry of Health, Malaysia</td>
<td>Pharmaceutical Services Division, MOH, Malaysia</td>
<td>2012</td>
<td>24</td>
</tr>
<tr>
<td>Preventable Medication Errors – Lookalike/Sound-alike Drug Names</td>
<td>Atsushi Kawano, Certina Ho, ISMP Canada</td>
<td>2014</td>
<td>6</td>
</tr>
<tr>
<td>List of look-alike drug names with recommended Tall man letters</td>
<td>FDA &amp; ISMP</td>
<td>2016</td>
<td>6</td>
</tr>
</tbody>
</table>
**Annex-A**

FDA list of Look Alike Drug names approved in MOH with Recommended Tall Man letters

<table>
<thead>
<tr>
<th>Recommended Name</th>
<th>Recommended Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>clomiPHENE</td>
<td>clomiPHENE citrate 50mg (03/1219)</td>
</tr>
<tr>
<td>clomiPRAMINE</td>
<td>clomiPRAMINE hydrochloride 25mg (03/152)</td>
</tr>
<tr>
<td></td>
<td>clomiPRAMINE hydrochloride 10mg (03/147)</td>
</tr>
<tr>
<td>cycloSERINE</td>
<td>cycloSERINE 250mg (03/1575)</td>
</tr>
<tr>
<td>cicloSPORINE</td>
<td>cicloSPORINE 25mg (03/25140)</td>
</tr>
<tr>
<td></td>
<td>cicloSPORINE 50mg (03/25109)</td>
</tr>
<tr>
<td></td>
<td>cicloSPORINE 100mg (03/25114)</td>
</tr>
<tr>
<td></td>
<td>cicloSPORINE Oral solution 100mg/ml, 50ml (02/4010)</td>
</tr>
<tr>
<td></td>
<td>cicloSPORINE injection 50mg/ml 1ml IV (01/482)</td>
</tr>
<tr>
<td>cycloPHOSPHAmide</td>
<td>cycloPHOSPHAmide 100mg IV (01/1266)</td>
</tr>
<tr>
<td></td>
<td>cycloPHOSPHAmide 200mg (01/4288)</td>
</tr>
<tr>
<td></td>
<td>cycloPHOSPHAmide 500mg (01/503)</td>
</tr>
<tr>
<td></td>
<td>cycloPHOSPHAmide 50mg (03/2034)</td>
</tr>
<tr>
<td>DAUNOrubicin</td>
<td>DAUNOrubicin 20mg (01/681)</td>
</tr>
<tr>
<td>DOXOrubicin</td>
<td>DOXOrubicin hydrochloride 10mg (01/21)</td>
</tr>
<tr>
<td></td>
<td>DOXOrubicin hydrochloride 50mg (01/220)</td>
</tr>
<tr>
<td></td>
<td>DOXOrubicin hydrochloride 2mg/ml (Liposomal) (01/152)</td>
</tr>
<tr>
<td></td>
<td>DOXOrubicin hydrochloride 50mg “Liposomal” (01/90)</td>
</tr>
<tr>
<td>DOBUTamine</td>
<td>DOBUTamine hydrochloride 250 mg per vial or ampoule (01/959)</td>
</tr>
<tr>
<td>DOPamine</td>
<td>DOPamine hydrochloride 40mg/ml 5ml. (01/2385)</td>
</tr>
<tr>
<td>hydrALAZINE</td>
<td>hydrALAZINE 25mg (03/189)</td>
</tr>
<tr>
<td></td>
<td>hydrALAZINE 20 mg/ml or dihydralazine mesilate 25 mg/ml (01/147)</td>
</tr>
<tr>
<td>HydroXYzine</td>
<td>hydroXYzine hydrochloride 10mg (03/299)</td>
</tr>
<tr>
<td></td>
<td>hydroXYzine hydrochloride 25mg (03/283)</td>
</tr>
<tr>
<td></td>
<td>hydroXYzine HCL 10mg/5ml syrup 150 ml (02/20006)</td>
</tr>
<tr>
<td>medroxyPROGESTERone</td>
<td>medroxyPROGESTERone acetate 5mg (03/7995)</td>
</tr>
<tr>
<td></td>
<td>medroxyPROGESTERone acetate 10mg (03/6484)</td>
</tr>
<tr>
<td></td>
<td>medroxyPROGESTERone acetate 100mg (03/7993)</td>
</tr>
<tr>
<td>methylPREDNISolone</td>
<td>methylPREDNISolone125mg/vial (01/2909)</td>
</tr>
<tr>
<td></td>
<td>methylPREDNISolone acetate 40mg/ml (01/770)</td>
</tr>
<tr>
<td></td>
<td>methylPREDNISolone sodium succinate 500mg (01/4859)</td>
</tr>
<tr>
<td></td>
<td>methylPREDNISolone sodium succinate 1gm (01/4838)</td>
</tr>
<tr>
<td>vinBLAStine</td>
<td>vinBLAStine sulphate 10mg (01/5570)</td>
</tr>
<tr>
<td>vinCRIStine</td>
<td>vinCRIStine sulphate 1mg/ml, 1ml (01/3510)</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION
Hazardous Drugs (HDs) are drugs known or suspected to cause adverse health effects from exposures in the workplace. Hazardous drugs include those used for cancer chemotherapy, antiviral drugs, hormones, some bioengineered drugs and other miscellaneous drugs. The majority of HDs belong to the category of antineoplastic drugs.

Cytotoxic drugs inhibit or prevent the function of cells within the body, the most common forms of cytotoxic drugs are known as antineoplastic, and sometimes these terms are used interchangeably. Some of these drugs may be used to treat non-cancerous conditions such as rheumatoid arthritis and psoriasis.

The National Institute for Occupational Safety and Health (NIOSH) in the United States is taking the lead in classifying hazardous drugs. They indicate the drugs that should be handled as hazardous and as such standard precautions around hazardous drugs should be taken.

2.0 SCOPE
Handling of hazardous drugs including receipt, storage, transport, preparation, dispensing, clean-up (spills) and disposal.

3.0 PURPOSE
3.1 To establish processes and requirements to support the safe handling of hazardous medications.

3.2 Describe practices and quality standards for handling hazardous drugs in healthcare settings to minimize exposure to help promote patients and worker safety, and environmental protection.

4.0 DEFINITION
4.1 Hazardous Drugs: Are drugs that exhibit one or more of the following characteristics:
   • Carcinogenic (can cause cancer).
   • Teratogenic (can cause developmental damage to a fetus).
   • Reproductive toxic (decreases in fertility, or lead to fetal loss during pregnancy).
   • Organ toxic at low doses (e.g., liver damage, local necrosis of exposed tissue, etc.).
   • Genotoxic (causing deleterious action on a cell’s genetic material affecting its integrity).
   • Have characteristics and toxicity similar to an existing hazardous drug.
5.0 POLICY

5.1 All hazardous Drugs shall be classified, labeled, and listed in areas where they are stored or used. The attached list of Hazardous items approved by MOH (Annex-A) shall be reviewed periodically as per the recommendation of International Institutions.

5.2 Care to be taken on handling high risk tasks that may expose workers to hazardous drugs that may include, but are not limited to:

- Counting, crushing or breaking powdered tablets.
- Preparing, handling, administering, and disposing of solutions.
- Handling and disposing of drug administration equipment, contaminated waste, and patient body fluids, feces and urine.
- Cleaning up spills and/or contaminated excreted bodily fluids.

5.3 The pharmacy personnel who generate hazardous waste must ensure proper identification, collection, documentation, packaging and disposal of hazardous material, and be able to manage hazardous spills as outlined according to the Infection Control Policy and Procedures and Material Safety Data Sheets (MSDS).

5.4 No pharmacy staff who are attempting to conceive, pregnant, or breast feeding will be allowed to work in areas for handling hazardous medications. Discuss concerns about pregnancy, breast-feeding or planned pregnancy with your supervisor.

5.5 Report any exposure (direct and indirect contact / skin puncture) with hazardous medication to immediate supervisor.

5.6 The Pharmacy and Medical Stores Department shall provide and maintain Material Safety Data Sheets (MSDS) for all hazardous medications within the department.

6.0 PROCEDURE

6.1 Receiving Hazardous Drugs:
- Should have P&P for receiving HD.
- Should come from supplier sealed in plastic.
- Must be delivered to HD storage area immediately.
- Must wear appropriate PPE during receipt.
- Spill kit accessible in receiving area.

6.2 Storage of Hazardous Drugs:
- The Pharmacy staff working in areas where Hazardous Drugs are used or stored are aware of and know how to safe handling of these drugs.
- Hazardous drugs should be stored in an area with sufficient general exhaust ventilation to dilute and remove any airborne contaminants.
- Segregation of hazardous drug inventory from other drug inventory improves control and reduces the number of staff members potentially exposed to the danger.
- Hazardous drugs placed in inventory must be protected from potential breakage by storage in bins that have high fronts and on shelves that have guards to prevent accidental falling. The bins must also be appropriately sized to properly contain all stock.
- Care should be taken to separate hazardous drug inventory to reduce potential drug errors (e.g., pulling a look-alike vial from an adjacent drug bin). All staff members must wear double gloves when stocking and inventorying these drugs and selecting hazardous drug packages for further handling.

- HDs which can be stored with other drugs:
  - Non-antineoplastic.
  - Reproductive risk only.
  - Final dosage forms of antineoplastic HD

- HDs which stored separately in a negative pressure room:
  - Antineoplastic HDs requiring manipulation.

- Sterile and non-sterile HDs may be stored together: Exception: Only HDs used for sterile compounding may be stored in the negative pressure buffer room

- Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure room.

- Staff handling hazardous drugs or cleaning areas where hazardous drugs are stored or handled must be trained to recognize the unique identifying labels used to distinguish these drugs and areas.

6.3 Compounding of Hazardous Drugs:

- Must follow USP Chapters 795 and 797.
- Must be done in proper engineering controls.
- Sterile and non-sterile compounding must use plastic backed preparation mat on work surface.
- Must use disposable or clean dedicated equipment: Mortars, pestles, spatulas.
- Labeling cannot introduce contamination into non-HD area.

6.4 Labeling of Hazardous Drugs

- HD requiring special handling precautions must be clearly labeled at all times during their transport throughout the facility.
- Warning labels and signs must be clear to all personnel handling HDs.
- All personnel who work with or around hazardous drugs must be trained to appropriately perform their jobs using the established precautions and required PPE.
- Packaging labeling to contain “Cytotoxic handle with care”
- Tablet containers should be labeled “Do not cut or crush”

6.5 Packaging of Hazardous Drugs

- Containers and materials must maintain: Physical integrity, stability, sterility (if needed) and protect HD from damage, leakage, contamination and degradation.
- Protect healthcare workers who transport HD.
6.6 Dispensing Final Dosage Forms:
- HD requiring no manipulation other than counting final dosage form may be dispensed without any further requirements for containment, unless Manufacturer requires containment or visual indicators of HD exposure is present.
- Risk Assessment to be considered to all other types of HDs to be dispensed.

6.7 Transport:
- All transport of hazardous drug packages must be done in a manner to reduce environmental contamination in the event of accidental dropping. Hazardous drug packages must be placed in sealed containers and labeled with a unique identifier. Carts or other transport devices must be designed with guards to protect against falling and breakage.
- HDs must be transported in hard walled containers, securely closed and sealed to minimize breakage or leakage.
- HDs cannot be transported in a pneumatic tube.
- When shipping outside facility: Ensure labels and accessory labeling include storage instructions, disposal instructions and HD category information in format consistent with courier’s policies.
- All individuals transporting HDs must have safety training that includes spill control and have spill kits immediately accessible.

6.8 Cleaning the Compounding Area:
- Cleaning and Disinfecting the Compounding Area section in USP 797 applies to both sterile and non-sterile HD compounding areas.
- Decontamination must be done:
  - Between compounding different HDs.
  - Any time a spill occurs.
  - Before and after certification.
  - Any time voluntary interruption occurs.
  - If ventilation tool is moved.
- May decrease HD contamination introduced into Containment Primary Engineering Control (C-PEC) if wipe down HD containers:
  - Use alcohol, sterile water, peroxide, or sodium hypochlorite.
  - Spray the wiper not the HD container.
  - Solution used cannot alter the HD container label.
  - Areas under work tray of C-PEC must be cleaned monthly.
  - May need to wear an approved respirator.

6.9 Spill Control:
- Personnel must be trained in handling spills.
- Spills must be contained and cleaned immediately by qualified personnel with appropriate PPE.
- Qualified personnel must be available at all times.
- Signs restricting access to spill area must be available.
- Evacuate all personnel from the area and close all doors.
- Ensure adequate ventilation.
- Spill kits must be readily available in all areas HDs are handled.
- Dispose of spill kits as hazardous waste.
- Document circumstances and management of spills.

6.10 Disposal:
- Personnel removing hazardous waste must be trained.
- All sharps, including hypodermic needles and syringes, suture needles, knife blades, trocars from drains and opened glass ampoules of medicines shall be disposed of into puncture-resistant sharp containers.
- All other hazardous drugs not labeled or listed for disposal in should be placed in an appropriate bin per the entity’s guidelines for non-hazardous waste disposal.
- Contaminated gloves and other disposable PPE will be placed in a biohazard box.
- Gloves and other disposable PPE that are not contaminated may be placed in the trash.
- Needles and syringes must not be crushed, clipped, or capped, but will be placed directly in the needle box.

6.11 Personnel Training:
- Applies to all personnel based on job function: receipt, storage, compounding, repackaging, dispensing, administering, disposing.
- The staff that is exposed to handling hazardous materials should be trained on how to handle spills and the appropriate use of personnel protective clothing and equipment.
- Must occur before independently handles HDs.
- Must be demonstrated by each employee.
- Training to be reassessed:
  - Every 12 months
  - When new HD or new equipment is used.
  - With a new or significant change in process or P&P.
- Confirm in writing that personnel of reproductive capabilities understand the risks of HDs.

6.12 Personnel Safety:

The following exposure control program elements should be selected and implemented based on a risk assessment exposure control program elements:
• Engineering Control includes:
  - General and local ventilation systems (e.g., class II type B2 or III biological safety cabinets (BSC))
  - Compounding aseptic containment isolators.
  - Facility design and layout (e.g., airlocks, negative pressure rooms).
  - Safety engineered needles (SENs) and needleless systems.
  - Closed-system drug transfer devices (CSDTD).

• Administrative / Safe Work Practice Controls include:
  - Hazardous drug inventory, product safety sheets, and labeling system.
  - Management policies (e.g., purchasing controls, restricted areas, PPE and techniques for safely removing PPE, respiratory protection program, good hygiene practices including hand hygiene, isolation and securing of medications).
  - Scheduling and job rotation (e.g., limiting frequency and duration, protection for pregnant workers).
  - Information, instruction and training programs (e.g., health risk information and safe handling precautions that may include: the risks and hazards of exposure; appropriate equipment and engineering controls; hand hygiene; use of PPE; environmental cleaning; what to do in case of exposure).
  - Safe work practices (e.g., drug preparation, handling and administering techniques, cleaning and decontamination surfaces and equipment, use of plastic backed absorbent material to reduce dispersion and facilitate the clean-up of any spilled medication).
  - Spill control protocols (e.g. spills kits and use of emergency eyewash stations and showers).
  - Procedures for safe handling and disposal of cytotoxic waste.
  - Medical surveillance program.
  - Accident/incident reporting and investigation.
  - Post accidental exposure and follow up protocol.
  - Workplace inspections and compliance observations (e.g., assessment of techniques).
  - Occupational hygiene / environmental monitoring.
  - Regular maintenance of equipment and certification if applicable (e.g. Class II BSC requires certification annually).

• Personal Protective Equipment includes:
  - Disposable gowns made of a lint-free, low permeability fabric.
  - Face and eye protection (e.g., when splash, spray or aerosols are possible.)
- Approved respirator when there is a risk of inhaling drug aerosols (e.g., spill cleanup, and other emergency situations).
- Approved chemotherapy gloves, thicker gloves (.18 to .23 mm), or the use of two pairs of good quality, powder-free disposable nitrile or neoprene gloves (as specified by a risk assessment and review of the manufacture’s recommendations).

**7.0 RESPONSIBILITY**

Pharmacy and Medical Stores Departments in Healthcare Units:

- All concerned staff shall take the necessary protective measures in receiving storage, compounding labeling, packaging, dispensing and disposal of hazardous drugs.
- The staff that is exposed to handling hazardous materials should be trained on how to safely handle the hazardous drugs, deal with spills and the appropriate use of personnel protective clothing and equipment.

**8.0 RELATED DOCUMENTS**

8.1 Health Unit own Infection Control Policy and Procedures.
8.2 High Alert/High Risk Medications (MOH-DGMS-PH-33)
8.3 Pharmacy Departmental Safety Policy (MOH-DGMS-PH-06)

**9.0 REFERENCES**

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASHP Guidelines on Handling Hazardous Drugs</td>
<td>ASHP Council of Professional Affairs</td>
<td>2006</td>
<td>20</td>
</tr>
<tr>
<td>Safe Handling of Hazardous Drugs in Healthcare, PSHSA Ontario</td>
<td>Public Services Health &amp; Safety Association</td>
<td>2013</td>
<td>9</td>
</tr>
<tr>
<td>NIOSH List of Antineoplastic and other hazardous drugs in health care settings</td>
<td>NIOSH</td>
<td>2014</td>
<td>34</td>
</tr>
<tr>
<td>Safe Handling of Cytotoxic drugs and related waste</td>
<td>S. Australia Health Services.</td>
<td>2015</td>
<td>172</td>
</tr>
<tr>
<td>USP Chapter 800 Hazardous Drugs – Handling in Healthcare Settings</td>
<td>USP</td>
<td>2017</td>
<td>20</td>
</tr>
</tbody>
</table>
### Annex-A

#### Table 1

**Group 1: Antineoplastic drugs**

<table>
<thead>
<tr>
<th>SL.</th>
<th>Drug</th>
<th>SL.</th>
<th>Drug</th>
<th>SL.</th>
<th>Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Amsacrine</td>
<td>22</td>
<td>Epirubicin</td>
<td>43</td>
<td>Mercaptopurine</td>
</tr>
<tr>
<td>2</td>
<td>Anastrozole</td>
<td>23</td>
<td>Erlotinib</td>
<td>44</td>
<td>Methotrexate</td>
</tr>
<tr>
<td>3</td>
<td>Azacitidine</td>
<td>24</td>
<td>Etoposide</td>
<td>45</td>
<td>Mitomycin</td>
</tr>
<tr>
<td>4</td>
<td>BCG</td>
<td>25</td>
<td>Everolimus</td>
<td>46</td>
<td>Mitoxantrone</td>
</tr>
<tr>
<td>5</td>
<td>Bendamustine</td>
<td>26</td>
<td>Exemestane</td>
<td>47</td>
<td>Nilotinib</td>
</tr>
<tr>
<td>6</td>
<td>Bicalutimide</td>
<td>27</td>
<td>Fludarabine</td>
<td>48</td>
<td>Oxaliplatin</td>
</tr>
<tr>
<td>7</td>
<td>Bleomycin</td>
<td>28</td>
<td>Fluorouracil</td>
<td>49</td>
<td>Paclitaxel</td>
</tr>
<tr>
<td>8</td>
<td>Bortezomib</td>
<td>29</td>
<td>Flutamide</td>
<td>50</td>
<td>Pemetrexed</td>
</tr>
<tr>
<td>9</td>
<td>Busulfan</td>
<td>30</td>
<td>Fulvestrant</td>
<td>51</td>
<td>Pertuzumab</td>
</tr>
<tr>
<td>10</td>
<td>Capecitabine</td>
<td>31</td>
<td>Gemcitabine</td>
<td>52</td>
<td>Procarbazine</td>
</tr>
<tr>
<td>11</td>
<td>Carboplatin</td>
<td>32</td>
<td>Goserelin</td>
<td>53</td>
<td>Sorafenib</td>
</tr>
<tr>
<td>12</td>
<td>Chlorambucil</td>
<td>33</td>
<td>Hydroxyurea</td>
<td>54</td>
<td>Sunitinib</td>
</tr>
<tr>
<td>13</td>
<td>Cisplatin</td>
<td>34</td>
<td>Idarubicin</td>
<td>55</td>
<td>Tamoxifhen</td>
</tr>
<tr>
<td>14</td>
<td>Clofarabine</td>
<td>35</td>
<td>Ifosfamide</td>
<td>56</td>
<td>Temozolomide</td>
</tr>
<tr>
<td>15</td>
<td>Cyclophosphamide</td>
<td>36</td>
<td>Imatinib</td>
<td>57</td>
<td>Thioguanine</td>
</tr>
<tr>
<td>16</td>
<td>Cytarabine</td>
<td>37</td>
<td>Irinotecan</td>
<td>58</td>
<td>Topotecan</td>
</tr>
<tr>
<td>17</td>
<td>Dacarbazine</td>
<td>38</td>
<td>Letrozole</td>
<td>59</td>
<td>Triptorelin</td>
</tr>
<tr>
<td>18</td>
<td>Dactinomycin</td>
<td>39</td>
<td>Leuprolide</td>
<td>60</td>
<td>Vinblastine</td>
</tr>
<tr>
<td>19</td>
<td>Dasatinib</td>
<td>40</td>
<td>Lomustine</td>
<td>61</td>
<td>Vincristine</td>
</tr>
<tr>
<td>20</td>
<td>Docetaxel</td>
<td>41</td>
<td>Megestrol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Doxorubicin</td>
<td>42</td>
<td>Melphalan</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Table 2

**Group 2: Non-antineoplastic hazardous drug**

<table>
<thead>
<tr>
<th>SL.</th>
<th>Drug</th>
<th>AHFS classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Abacavir</td>
<td>Nucleoside and reverse transcriptase inhibitors</td>
</tr>
<tr>
<td>2</td>
<td>Carbamazepine</td>
<td>anticonvulsants, miscellaneous</td>
</tr>
<tr>
<td>3</td>
<td>Azathioprine</td>
<td>immunosuppressants</td>
</tr>
<tr>
<td>4</td>
<td>Chloramphenicol</td>
<td>chloramphenicols</td>
</tr>
<tr>
<td>5</td>
<td>Cyclosporine</td>
<td>immunosuppressive agents</td>
</tr>
<tr>
<td>6</td>
<td>Deferiprone</td>
<td>heavy metal antagonists</td>
</tr>
<tr>
<td>7</td>
<td>Entecavir</td>
<td>Nucleosides and nucleotides</td>
</tr>
<tr>
<td>8</td>
<td>Estradiol</td>
<td>estrogens</td>
</tr>
<tr>
<td>9</td>
<td>Estrogen/ progesterone combinations</td>
<td>contraceptives</td>
</tr>
<tr>
<td>10</td>
<td>Estrogens, conjugated</td>
<td>estrogens</td>
</tr>
<tr>
<td>11</td>
<td>Fingolimod</td>
<td>biologic response modifiers</td>
</tr>
<tr>
<td>12</td>
<td>Ganciclovir</td>
<td>Nucleosides and nucleotides</td>
</tr>
<tr>
<td>13</td>
<td>Leflunomide</td>
<td>disease-modifying antirheumatic agents</td>
</tr>
<tr>
<td>14</td>
<td>Lenalidomide</td>
<td>biologic response modulators</td>
</tr>
<tr>
<td>15</td>
<td>Medroxyprogesterone acetate</td>
<td>Incretin mimetics</td>
</tr>
<tr>
<td>16</td>
<td>Mycophenolate mofetil</td>
<td>immunosuppressive agents</td>
</tr>
<tr>
<td>17</td>
<td>Mycophenolic acid</td>
<td>immunosuppressive agents</td>
</tr>
<tr>
<td>18</td>
<td>Nevirapine</td>
<td>Non-nucleoside reverse transcriptase inhibitors</td>
</tr>
<tr>
<td>19</td>
<td>Paliperidone</td>
<td>atypical antipsychotics</td>
</tr>
<tr>
<td>20</td>
<td>Phenytoin</td>
<td>hydantoins</td>
</tr>
<tr>
<td>21</td>
<td>Progesterone</td>
<td>progestins</td>
</tr>
<tr>
<td>22</td>
<td>Progestins</td>
<td>contraceptives</td>
</tr>
<tr>
<td>23</td>
<td>Propylthiouracil</td>
<td>antithyroid agents</td>
</tr>
<tr>
<td>24</td>
<td>Risperidone</td>
<td>Atypical anti-psychotics</td>
</tr>
<tr>
<td>25</td>
<td>Sirolimus</td>
<td>immunosuppressive agents</td>
</tr>
<tr>
<td>26</td>
<td>Spironolactone</td>
<td>mineralocorticoid receptor antagonists</td>
</tr>
<tr>
<td>27</td>
<td>Tacrolimus</td>
<td>immunosuppressive agents</td>
</tr>
<tr>
<td>28</td>
<td>Thalidomide</td>
<td>biologic response modulators</td>
</tr>
<tr>
<td>29</td>
<td>Valganciclovir</td>
<td>Nucleosides and nucleotides</td>
</tr>
<tr>
<td>30</td>
<td>Zidovudine</td>
<td>Antiretroviral agents</td>
</tr>
</tbody>
</table>
Table 3

<table>
<thead>
<tr>
<th>SL.</th>
<th>Drug</th>
<th>AHFS classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Acitretin</td>
<td>vitamin A</td>
</tr>
<tr>
<td>2</td>
<td>Cabergoline</td>
<td>Ergot derivative dopamine receptor agonists</td>
</tr>
<tr>
<td>3</td>
<td>Choriogonadotropin</td>
<td>gonadotropins</td>
</tr>
<tr>
<td>4</td>
<td>Clomiphene</td>
<td>Estrogen agonist-antagonists</td>
</tr>
<tr>
<td>5</td>
<td>Clonazepam</td>
<td>benzodiazepines</td>
</tr>
<tr>
<td>6</td>
<td>Colchicine</td>
<td>anti-gout agents</td>
</tr>
<tr>
<td>7</td>
<td>Dinoprostone</td>
<td>oxytocics</td>
</tr>
<tr>
<td>8</td>
<td>Finasteride</td>
<td>5-alpha reductase inhibitors</td>
</tr>
<tr>
<td>9</td>
<td>Fluconazole</td>
<td>azoles</td>
</tr>
<tr>
<td>10</td>
<td>Gonadotropin, chorionic</td>
<td>gonadotropins</td>
</tr>
<tr>
<td>11</td>
<td>Misoprostol</td>
<td>prostaglandins</td>
</tr>
<tr>
<td>12</td>
<td>Oxytocin</td>
<td>oxytocics</td>
</tr>
<tr>
<td>13</td>
<td>Pamidronate</td>
<td>bone resorption inhibitors</td>
</tr>
<tr>
<td>14</td>
<td>Paroxetine</td>
<td>Selective serotonin uptake inhibitors</td>
</tr>
<tr>
<td>15</td>
<td>Plerixafor</td>
<td>Hematopoietic agents</td>
</tr>
<tr>
<td>16</td>
<td>Ribavirin</td>
<td>nucleosides and nucleotides</td>
</tr>
<tr>
<td>17</td>
<td>Testosterone</td>
<td>androgens</td>
</tr>
<tr>
<td>18</td>
<td>Topiramate</td>
<td>anticonvulsants, miscellaneous</td>
</tr>
<tr>
<td>19</td>
<td>Tretinoin</td>
<td>cell stimulants and proliferants</td>
</tr>
<tr>
<td>20</td>
<td>Valproate/valproic acid</td>
<td>anticonvulsants, miscellaneous</td>
</tr>
<tr>
<td>21</td>
<td>Vigabatrin</td>
<td>anticonvulsants, miscellaneous</td>
</tr>
<tr>
<td>22</td>
<td>Voriconazole</td>
<td>azoles</td>
</tr>
<tr>
<td>23</td>
<td>Warfarin</td>
<td>Coumarin derivatives</td>
</tr>
<tr>
<td>24</td>
<td>Zoledronic acid</td>
<td>bone resorption inhibitors</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

Drug recall is an action taken to withdraw or remove the drugs from distribution or use including corrective action for which deficiencies are reported in quality, efficacy or safety. The defective products related to quality includes not of standard quality, adulterated or spurious drugs.

Safety and efficacy related recalls include serious adverse reactions and death. Recalls also include prohibited drugs and also those products for which product licenses are suspended or cancelled.

Recall types are classified according to FDA as follows:

- Class I Recall: A situation in which there is a reasonable probability that the use of or exposure to a violated product will cause serious adverse health consequences or death.
- Class II Recall: A situation in which use of or exposure to a violated product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III Recall: A situation in which use of or exposure to a violated product is not likely to cause adverse health consequences.

2.0 SCOPE

This policy is applicable to all products purchased by MOH, which are recalled due to defective quality, safety or efficacy.

3.0 PURPOSE

3.1 To ensure that drugs that have been recalled by the Manufacturers or the Competent Health Authorities for safety hazards are removed, properly disposed of, and appropriate substitute product is obtained.

3.2 To protect patients from defective and sub-standards medication products.

4.0 DEFINITION

Drug Recall: The actions taken for removal of distributed drug that may present a risk or health hazard as declared by a Manufacturer or National/International Drug Control body.

5.0 POLICY

5.1 All recalled products shall be removed immediately from the Central drug Stores in (DGMS) /Regional Medical Stores (Nizwa, Salalah), Pharmacy & Medical Stores, Patient Care areas and all storage areas in all Health Units. The recalled product shall be quarantined until returned to the manufacturer by DGMS.
5.2 Products recalled directly by Royal Hospital shall be intimated promptly to the Directorate General of Medical Supplies, with full details (product name, manufacturer, batch number etc.) for information and necessary action.

5.3 A medication recalled is usually due to, but are not limited to the following reasons:
- Inadequate or faulty packaging or contamination.
- Inadequate or confusing labeling.
- Deterioration or contamination of medications.
- Medications that professionals consider to be defective or undesirable.

5.4 Recall Notification usually received from one of the following:
- The Manufacturer or Supplier of the item.
- Directorate General of Medical Supplies (DGMS) based on recommendations of the Quality Management & Patients Safety Department in response to reports from Health Units.
- The National drug regulatory authority (DGPA&DC) or International Competent Health Authority.

6.0 PROCEDURE

Notification Receipt in DGMS:
6.1 Upon Receipt of Product Quality Problem Report from the Health Authority or the Manufacturer or from the Health Units, DGMS should verify the receipt of the complaint batch (s) and presence of any quantity of the reported batch in the stock, also to whom it has been issued.

Assessment of report
6.2 The classification, level and strategy of recall are determined depending on the potential hazard of the defective product and the extent of product distribution.

Recall Initiation:
6.3 Recall initiation should be prepared by the Quality Management & Medicines Safety Department and approved by the Director General of Medical Supplies in the attached format. (Annex A)

6.4 An Issue Voucher for the concerned Supplier should be processed immediately for all recalled batches available in Central & Regional Stores, in DGMS to block issue of recalled batches. Accordingly the item should be handed over to the Receiving Section along with the Issue Voucher for keeping in quarantine.

6.5 DGMS to circulate the recall notification to the Health Units on the same day of receiving the recall notification by the rapid mode of transmission (Fax and Email) with copies to DGPA&DC and all other concerned parties.

6.6 In response to DGMS letter Health Units to withdraw immediately the recalled batches from the Medical Stores and Pharmacy areas including Inpatient Pharmacy, Unit dose prepackaging, Compounding Area, IV room, Discharge, Outpatient Pharmacy, stock storage area at all Nursing Units maintaining the indicated batches as floor stock.
6.7 All outpatient orders/prescriptions must be checked to determine if any orders have been dispensed with the affected batch number. The affected patients should be contacted for Class I recalls, if necessary.

6.8 Copies of the recall letters to be sent to DGP&DC and other Governmental Institutions participated in purchase of the item through MOH Tenders.

6.9 The Medical Staff and Nursing Services in the Health Units should be notified about the recalled medication through the Pharmacy and Medical Store Department.

6.10 All collected recalled medications must be labeled as “RECALLED MEDICATIONS” and quarantined to avoid inadvertently use by any Healthcare providers.

6.11 Recalled batches to be returned to the Central Drug Stores in DGMS / Regional Medical Stores within a week’s time, and the same should be entered in DGMS inventory system as Hospital Return (Recall) immediately on receipt, without posting at this stage.

6.12 Returned batches from Regional Medical Stores and Health Units must be kept in Central Stores in DGMS in quarantine, away from shelves in sealed cartons carrying a label “RECALLED MEDICATIONS”.

6.13 All recalled items from Health Units should be compiled, posted in the system within two weeks from the date of recall initiation and accordingly the issue voucher to the concerned supplier should be generated and approved accordingly.

6.14 The entire stock of recalled batches received from DGMS and Health Units should be returned back to the Supplier/Manufacturer along with the Issue Voucher for safe disposal and replacement with freshly manufactured batch of acceptable quality or reimbursement if it no longer needed.

Recall Follow –Up- Actions :

6.15 The Manufacturer should provide Root Cause Identification along with Corrective & Preventive Plan of Action (CAPA).

6.16 The Drug Recall Log should be maintained and documented in the inventory management system as well as in database of DGMS Quality Reporting Program and the Quality Management system Non Conformance Log. It should contain the generic and trade names, manufacturer names, country of origin, batch number, manufacturing, expiry dates and the reasons for the recall.

7.0 RESPONSIBILITY

Directorate General of Medical Supplies (DGMS):

- To initiate drug recalls of defected batches and withdraw the stock from the entire MOH distribution chain accordingly

Pharmacy & Medical Stores Departments in Healthcare Units:

- To remove the recalled item immediately from the shelves, quarantine it and return to DGMS within a week’s time.

8.0 RELATED DOCUMENTS

Drug Quality Reporting Program (MH-DGMS-PH-43)

Procurement of Medical Supplies (MH-DGMS-PH-11)
## 9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Addressing drug and devices recalls in hospitals</td>
<td>California state board of pharmacy</td>
<td>2010</td>
<td>7</td>
</tr>
<tr>
<td>Guides on Recall and Rapid alert System for Drugs</td>
<td>Central Drugs Standard Control Organization, MOH and Family Welfare, India</td>
<td>2012</td>
<td>28</td>
</tr>
<tr>
<td>Regulatory Procedure Manual – Chapter 7 Recall Procedures</td>
<td>FDA USA</td>
<td>2013</td>
<td>77</td>
</tr>
<tr>
<td>A Guide to Defective Medicinal Products</td>
<td>MHRA UK</td>
<td>2013</td>
<td>28</td>
</tr>
<tr>
<td>Pharmaceutical Products Recall Guidelines</td>
<td>Dept. of Health, Hong Kong</td>
<td>2017</td>
<td>27</td>
</tr>
</tbody>
</table>
Annex- A

Sultanate of Oman  
Ministry of Health  
Directorate General of Medical Supplies

DRUG RECALL PROCESSING FORM

<table>
<thead>
<tr>
<th>Date of receipt of Recall notification:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Recalled by:</td>
<td>Manufacturer / Statutory / DGMS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medication description:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic Name:</td>
<td>Brand Name:</td>
</tr>
<tr>
<td>Manufacturer:</td>
<td>Batch No.(s) :</td>
</tr>
<tr>
<td>Manufacturing date:</td>
<td>Recall class:</td>
</tr>
<tr>
<td>&amp; Expiry date:</td>
<td></td>
</tr>
<tr>
<td>Quantity received:</td>
<td>Quantity available:</td>
</tr>
<tr>
<td>Quantity issued:</td>
<td></td>
</tr>
</tbody>
</table>

Recall Reasons :

Head , QM & Med Safety Section

Signature: Date:

Director General:

Signature: Date:
1.0 INTRODUCTION

Extemporaneous compounding is the preparation of a therapeutic product for an individual patient in response to an identified need. It is a practical way to have medicines supplied when there is no other option. Extemporaneously compounded medicines may be useful when a required dose or dose form is unavailable commercially, or for individualized dosing.

Unlike registered medicines, compounded preparations have not generally been assessed for safety and efficacy. Their use is off label and is based on extrapolation from the component ingredients. Short-term expiry dates are provided for compounded products unless their stability has been assessed.

2.0 SCOPE

Safe extemporaneous compounding practice in Pharmacy Departments.

3.0 PURPOSE

To describe the guidelines for compounding of the extemporaneous pharmaceuticals in the Pharmacy Laboratories in MOH Health Units.

4.0 DEFINITION

Extemporaneous Pharmaceutical Compounding: Is the process of mixing drugs by a Pharmacist/ Assistant pharmacist or modifying the concentration of a drug from that of the original manufacturer to fit the unique needs of a patient.

5.0 POLICY

The following policy and procedure is to be considered as a guide and reference on the responsibilities of the Pharmacists / Assistant pharmacists in compounding and dispensing drugs.

5.1 The extemporaneous products are many and varied therefore it should be restricted to the following cases:

- The finished product is not available commercially in the desired form.
- The concentrations of the product need individualization.
- Hypersensitivity to commercial products e.g. Preservatives.

5.2 An alternative drug or alternative method should be considered first. For example, tablet dispersion than extemporaneous oral preparation.

5.3 Critical compounding processes should be validated to ensure that procedures, when used, would consistently result in the expected qualities in the finished preparation. Certain technically difficult or high-risk preparations should not be prepared extemporaneously. Ethanol should be avoided.
5.4 The quantities to be dispensed should not in any case exceed that which may be used within that period of safety, expiry date and or beyond the treatment duration.

5.5 The use of the product should be monitored & observed for any signs of physical instability such as colour change or difficulty in re-suspension to ensure that finished preparations have their expected potency, purity, quality, and characteristics, at least until the labelled beyond-use date (expiry date).

5.6 The patient or the caregiver should be counselled about proper use, storage, expiry date and evidence of instability in the compounded preparation at the time of dispensing. Follow-up contact with the patient is recommended to ascertain that the product is physically stable and no adverse effects have occurred.

5.7 Tertiary/Regional Hospitals equipped with the necessary extemporaneous facilities should compound and supply the products to Primary and Secondary Health Care Institutions for referral cases.

5.8 Pharmacists and Assistant pharmacists involved in drug compounding shall be properly trained for the type of compounding conducted, prior to commencing any compounding and shall perform through didactic instruction in the theory and practice of compounding with regular evaluation of techniques (for low, medium and high-risk levels).

5.9 The compounding area should be located sufficiently away from routine dispensing and counselling functions, and should have adequate designated space and shall be well lighted, have smooth work surfaces, free of cracks and crevices, maintained in clean, orderly and sanitary conditions. The compounding area (pharmacy lab) should have a clean working bench with a smooth surface, and a sink with water supply and stainless steel surface.

5.10 The compounding, weighing and measuring equipment used shall be of appropriate design and capacity and of suitable composition not reactive, additives or absorptive to the compounded ingredients and shall be maintained in good working order.

5.11 The container for compounded products should be appropriate for the dosage form compounded. The container should not interact physically or chemically with the product. Glass containers are recommended to ensure containers inertness, visibility, strength, rigidity, moisture protection and ease of re-closure.

5.12 The product must be labelled with the necessary particulars or documentation referenced with generic name, strength, dosage form, volume, preparation date, expiry date, pharmacy lot Number, storage conditions, instructions for use, etc.

5.13 The worksheet for each compounded product should include the formula, procedure, labelling instructions, source of the formula, batch number, expiry date, patient details, name and signature of the compounder and the cross checked compounding supervisor.

5.14 Each step of compounding should be documented including compounding formulae and procedures, a log of all compounded items including batch records, name and signature of compounder and must also include the patient’s and prescription details, and date of dispensing. The supervising pharmacist also should sign the compounding records. The records must be kept for a period of one year.

5.15 The compounder should ensure that each batch retain all the qualities within the specified limits until the labeled expiration date.
5.16 The compounder should consider the availability of necessary storage facility with the patient while allotting the expiry date of the preparation, to ensure the potency during the shelf life.

6.0 PROCEDURE

6.1 Refer to the MOH Oral Extemporaneous Formulation Manual 2nd Edition 2015 or the latest published edition if any, to prepare the requested formulations and follow the conditions closely. Modifications to published formulations are only appropriate if there are no detrimental effects on stability.

6.2 For new formulae, which are not included in above manual, Royal Hospital and Sultan Qaboos Hospital should provide one month supply for referral cases with the Methods of Preparation for future use by the Regional Hospitals.

6.3 Only oral and topical preparations are to be extemporaneously prepared. Make the proper calculations of the dosages and concentrations of the medicine required by the physician order or according to the preparation book.

6.4 GMP Requirements: Ensure that all the following requirements of Good Compounding Practices for non-sterile extemporaneous preparations requirements contained in MOH Extemporaneous Manual are strictly followed:

- Responsibilities of the compounder.
- Personnel, training & Attire.
- Procedures & Documentation.
- Drug Compounding Facilities.
- Drug Compounding equipment.
- Component requirements.
- Packaging and Drug Product Containers.
- Compounding Controls.
- Labeling.
- Compounding records and documents.
- Formulation record.
- Compounding record.
- Compounded preparations.
  - Capsules, powders, lozenges & tablets.
  - Emulsions, solutions and suspensions.
- Compounding process.
- Levels of Compounding.
- Quality Control.
- Verification.
- Patient Counseling.
- Packaging.
- Stability of Compounded Preparations.
- Stability Criteria and beyond use dating.
6.5 General steps in the compounding process:
The steps to be followed before, during, and after compounding can be grouped into five categories: preparatory, compounding, final check, sign-off, and cleanup steps. These are summarized in the sidebar below.

6.5.1 Preparatory
a. Judging the suitability of the prescription in terms of its safety and intended use and the dose for the patient.
b. Performing the calculations to determine the quantities of the ingredients needed.
c. Selecting the proper equipment and making sure it is clean.
d. Donning the proper attire and washing hands.
e. Cleaning the compounding area and the equipment, if necessary.
f. Assembling all the necessary materials and ingredients to compound and package the prescription.

6.5.2 Compounding
g. Compounding the prescription according to the formulary record or the prescription, using techniques according to the art and science of pharmacy.

6.5.3 Final check
h. Checking, as indicated, the weight variation, adequacy of mixing, clarity, odor, color, consistency, and ph.
i. Entering the information in the compounding log.
j. Labeling the prescription.

6.5.4 Sign-off
k. Signing and dating the prescription, affirming that all of the indicated procedures were carried out to ensure uniformity, identity, strength, quantity, and purity.

6.5.5 Cleanup
l. Cleaning and storing all equipment.
m. Cleaning the compounding area.

6.6 General compounding procedure:
• The pharmacist shall write down the name of the materials used and the calculated amounts in the log book.
• The pharmacist shall weigh material according to the calculated amounts and carry on with the preparation and sign on the preparation working sheet. Another Pharmacist should check these preparations and co-sign.
• The pharmaceutical preparations are then placed in bottles or containers and properly labeled.
• The label should contain the name of the prepared medicine, strength or concentration, batch number, direction for use, expiration date, storage conditions and initials of the preparing pharmacist.
The pharmacist shall attach any auxiliary labels that may be required to the bottle or container.

The pharmacist shall record the name of the prepared medicine, the strength, batch number, expiration date, and the preparation number on the log book.

The pharmacist shall check the expiration date of the raw materials, and other chemicals periodically.

The pharmacist shall check the validity of the prepared items and discard any batch that changes in color, odor, and/or appearance.

The pharmacist shall request the raw materials and chemicals weekly from the medical store, or whenever needed.

7.0 RESPONSIBILITY

The compounding pharmacists/Asst. pharmacists in Healthcare Units:

- Shall follow strictly the safe compounding guidelines as per the international standards.

Head of Pharmacy/Compounding Supervisor:

- Shall ensure that the compounding staff are competent and the process is conducted as per the approved safe compounding procedures.

8.0 RELATED DOCUMENTS

8.1 Off Label Use of Medications (MH-DGMS-PH-26)

8.2 High Alert Medications (MH-DGMS-PH-35)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paediatric Drug Formulations – Sixth Edition</td>
<td>Milap A Nahata Vinitha B Pai</td>
<td>2011</td>
<td>420</td>
</tr>
<tr>
<td>Formulation in Pharmacy Practice - eMixo</td>
<td>Extemporaneous Compounding Pharmacist Group, New Zealand</td>
<td>2014</td>
<td>450</td>
</tr>
<tr>
<td>United States Pharmacopeia (USP) 39th edition, National Formulary 34.</td>
<td>USP</td>
<td>2017</td>
<td>7580</td>
</tr>
<tr>
<td>British Pharmacopoeia. (BP) - 2017</td>
<td>BP Commission Secretariat of MHRA</td>
<td>2017</td>
<td>6000</td>
</tr>
<tr>
<td>Extemporaneously Compounded Medicines, Australian Prescriber Journal</td>
<td>James R &amp; Kathryn J</td>
<td>2017</td>
<td>4</td>
</tr>
<tr>
<td>Guidelines of Compounding of Medicines</td>
<td>Pharmacy Board of Australia</td>
<td>2017</td>
<td>16</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

This policy and procedures are not the sole or primary source of information for pharmacists regarding compounding, they do not aim to restate or summarize the already published and widely accepted information such as the compounding information contained in the United States Pharmacopeia (USP Chapter 797), or the practice standards on compounding published by the profession, and the requirements outlined in relevant references.

USP General Chapter <797> provides standards for compounding sterile preparations to promote patient safety and prevent harm. These standards help ensure patients receive quality preparations that are free from contaminants and are consistent in intended identity, strength and potency. This General Chapter describes a number of requirements, including responsibilities of compounding Pharmacist and Technician, training, environmental monitoring, storage and testing of finished preparations.

2.0 SCOPE

All sterile compounded pharmaceuticals aseptically prepared in MOH hospitals.

3.0 PURPOSE

To provide guidelines for safe operation and maintenance of good quality intravenous (IV) admixture and sterile product preparations.

4.0 DEFINITION

Compounding: Is defined by FDA as “The preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner’s prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice.”

5.0 POLICY

5.1 Pharmacy Department considers United States Pharmacopeia (USP Chapter 797) to be the accepted reference for all issues related to sterile product preparations, professional, technical, and quality assurance practice.

5.2 Compounding must be done in appropriate facilities and working environments and using appropriate equipment. The Laminar Air Flow Hoods (LAFH) shall be used in the preparation of all sterile products, including all IV admixtures and extemporaneous sterile preparations. The LAFH provides bacteria free and dust free work environment which minimizes the chance of product contamination.

5.3 A compounded medicine should be prepared only in circumstances where:

• An appropriate commercial product is unavailable.
• A commercial product is unsuitable (e.g. if a patient experienced an allergy to an excipient in the commercial product).
5.4 Particular care should be exercised by pharmacists who are requested to compound medicines for which there are no precedents in the reputable references, and for which there is inadequate published safety, efficacy, pharmacokinetic and clinical data on the intended formulation. Examples of such products could include (but are not limited to):

- Preparations containing hormones.
- Preparations compounded for topical use that contain drugs for which only oral use is well established.
- Modified release medicine in the absence of good pharmacokinetic and clinical data on the precise formulation intended for use, or
- Parenteral medicines containing combinations of ingredients where there is no compatibility data.

5.5 Compounding Pharmacist / Asst. pharmacist are responsible for ensuring that CSPs are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed.

5.6 Compounding supervisors shall ensure through either direct measurement or appropriate information sources, that specific CSPs maintain their labeled strength within monograph limits for USParticles, or within 10% if not specified, and all CSPs are prepared in a manner that maintains sterility and minimizes the introduction of particulate matter.

5.7 Compounding Pharmacist / Asst. pharmacist shall be adequately skilled, educated, instructed, and trained in aseptic techniques to perform correctly their sterile compounding duties. Engagement of an expert or mentor to assist with this process is encouraged.

5.8 Where a suitably trained and experienced individual assists with the physical compounding of a medicine, it remains the pharmacist’s responsibility to:

- Conduct a risk assessment for the product being compounded, and ensure that all risks are appropriately managed.
- Ensure all weighing and measuring is conducted appropriately.
- Ensure all packaging and labeling of the compounded product is appropriate.
- Ensure that the product has been compounded in accordance with pharmacopoeial formulations when available, and in a manner which ensures quality and efficacy of the product,
- Ensure that the compounding procedure has been documented appropriately.
- Approve the supply of the medicine to the consumer, whether a prescription medicine or over the counter medicine, and
- Counsel the patient and ensure that the patient is provided relevant information about the compounded product.

6.0 PROCEDURE

6.1 Adequate pharmacy staff will be available for the preparation of sterile products during regular hours of pharmacy operation.

6.2 Organizational practices employed for compounding sterile preparations are in compliance with USP standards related to sterile compounding.
6.3 Compounding must be in response to a prescription. The quantity of compounded medicine to be supplied should be a single unit of issue for the treatment of a particular patient. For prescribed medicines, if the quantity is not specified by the prescriber, this must be confirmed with the prescriber.

6.4 In preparing a compounded medicine, a corresponding formulation in a reputable reference should be used by the pharmacist when available. Compounding pharmacists must have available appropriate reference texts relevant to their area of compounding. These should be in the form of a published document (hard copy) or via electronic means, such as a computer. Examples may include the following:

- Trissel’s Stability of Compounded Formulations - Trissel LA.
- Pharmaceutical Calculations - Howard C. Ansel and Mitchell J. Stoklosa.
- Australian Injectable Drugs Handbook - The Society of Hospital Pharmacists of Australia.
- Ansel’s Pharmaceutical Dosage Forms and Drug Delivery Systems - Loyd Allen.

6.5 Demonstrating competence to undertake complex compounding, to ensure safety of the public who access their services, themselves and the staff working under their supervision, involves:

- Conducting a self-assessment against the practice profile to identify the competencies relevant to the areas of complex compounding being carried out.
- Identifying CPD needs relevant to these identified competencies and documenting these in the form of a CPD plan.
- Undertaking CPD activities (including a training program) that address identified continuing professional development needs, and
- Gaining experience until competence is achieved, in premises that are adequately designed, equipped and maintained.

6.6 If requested to compound a medicine for a patient that has been previously compounded by another pharmacist and/or at another pharmacy, the pharmacist must take reasonable steps to ensure themselves that the requested product has been compounded consistently with previous supplies. This is particularly important for high-risk medicines such as those with a narrow therapeutic index, or for modified-release preparations.

6.7 Parenteral medicines compounded by a pharmacist for administration to a specific patient should be assigned a shelf life of up to 24 hours given that a longer expiry may result in:

- Enhanced chemical instability of the compounded medicine which may result in reduced therapeutic activity, or enhanced toxicity caused by degradation products.
- Increased likelihood of microbial contamination of the compounded product, and
• Increased likelihood of dose administration errors associated with the compounded medicine, for example an infusion bag that was compounded before a dose change, being incorrectly administered to a patient.

6.8 Appropriate Personnel Protective Equipment (PPE) shall be worn when compounding in a Biological Safety Cabinet (BSC) or Compounding Aseptic Containment Isolator (CACI).

6.9 Most microorganisms in sterile areas are contributed by humans, thus every effort must be made to reduce shedding from skin, hair and clothes. The following shall be considered:

• All jewelry including watches must be removed. Nails must be of acceptable length and must be free of polish since it flakes easily.

• Hands, nails and forearms up to the elbows will be meticulously washed for at least thirty (30) seconds with anti-bacterial soap cleaning agent approved for use in the Hospital. A nail brush must be used to scrub under the nails.

• Sterile disposable gloves shall be worn and rinsed frequently with sterile isopropyl alcohol (IPA) during processing. The gloves should be changed if the integrity is compromised. Fingertip sampling will be performed for each sterile preparation staff once a month as a quality control.

• The plunger of a syringe that is to be used repeatedly for withdrawing a drug should never be touched or have contact with any surface as the inside of the barrel will be contaminated when the plunger is thrust into the syringe. Only disposable syringes and needles are used to prepare sterile products.

• All rubber stoppers and ampoule necks must be cleaned with an alcohol swab prior to withdrawing the contents.

• If there is any possibility that a sterile product may have been contaminated, avoid all risk by discarding the product and starting over.

6.10 Laminar Air Flow Hoods (LAFH) guidelines:

• The LAFH shall operate twenty-four (24) hours a day. If switched off for any reason, it must operate for at least thirty (30) minutes prior to use. Pre-filters will be changed every three (3) months (as per manufacturer handout) by Biomedical Engineering personnel. A log will be maintained to record the date pre filters are changed.

• The LAFH shall be cleaned thoroughly three (3) times with sterile water for irrigation (to remove soluble residues) and sterile IPA (residue-free disinfectant) on appropriate surfaces with low-shedding wipes. The hood work surface shall also be re cleaned with sterile water for irrigation and sterile IPA every 30 minutes between different preparations.

• For horizontal laminar, do not use IPA alcohol on the Perspex top and sides due to compatibility. Clean the Perspex and sides with germicidal detergent or sodium hypochlorite solution (bleach germicidal, Clorox) at 1:10 dilution once daily at approximately 2130, clean inside fiber glass panel (polycarbonate) with germicidal detergent or Clorox 1:10. For biohazard laminar, do not use Clorox 1:10 on any surface. The ultraviolet (UV) light shall be employed after the final daily cleaning and whenever the hoods are not in use. Always use low-shedding wipes for cleaning.
• Airflow in the LAFH shall be measured by the Biomedical Engineering Department periodically (at least every 6 months) as recommended by manufacturer manual.

• On a monthly basis, airflow sterility will be checked with culture plates obtained from the Laboratory. These plates will be exposed in the hood for twenty (20) minutes, one each in the left, center and right side of the work area and midway back in the hood. A fourth plate left unexposed shall serve as a control. All plates will be sent to Laboratory along with the proper form for forty-eight (48) hour cultures or more as needed for growth of organisms if any. Culture report files will be maintained in the Pharmacy.

• In the event of any growth on the culture plates, the area will be thoroughly cleaned and other appropriate action taken as necessary, i.e. repair filter, check airflow, re-clean hood. Additional plates will be exposed until cultures are negative. All batches prepared in the LAFH during the positive hood culture period shall be discarded.

• Avoid introducing non-sterile items into the hood. This includes paper labels and physician order sheets. The hood must not be used as a desktop. All other preparation related materials should be sprayed adequately with IPA before being introduced into the sterile room and hood workbench.

• Only those materials necessary for the preparation of a given sterile product are permitted in the LAFH. The LAFH should be kept free of any unnecessary bottles, vials, sharp container, etc. Objects that must be stored in the hood should be placed along the sides of the work area since placing them in the back of the hood interrupts airflow and increases the risk of contamination from non-sterile objects.

• Traffic and movement around the LAFH must be kept to a minimum to prevent currents of non-sterile room air from entering the hood and contaminating the work area. Movement within the hood must also be minimized and personnel should refrain from touching the face, hair or any other surface that has not been disinfected. Coughing, sneezing or talking into the hood must also be avoided. Person with any sign of infection must not be allowed to enter IV room or prepare any sterile products.

• All work must be performed at least six inches or more from the front edge of the LAFH counter. The outer edge of the counter is easily contaminated due to the disruption of the interface of laminar airflow with non-sterile room air.

• All manipulations within the LAFH should take place in uninterrupted airflow. Nothing should come between the HEPA filter and the surface meant to keep sterile. The hands should not block sterile airflow around the needle and syringe. Sterile surfaces that are to come into contact with sterile products must not be exposed to non-sterile air or touch a non-sterile surface or object.

6.11 Procedures related to sterile/clean/buffer room and anteroom (not hoods):

• On monthly basis, culturing of workbenches shall be performed. Contact plates will be utilized and placed one meter apart over sterile room workbenches. Along with plates for hood culturing, contact plates will be sent to Laboratory with the proper form for forty-eight (48) hour cultures or more as needed for growth of organisms if any. Culture report files will be maintained in the Pharmacy.
• Volumetric air sampling (by qualified/certified staff/equipment) for sterile/clean room and anteroom shall be performed at least semiannually. The process is to ensure air particle sterility and particles/unit of measures and is acceptable according to sterile/clean room standards.

• Cleaning of sterile room floors will be performed by housekeeping daily with dedicated buckets and mops. Use of appropriate garbing is a must.

• Workbenches will be cleaned by pharmacy staff daily.

• Shelves will be cleaned by pharmacy staff and housekeeping staff regularly as per schedule.

• Approved germicidal detergent shall be utilized on cleaning surfaces.

• Pressure gauge shall be maintained and monitored between buffer area and anteroom, and anteroom and the rest of pharmacy. The purpose is to monitor pressure since sterile room and anteroom should have positive pressure at all time.

6.12 Labeling of Sterile Products:

• All products will be clearly labeled as follows:
  ✓ Name, ID and Room number of patient.
  ✓ Identity, concentration or strength and volume dispensed.
  ✓ Dosing instructions including route and frequency.
  ✓ Storage instructions and any other special requirements.
  ✓ Expiration date and time.

• In addition to items listed above labels on all IV products will specify:
  ✓ High alert and look-alike/sound-alike medications.
  ✓ Base solution, additives and quantities of each.
  ✓ Infusion rate in ml/hr. and total hours to infuse.
  ✓ The time administration is scheduled.
  ✓ Initials of compounding and checker.

• Labels applied to admixture containers should be placed so they may be read in the inverted position during infusion. The Pharmacy label should be placed in a manner that leaves the original label on the base fluid visible for identification and checking.

• Labels applied to bottles of irrigation solutions shall be applied right side up (rather than inverted). The label should clearly state the capital letters: “FOR IRRIGATION ONLY”.

6.13 An IV Preparation Card will be prepared for each admixture ordered and prepared:

• To serve as a working record and compounding log to be signed off by the preparer and pharmacist checking the final admixture.

• Admixture contents, frequency of administration and patient identification information are all contained on the perforated adhesive strip at the bottom of the computer-generated admixture label which is affixed to the top of the IV Preparation Card.
• All IV admixtures and extemporaneous sterile products will be checked and signed off by a Pharmacist I or Pharmacist II prior to dispensing. The checking will include assurance particle free finished products, regular finished product appearance and color, proper documentation along with a review of all empty vials and components used for the sterile product, and others as deemed necessary based on professional judgment.

• Recapping of used needles is discouraged for safety to avoid accidental injury. Instead, use of special needles “e.g. BD Eclipse Needle” is recommended since recapping for checking purposes is possible and safe with special recapping design.

• All ingredients used for compounding extemporaneous preparations, along with their manufacturer, lot number and expiry date, are recorded on Extemporaneous Compounding Record which details the procedure followed for each final product. All extemporaneous preparations are issued a lot number which allows for tracking back to the original prep sheet if necessary.

• Nursing staff must notify Pharmacy of any IV schedule changes required or of any infusion solutions running ahead or behind schedule.

• Discontinued additive solutions: Upon discontinuation orders, the Pharmacist will discontinue (DC) the order on the computerized patient profile. Any discontinued IV solutions already prepared will be marked “DC” on the label and stored for possible use before original expiration time.

6.14 Review of Standard Workflow Procedure:

• Upon receipt in the Pharmacy, orders for sterile products are screened for completeness and appropriateness. Orders are then entered in the Pharmacy computer system on the individual patient’s medication profile.

• The Pharmacist, aided by the computer, reviews the order and the patient profile for allergies, duplicate therapy, drug interactions, contraindications and general appropriateness of therapy prior to compounding.

• The Pharmacist must also ensure correct dosage and determine stability of the finished product. Current stability and compatibility references are maintained in the dispensing area. Lot numbers and expiry dates are assigned to all extemporaneous preparations upon entry in the computerized patient profile.

• Drug inventory in the compounding area is minimized to avoid intermingling of products.

• Sufficient space for drug storage is provided to permit SEGREGATION of each drug. Concentrated electrolytes are SEGREGATED (stored separately) from other inventory.

6.15 Master Formulation Record is maintained for each BATCH of prepared CSPs and includes the following information:

• Preparation name, strength, and dosage form.

• Physical description of the final preparation.

• Identities and amounts of all ingredients.

• Theoretical (expected) yield.
• Appropriate container–closure systems.
• Complete instructions for preparing the CSP, including equipment, supplies, and a
  Description of the compounding steps.
• Beyond-use date (BUD) and storage requirements.
• Quality control procedures (e.g., pH, filter integrity, and visual inspection).
• Sterilization method, if applicable (e.g., filter, steam, or dry heat).
• Any other information needed to describe the operation and ensure its consistent
  repeatability (e.g., adjusting pH, tonicity and/or temperature).

6.16  Reporting of adverse events:
• As is the case with any medicine, the use of compounded medicines may result in
  the occurrence of adverse events. While it may be difficult to determine whether
  a particular medicine has caused an adverse event in an individual case, all reports
  can help to accumulate evidence of the possible role of an ingredient or product
  in causing an adverse event.
• Pharmacists should report all suspected adverse reactions to compounded
  medicines.

7.0  RESPONSIBILITY

The compounding pharmacists/Asst. pharmacists in Healthcare Units:
• Shall follow strictly the safe compounding guidelines as per the international
  standards.

Head of Pharmacy/Compounding Supervisor:
• Shall ensure that the compounding staff are competent and the process is
  conducted as per the approved aseptic safe compounding standards.

8.0  RELATED DOCUMENTS

N/A

9.0  REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States Pharmacopeia (USP Chapter 797) Pharmaceutical Compounding - Sterile Preparations</td>
<td>USP</td>
<td>2012</td>
<td>39</td>
</tr>
<tr>
<td>Guidelines on Compounding of medicines</td>
<td>Pharmacy Board of Australia</td>
<td>2015</td>
<td>15</td>
</tr>
<tr>
<td>ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations</td>
<td>ISMP</td>
<td>2016</td>
<td>22</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

Total Parenteral nutrition (TPN) serves as an important therapeutic modality that is used in adults, children, and infants for a variety of indications. The appropriate use of this complex therapy aims to maximize clinical benefit while minimizing the potential risk for adverse events. Despite being classified and acknowledged as a high-alert medication, only 58% of organizations have precautions in place to prevent errors and patient harm associated with TPN. Complications can occur as a result of the therapy and as the result of the TPN process.

Regardless of the setting or the number of patients treated in a given facility, the classification of TPN as a high-alert medication requires healthcare organizations to develop evidence-based policies and procedures related to TPN.

2.0 SCOPE

Review, processing and safe preparation of TPN orders in MOH Health Units.

3.0 PURPOSE

To describe the process for reviewing and processing TPN orders to provide intravenous nutritional preparations to malnourished patients, for adequate time with maximum therapeutic benefit, minimum adverse effects, and without any drug wastage.

4.0 DEFINITION

Total Parenteral Nutrition (TPN): Is a nutritionally hypertonic compounded solution which provides glucose, amino acids, lipid emulsion, vitamins and trace minerals via a central / peripheral venous access. It is commonly ordered for patients in situations when oral / enteral feedings cannot meet the patient’s nutritional needs due to malfunction of the GI tract. The goal of TPN Therapy is to replenish depleted stores of protein, promote wound healing, weight maintenance, immunocompetence, and nitrogen balance.

5.0 POLICY

5.1 This policy is a supportive guide and not intended to replace the policies, procedures or processes followed in the hospitals for preparation of TPN which shall adhere to the procedures stated in the related international references. It is particularly focused on preparation by Pharmacy staff and not related to other aspects related to prescribing or administration by other health care professionals.

5.2 Hospitals shall use a standardized process for TPN management, and this process shall include clinicians with expertise in the area of nutrition support, preferably from multiple disciplines.

5.3 Healthcare organizations shall develop written policies and procedures for all aspects of TPN therapy and Safe Practices for Parenteral Nutrition.
5.4 The patient and caregivers shall be informed of the risks and benefits associated with TPN.

5.5 A comprehensive TPN education program and competency assessment shall be developed for healthcare professionals who are involved in the care of patients receiving TPN therapy, and competency should be assessed at least annually.

5.6 Standardized electronic TPN orders (e.g., a computerized prescriber order entry [CPOE] system) should be used to prescribe TPN for all patients. Handwritten orders to prescribe TPN should be avoided due to potential for error. Verbal and telephone orders for TPN should be avoided.

5.7 TPN order templates shall be designed so they are clear and easily understood by all healthcare professionals involved in the care of patients receiving TPN.

5.8 The healthcare organization shall develop criteria to evaluate and identify pharmacists who are competent to review and verify TPN orders which includes:
   • Pharmacists responsible for the review and verification of TPN orders should have completed specialty residency training and/or be certified by a recognized certifying body.
   • In the absence of pharmacists with specialty residency training or certification, the organization should provide formal training programs to increase knowledge and skills in nutrition support and with a goal of becoming certified in nutrition support. Training should focus on evaluating dosage of macronutrients and micronutrients, compounding as well as stabilities in TPN.

5.9 Quality improvement programs should be in place to report, track, and analyze errors associated with the TPN order review and verification process.

5.10 Healthcare organizations shall require annual competency evaluations of pharmacists and pharmacy technicians involved in preparation of compounded sterile preparations (CSPs). This should include:
   a. Calculations.
   b. Compounding base solutions.
   c. Preparing dilutions or aliquots.
   d. Aseptic technique manipulations.
   e. Using technology (i.e., ACD) for preparation.
   f. Anticipating incompatibilities (calcium, phosphate).

6.0 PROCEDURE

6.1 The essential components or attributes for safely transmitting TPN orders to pharmacists for review and verification:
   • TPN should be prescribed using a CPOE system that is fully integrated with an automated compounding device (ACD).
   • In the absence of a fully integrated system, TPN should be prescribed using a standardized order template.
• Verbal and telephone orders for TPN should be avoided except for pharmacist to prescriber communication to modify or clarify the order.

• Order data should be in a standardized format, including standardized sequence of ingredients, standard units, standard formulas, and formulation options.

• TPN orders should be compounded when supported by properly trained personnel who regularly perform this task. This is usually during the daytime hours.

• TPN orders shall be reviewed by a knowledgeable and skilled pharmacist to assess that the order is clear and complete.

6.2 The TPN order shall include the following elements:

• Complete patient identifiers (patient name, medical record number or other unique identifiers, patient location).
• Birth date and/or age.
• Allergies and associated reactions.
• Height and dosing weight in metric units.
• Diagnosis, Indication(s) for TPN.
• Administration route/vascular access device (peripheral vs central).
• Contact information for prescriber.
• Date and time order submitted.
• Administration date and time.
• Volume and infusion rate.
• Infusion schedule (continuous or cyclic).
• Type of formulation (dextrose/amino acids with separate infusion of IVFE or total nutrient admixture)

6.3 All TPN ingredients shall be ordered as follows:

• Ingredients ordered as amounts per day (for adult patients) or amounts per kilogram per day (for pediatric and neonatal patients) rather than in amounts per liter, percent concentration, or volume. “Amount per day” refers to macronutrients in grams per day and micronutrients in mEq, mmol, mcg, or mg per day.
• Electrolytes shall be ordered as the complete salt form rather than the individual ion.

6.4 The TPN order should contain the full generic name for each ingredient. Brand names should only be used when multiple products exist and/or when the brand name may assist in identifying unique properties of the specific dosage form.

6.5 TPN orders shall undergo a formulation safety review that includes the following elements:

• All ingredients are evaluated for compatibility with each other. Calcium-phosphate precipitation risk should be assessed according to institutional policies and procedures.
• TPN formulation is evaluated for expected stability from the time of preparation until the time that administration of the TPN is complete. For example, emulsion stability of a total nutrient admixture should be evaluated.

• Modifications to the prescriber’s original TPN order shall be communicated to the prescriber (or their designee) and documented in the patient’s medical record in a manner that is auditable.

• All TPN orders requiring calculations or conversion of units of measure should undergo an independent double-check process prior to compounding the TPN formulation. All double-checks shall be documented and auditable.

6.6 The TPN Room shall be is a separate, sterilized, well ventilated room, and appropriately equipped with two safety cabinets for the preparation of sterile parenteral solutions, an apparatus for mixing solutions, a refrigerator, a desk, I.V. solutions, and other disposable items needed for work.


6.8 The TPN will be prepared in the pharmacy I.V admixture unit, the preparation should be done using aseptic technique and laminar air flow hood. TPN should be prepared by certified/trained TPN pharmacist. Double-checking is a must during the preparation of any TPN solution.

6.9 If available, the compounding of macronutrients is carried out by using auto mix compounder according to the machine manual. Micronutrients will be added manually & calcium must be added last.

6.10 Upon completion of adding all additives, the pharmacist checks the final bag for particulate matter, turbidity, leakage or any defects in the container.

6.11 The prepared solution’s label should contain the following:
  • The patient’s name.
  • Record and bed number (I.D).
  • Name of the drug.
  • Strength.
  • Route of Administration (Peripheral /Central).
  • Instructions for use.
  • Expiration date.
  • Storage conditions.

7.0 RESPONSIBILITY

The TPN compounding pharmacists/Asst. pharmacists in Hospitals:
  • Shall follow strictly the safe compounding guidelines for TPN preparations as per the international standards.

Head of Pharmacy/Compounding Supervisor:
  • Shall ensure that the compounding staff are competent and the TPN compounding process is conducted as per the approved aseptic safe compounding standards.
8.0 RELATED DOCUMENTS

8.1 Compounding Sterile Preparations (MH-DGMS-PH-40)
8.2 Pharmacy Departmental Safety Policy (MH-DGMS-PH-06)
8.3 High Alert Medications (MH-DGMS-PH-35)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aseptic Processing Chapter 18 - Preparation of Parenteral Nutrition TSET, ORG, UK</td>
<td>NHS Pharmaceutical Technical Specialist Education &amp; Training</td>
<td>2010</td>
<td>24</td>
</tr>
<tr>
<td>A.S.P.E.N. Parenteral Nutrition safety consensus recommendations.</td>
<td>Phil Ayers &amp; Others</td>
<td>2013</td>
<td>38</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION

Bevacizumab (Avastin) is a vascular endothelial growth factor (VEGF) specific angiogenesis inhibitor. It is approved by Food and Drug Administration (FDA, US) to treat metastatic colorectal cancer etc. Off-label uses include treatment of age-related macular degeneration (AMD).

Intravitreal bevacizumab administration is now used as a first line therapy for several diseases by many retina specialists and these accounts for more than 50% of anti-VEGF administrations in the US. Additionally, the markedly lower cost of bevacizumab as compared to similarly effective drugs has led it its adoption for treatment of exudative AMD throughout the world.

Bevacizumab for Ophthalmology use, is included by WHO in the Essential list of Medicines, March 2017 as cost effective and safe alternative.

It may be noted that any compounding of a single vial of drug into multiple dose units including Bevacizumab will carry some risk of microbial and particulate cross contamination beyond that associated with preparation of a single dose. This risk can be minimized by performing the procedure in an aseptic clean room using trained staff and storing the finished product in a refrigerator.

2.0 SCOPE

All Regional Hospitals in MOH equipped with a certified vertical laminar airflow hood and have competent trained pharmacists for aseptic compounding of Bevacizumab for ophthalmology use.

3.0 PURPOSE

3.1 To set a standard preparation guidelines and procedures for safe compounding of bevacizumab for Ophthalmic use, in the Pharmacy departments in MOH hospitals as per the international guidelines.

3.2 To provide a cost-effective and safe product to ensure appropriate management of the increasing cases of Neovascular age-related macular degeneration (AMD) and other approved indications in the Ministry according to international accepted norms.

4.0 DEFINITION

Compounding: Is defined by FDA as “The preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner’s prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice.”

5.0 POLICY

5.1 Only Pharmacists and Assistant Pharmacists trained and proficient in the aseptic techniques and procedures should be authorized to prepare Bevacizumab for ophthalmic use.
5.2 Only regional hospitals equipped with a certified vertical laminar airflow hood and have properly trained pharmacists shall perform the compounding of Bevacizumab for ophthalmology use.

5.3 Bevacizumab has to be prescribed by Consultant and Sr. Specialist Ophthalmologists, and to be given by competent trained ophthalmologists as per the Central Drug committee (CDC) decision. Al Nahdha hospital should maintain an updated list of trained doctors.

5.4 An updated list of Pharmacists and Assistant Pharmacists trained in compounding of Bevacizumab should be maintained at Al Nahdha Hospital with a copy to DGMS.

6.0 PROCEDURE

6.1 Compounding of Bevacizumab 1.25mg/0.05mL for ophthalmic must be performed strictly as per the attached procedure (Annex A).

6.2 The pharmacist should assign appropriate expiration dates to the compounded Bevacizumab products; based on documented stability data. The total shelf should not exceed forty days (40) maximum. Injecting freshly prepared products is always advisable to minimize the potential microbial growth.

6.3 The compounded product must be labeled with the necessary particulars or documentation referenced with Generic name, Strength, Dosage form, Volume, Preparation date, Expiry date, Pharmacy Lot Number, Storage conditions, Instructions for use, etc.

6.4 The preparation worksheet (Annex-B) for each compounded batch should include the formula, procedure, labeling instructions, source of the formula, batch number, expiry date, name and signature of the compounder and the cross checked by compounding supervisor.

6.5 A log in the compounding facility shall include details of all compounded items like batch records, name and signature of compounder and date of dispensing. The supervising pharmacist also should sign the compounding records. The records must be kept for a period of one year.

6.6 Details of patient’ name and pharmacy batch no. administered must be maintained in the log/system in the facility where Bevacizumab is injected.

6.7 Two Random syringes from each batch should be sent for bacterial culture sensitivity testing. Only when culture is found to be negative the released batches should be send for use.

6.8 Transport of products prepared in Royal Hospital or Al Nahdha Hospital to other regional hospitals should be made through direct transport in a cool box with appropriate number of ice bags. Data logger thermometer should be used to ensure the maintenance of cold chain storage during transport at (2-8°C). Temperature readings should be documented and filed.

6.9 Quality-assurance principles for compounding sterile products should be followed, and methods should be established to validate all procedures and processes related to sterile product preparation.

6.10 The compounder should adhere to established safety guidelines for handling cytotoxic or other hazardous agents, while preparing of ophthalmmic products from such products.
7.0 RESPONSIBILITY

The compounding pharmacists/Asst. pharmacists in Hospitals:

- Shall follow strictly the safe compounding guidelines as per the international standards.

Head of Pharmacy/ Compounding Supervisor:

- Shall ensure that the compounding staff are competent and the process is conducted as per the approved safe compounding procedures.

8.0 RELATED DOCUMENTS

Compounding Sterile Preparations Policy (MOH-DGMS-PH-40)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safe Preparation and Administration of Intravitreal Bevacizumab Injections</td>
<td>Beth Anne Frost, Marion A. Kainer, The New England Journal of Medicine</td>
<td>2011</td>
<td>1</td>
</tr>
<tr>
<td>Bevacizumab in eye conditions: issues related to quality, use, efficacy and safety, report by the decision support unites. Nice published version</td>
<td>Edith Poku, John Rathbone, Emma Everson-Hock, Munira Essat, Ruth Wong, Abdullah Pandor, Allan Wailoo</td>
<td>2012</td>
<td>171</td>
</tr>
<tr>
<td>Evaluation of compounded bevacizumab prepared for intravitreal injection, JAMA Ophthalmology</td>
<td>Yannuzzi NA1, Klufas MA1, Quach L2, Beatty LM2, Kaminsky SM2, Crystal RG2, D’Amico DJ1, Kiss S1. Dept. of Ophthalmology, New York</td>
<td>2015</td>
<td>1</td>
</tr>
<tr>
<td>Section 21 Ophthalmological Preparations Bevacizumab - Addition Application submitted by International Council of Ophthalmology</td>
<td>Ivo Kocur WHO</td>
<td>2016</td>
<td>11</td>
</tr>
</tbody>
</table>
Annex - A

Compounding procedure for Bevacizumab 1.25mg/0.05mL

Product:
Bevacizumab 1.25mg/0.05mL Intravitreal/Subconjunctival 0.15 mL eye injection

Ingredients:
Bevacizumab 100 mg/4mL or 400mg/16 mL vial

Packaging:
0.15 mL sterile syringe (1.25mg/0.05mL plus 0.1ml overfill) OR as per the pack size recommended by the Consultant Ophthalmologist (0.12 mL, 0.13 mL, 0.15 mL)

Materials and requirements as per USP 797
- An aseptic clean room
- Trained pharmacists/Asst. Pharmacists
- Bevacizumab 100 mg/4mL or 400mg/16 mL vial
- 1 mL syringe, a sterile Luer-Lock,
- Refrigerator graded at 4°C
- Cool box with data logger thermometer (maintain cold chain 2-8°C)

Method of preparation:
Under a vertical flow hood, using precautions for handling cytotoxic;
1. Spray the vial with Industrial Methylated Spirit IMS 70% inside cytotoxic cabinet. Let it dry
2. Aspirate the required volume for injection (total 0.15mL).
3. Remove the needle and cover with Leur-Lock.
4. Stick the appropriate label in the syringe and transfer in an amber plastic container and sealed.
5. Pick 2 samples randomly from each prepared batch and send to microbiology for culture with completed culture form.
6. Quarantine prepared products with note signed by the pharmacist until receiving result of the sterility test.
7. The attached worksheet for each compounded batch should be filled and signed by the Compounder, and cross checked by the Supervisor.
8. The details of all compounded items like batch number, preparation date, name of the compounder etc. shall be included in the Pharmacy Compounding log.
9. The released batches then send to the end user in appropriate cool box.

Sample label:
Bevacizumab 1.25mg/0.05mL + 0.1mL extra (Total 0.15mL)
Intravitreal
Pharmacy Lot No:
Preparation date:
Exp. Date:
Refrigerate at 2-8°C. Do not freeze.
Protect from light. Do not shake.

Stability:
Stable for 90 days as per references, but according to the risk of transfer and cold-chain management, it is preferable to be used within 40 days.

Storage:
- Refrigerate at 2-8°C, strive for 4°C
- Do not freeze
- Protect from light
- Do not shake

Special notes:
- The vial must be inspected visually for any discoloration or particulate matter before preparation.
- Discard any unused portion left in a vial.
- Check the results of sterility test since the product does not contain any microbial preservative.
- After releasing from microbiology sterility test, the pharmacist should sign for approval and later on can be distributed for another health unit. (Cold chain should be maintained, 2-8°C)
**PREPARATION WORKSHEET**

**Preparation Name:** Bevacizumab 1.25mg/0.05ml  
**Strength:** 1.25mg/0.05ml

<table>
<thead>
<tr>
<th>Sr</th>
<th>Ingredient Name</th>
<th>Quantities required for the preparation</th>
<th>Total No: of packs prepared</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Bevacizumab 100mg/4ml or 400mg/16ml Mfr:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Batch:</td>
<td>Exp:</td>
<td></td>
</tr>
</tbody>
</table>

**Total Volume required:** Each syringe contain 0.15ml (0.05ml plus 0.1ml overfill)  
**Pharmacy Batch No.:**

**Shelf Life:** 40 days  
**Expiry date:** / / 

**Procedure:**
1. Spray the vial with IMS 70% inside cytotoxic cabinet. Let it dry.
2. Aspirate the required volume for injection plus extra (total 0.15ml)
3. Remove the needle cover with luer lock.
4. Stick the appropriate label in the syringe and transfer in an amber plastic container and sealed.
5. Inform the ward and ask medical orderly to send it along with log book for issuing and receiving.

**Storage:**
Protect from light and refrigerate. (2-8°C)

**Stability:**
40 days refrigerated

**Label:**
Print and Fix the label instructions supplied to the patient

**Prepared by:** .................................................. Date: ........../........../.............

**Checked by:** .................................................. Date: ........../........../.............
1.0 INTRODUCTION

Food and Drug Administration in the United States (FDA, US) has operated an efficient Drug Quality Reporting System since the early 1970’s, which encourages health care professionals to voluntarily, report observed or suspected defects or drug quality problems.

The Directorate General of Medical Supplies, DGMS is operating a structured and well defined Drug Quality Reporting Program (DQRP), since 2002 with the objective to monitor and improve the quality, efficacy and safety of medicines procured by MOH and encourages health care professionals to voluntarily report observed or suspected defects or quality problems aiming to:

- Rapidly identify significant health hazards.
- Monitor and improve the quality of medicines.
- Operate an efficient centralized reporting system.
- Support Ministry of Health procurement policy of generic drugs.
- Maintain database on quality information of procured items for guidance in the selection process during the tenders.
- Exchange quality reports between MOH in other GCC Countries.

2.0 SCOPE

Quality Surveillance of medicines purchased by MOH.

3.0 PURPOSE

3.1 Operate efficient centralized quality surveillance and reporting system to monitor and ensure good quality, efficacy and safety of Drugs purchased by the Ministry of Health.

3.2 Efficient pharmacovigilance and risk minimization practices.

4.0 DEFINITION

Drug Quality Reporting System: Is a mechanism that facilitates voluntary drugs quality problems reporting by the healthcare professionals to identify product quality issues that require corrective action to ensure patients safety.

5.0 POLICY

5.1 DGMS shall operate an efficient drug quality reporting program in coordination with all concerned parties to ensure efficacy and safety of drugs purchased by MOH as per the required specifications.

5.2 If a product defect is suspected to be a widespread problem which may be detrimental to patients, the Quality Report should be forwarded to DGMS within 24 hours for urgent processing.
5.3 Health care professional are encouraged to report voluntary drug quality problems encountered during their practice.

6.0 **PROCEDURE**

6.1 The Reporting Mechanism:

- Health Care Professionals should fill-in the Drug Quality Reporting form (Annex A) and forward the same through the Director/Head of Pharmacy & Medical Stores in the Regions/Hospitals to Head of Quality Management & Medicines Safety, DGMS, MOH, Muscat through Fax: 22358333 / 22358340 or E-mail: dgms123moh@gmail.com. The original form and defected samples to be send by mail in a weeks’ time.

- Electronic copy of Quality Reporting Forms is readily available online in MOH website (https://www.moh.gov.om/documents/71477/121151 QUALITY+REPORTING+DRUG/) and the same will be available through Al Shifa system for ready reference.

- Sending Drug Quality reports for items purchased by the Directorate General of Medical supplies (DGMS) to other Directorates other than DGMS will not be considered or processed, as it may lead to delay in processing of actions and overlapping of responsibilities.

- The required quality issues to be reported as specified in the drug quality reporting form are:

  - Not effective: Patients complaint, Clinical evaluation.
  - Non-compliance with specifications: Chemical properties, Physical changes, Microbial contamination.
  - Difficulty in use: Taste, odour, size, opening, closure, storage, others.
  - Packaging Materials: look alike, outer pack, inner pack, label, cartons, poor quality.
  - Pack insert: Required information not available, others.

6.2 The Role of Pharmacists / Assistant Pharmacists in Health Units:

The Pharmacist / Assistant Pharmacist in the health units has an important role, which includes:

- Promote the quality reporting among health care professionals.
- Review the quality problem, provide essential information.
- Checking the stock of defected samples.
- Ensure that the designated drug quality forms is completed with full details including the item code, batch number, name of manufacturer, country of origin.
- Send the defected samples to DGMS.

6.3 Actions taken by DGMS:

Quality reports are processed in coordination with all concerned departments as follows:

6.3.1 Quality Management & Medicines Safety Section:

- To enter the quality reports in the DQRP database, screen and categorize the reports into three priority classifications depending on the severity of the problem as:
✓ Priority A: May pose serious health hazard.
✓ Priority B: Potentially significant manufacturing problem.
✓ Priority C: Routine follow-up.

• To send feedback to Health Units about the action taken by DGMS.
• To publish an annual booklet on drug quality reports received and distribute the same to all Health Units in MOH, other Governmental Health Institutions in Oman & Executive Office GCC Health Minister’s Council indicating the generic name of the drug, the manufacturer, batch no., the name of the reporting health unit(s), the profession of the reporter, the complaint and the action taken by DGMS against each item.
• To document and maintain quality reports data-base and take follow up actions as appropriate.

6.3.2 Department of Drug Stores/ Regional Medical Stores:
• To check physically the available stock for occurrence of similar complaint.
• To circulate to Health units informing about the complaints received to check their stock.
• To refer the suspected samples for QCL for re-analysis in case of physical changes and contamination.
• DDS to send recall letters for the defected products if recall process is initiated.

6.3.3 The Department of specification and Supplies :
• To communicate with the respective suppliers about the reported quality problems to provide clarification and the corrective and preventive action taken to avoid occurrence of such incidences.
• To communicate with the Suppliers to collect back any rejected or recalled products and to replace the same from fresh batches of acceptable quality.
• To consider the negative quality reports and looks alike reports on evaluation of the offers in the tenders and to exclude products that may pose health hazards to publics and products with poor quality.

7.0 RESPONSIBILITY

Directorate General of Medical Supplies (DGMS):
• Implement an efficient Drug Quality Reporting System for items purchased by MOH.
• Maintain database on quality information of procured items for guidance in the selection process during the incoming tenders.

Healthcare professionals in MOH units:
• Monitor and voluntarily report any drug quality problems to DGMS in the specified format.
8.0 RELATED DOCUMENTS

8.1 Procurement of Medicines (MOH-DGMS-PH-11)
8.2 Look Alike and Sound Alike (MOH-DGMS-PH-36)
8.3 Handling Drug Recalls (MOH-DGMS-PH-38)

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA Drug Quality Reporting System (DQRS)</td>
<td>USFDA</td>
<td>2015</td>
<td>15</td>
</tr>
</tbody>
</table>
### SULTANATE OF OMAN
### MINISTRY OF HEALTH
### DIRECTORATE GENERAL OF MEDICAL SUPPLIES

#### (Annex-A)

**DRUG QUALITY REPORTING FORM**

<table>
<thead>
<tr>
<th>Name of Health Unit</th>
<th>Governorate</th>
</tr>
</thead>
</table>

**PRODUCT:**

- Trade Name: ............................................
- Generic Name: ............................................
- Strength: ............................................
- Dosage form: ............................................
- Item code: ............................................
- Batch No: ............................................
- Mfg. date: ............................................
- Expiry date: ............................................

**Manufacturer & Country of Origin:** ............................................

**QUALITY PROBLEM (S):**

- ( ) Not effective: Patient’s Complaint ☐ Cliniсal evaluation ☐
  Specify ............................................

- ( ) Non-compliance with specifications: Chemical ☐ Physical ☐ Microbial ☐
  Specify ............................................

- ( ) Difficulty in use: Taste ☐ Odour ☐ Size ☐
  Opening ☐ Closure ☐ Storage ☐ Others ☐
  Specify ............................................

- ( ) Packaging Materials: Look-alike ☐ Outer pack ☐ Inner pack ☐
  Cartons ☐ Poor Quality ☐ Labels ☐
  Specify ............................................

- ( ) Pack Insert: Required information not available ☐ Others ☐
  Specify ............................................

Tick (☐) in case of quality problem; specify details and forward defected samples of drug/s as applicable.

<table>
<thead>
<tr>
<th>Reporter’s name</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature</td>
<td>Date</td>
</tr>
</tbody>
</table>

**Note:** To be filled in by the Physician, Pharmacist / Assistant Pharmacist or Nursing Staff concerned and forwarded through the Director / Head of Pharmacy & Medical Stores to The Head of Quality Management & Medicines Safety, DG Office, DGMS, MOH, Muscat, Fax: 22358340 / 22358333 with copy to the Director of Drug Stores, DGMS.
1.0 INTRODUCTION

The Directorate General of Medical Supplies, DGMS is operating a structured and well defined Surgical and Laboratory Quality Reporting Program since 2008 which encourages health care professionals to voluntarily report observed or suspected defects or quality problems of medical devices purchased by the Ministry to rapidly identify significant health hazards and monitor and improve the quality of products.

Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices. In addition, medical devices include in vitro diagnostic products, such as general purpose lab equipment, reagents, and test kits, which may include monoclonal antibody technology. Certain electronic radiation emitting products with medical application meet the definition of medical device. Examples include diagnostic ultrasound products, x-ray machines and medical lasers.

FDA classifies medical devices based on the risks associated with the device as:

Class I: Low Risk Devices; Are subject to the least regulatory controls. Example, Bandages, dental floss, examination gloves, enema kits and elastic bandages. 47% of medical devices fall under this category and 95% of these are exempt from the regulatory process.

Class II: Medium Risk Devices; Require greater regulatory controls to provide reasonable assurance of the device’s safety and effectiveness. Example, electric wheelchair, some pregnancy test kits. 43% of medical devices fall under this category.

Class III: Highest Risk Devices; Are generally subject to the highest level of regulatory control, they must be approved by FDA before they are marketed. Example, implantable pacemakers and breast implants heart valves, brain stimulators, and coronary stent. 10% of medical devices fall under this category.

2.0 SCOPE

All Medical Devices (Surgical and Laboratory consumables) purchased by the Ministry of Health.

3.0 PURPOSE

3.1 Operate an efficient centralized quality surveillance and reporting system to monitor and ensure good quality, efficacy and safety of Medical Devices purchased by the Ministry of Health.

3.2 Efficient pharmacovigilance and risk minimization practices.
4.0 DEFINITION

A medical device: Is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is intended for use in the diagnosis, treatment/cure, mitigation or prevention of disease in humans or animals and does not act through chemical actions or which does not need to be metabolized before acting.

Medical Devices Quality Surveillance & Reporting: Is one of the Quality surveillance tools to monitor device performance, detect potential device-related safety issues of Surgical and laboratory consumables purchased by MOH and contribute to benefit-risk assessments of these products.

5.0 POLICY

5.1 DGMS shall continue to operate an efficient Medical Devices quality surveillance and reporting program in coordination with all concerned parties to ensure efficacy and safety of medical devices purchased by MOH as per the required specifications.

5.2 If a product defect is suspected to be a widespread problem which may be detrimental to patients, the Quality Report should be forwarded to DGMS with 24 hours for urgent processing.

5.3 Health care professionals, patients and caregivers are encouraged to submit voluntary reports about product quality issues, and therapeutic failures and serious adverse events that may be associated with use medical devices. These reports, along with data from other sources, can provide critical information that helps improve patient safety.

6.0 PROCEDURE

6.1 The Reporting Mechanism:

6.1.1 Health Care Professionals should fill the Surgical Quality Reporting Form (Annex A) or Laboratory Consumables Quality Reporting Form (Annex B) as applicable and forward the same through the Director/Head of Pharmacy & Medical Stores in the Regions/Hospitals to the Head of Quality Management & Medicines Safety, DGMS, MOH, Muscat through Fax: 22358333 / 22358340 or E-mail: dgms123moh@gmail.com The original form and defected samples to be send by mail in a weeks’ time.

6.1.2 Sending Surgical and Laboratory Quality reports for items purchased by the Directorate General of Medical supplies (DGMS) to other directorates other than DGMS will not be considered or processed, as it may lead to delay in processing of actions and overlapping of responsibilities.

6.1.3 Electronic copy of Quality Reporting Forms will be available online through Al Shifa system for ready reference.

6.1.4 Medical devices quality complaints reported may include; but not limited to:

- Failure
- Malfunction
- Improper or inadequate design
• Manufacturing Problem
• Labeling

6.2 The Role of Pharmacists / Assistant Pharmacists in Health Units:
The Pharmacist / Assistant Pharmacist in the health units has an important role, which includes:
• Promote the quality reporting among health care professionals.
• Review the quality problem, provide essential information.
• Checking the stock of defected samples.
• Ensure that the designated Surgical/Laboratory Reporting Quality Form is completed with full details of quality complaints including the DGMS item code, batch number, catalogue no., name of manufacturer, country of origin.
• Send the quality report along with the defected samples to DGMS.
• Provide the reporting health care professional with DGMS feedback, if available.

6.3 Actions taken by DGMS:
Quality reports are processed in coordination with all concerned departments as follows:

6.3.1 Quality Management & Medicines Safety Section:
• To enter the quality reports in the database, screen and categorize the reports into three priority classifications depending on the severity of the problem as:
  - Class I: Low Risk Devices;
  - Class II: Medium Risk Devices
  - Class III: Highest Risk Devices
• To send feedback to Health Units about the action taken by DGMS.
• To publish an annual booklet on Medical Devices quality reports received and distribute the same to all Health Units in MOH, indicating the action taken by DGMS against each item.
• To document and maintain quality reports data-base and take follow up actions as appropriate.

6.3.2 Department of Medical Stores/ Regional Medical Stores:
• To check physically the available stock for occurrence of similar complaint.
• To circulate to Health Units informing about the complaints received to check their stock.
• The Department of Medical Stores, DGMS to send recall letters for the defected products if recall process is initiated.

6.3.3 The Department of specification and Supplies:
• To communicate with the respective suppliers about the reported quality problems to provide clarification and the corrective and preventive action taken to avoid occurrence of such incidences.
• To communicate with the concerned suppliers to collect back any rejected or recalled products and to replace the same from fresh batches of acceptable quality.

• To consider the negative quality reports on evaluation of the offers in the tenders and to exclude products that may pose health hazards to publics and products with poor quality.

7.0 RESPONSIBILITY

Directorate General of Medical Supplies, DGMS

• Implement an efficient Medical Devices Quality Reporting System for items purchased by MOH.

• Maintain database on quality information of procured items for guidance in the selection process during the incoming tenders.

Health care professionals in MOH Healthcare units:

• Shall monitor and voluntarily report any Medical Device quality problems to DGMS in the specified format.

8.0 RELATED DOCUMENTS

N/A

9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/ journal/ articles/ Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vigilance Reporting for Medical Devices in the EU</td>
<td>Salma Michor</td>
<td>2009</td>
<td>6</td>
</tr>
<tr>
<td>Medical device reporting</td>
<td>Thomas Gray &amp; John W. Montana State Hospital</td>
<td>2015</td>
<td>3</td>
</tr>
<tr>
<td>Medical Devices Reporting (MDR)</td>
<td>Dept. of health &amp; Human Services, FDA</td>
<td>2017</td>
<td>32</td>
</tr>
</tbody>
</table>
Annex A

SULTANATE OF OMAN
MINISTRY OF HEALTH
DIRECTORATE GENERAL OF MEDICAL SUPPLIES

SURGICAL CONSUMABLES / DISPOSABLES
QUALITY REPORTING FORM

Health Unit: ......................................................... Governorate: .................................................
Name of the Department: ..........................................................................................................................

1. Item Description: .................................................................................................................. Code: ........
2. Cat. No.: ................................ Lot No./ Batch No.: ............................................................
3. Manufacturer: .........................................................................................................................

4. Detailed description of the problem encountered:
..........................................................................................................................................................

5. Is it batch related problem: Yes [ ] No [ ]

6. How frequent?
(a) With every piece [ ] (b) Most of the time [ ] (c) Very sporadic [ ]

7. Your experience with the item in question:
(a) Long time experience [ ] (b) Short time [ ] (c) First time (new arrival) [ ]

Please indicate date of receiving: ............................................................................................

8. Was the item used for indicated purpose: Yes [ ] No [ ]

9. Do you expect the above problem encountered by other users: Yes [ ] No [ ] No Idea [ ]

10. Could the problem be related to:
    a) Availability of New Devices [ ]
    b) Change of Techniques, Procedure [ ]
    c) Change of Equipment, Instrument [ ]

11. Do you recommend a suitable alternative? Yes [ ] No [ ]

If yes, give description: ..................................................................................................................

Reporter’s name: ......................................................... Designation: .................................................
Signature: .........................................................
Date: ......................................................... Health Unit stamp

Note: To be filled in by the staff concerned and forwarded through the Director / Head of Pharmacy & Medical Stores to The Head of Quality Management & Medicines Safety, DGMS, MOH, Muscat, Fax: 22358340 / 22358333 with a copy to the Director of Medical Stores, DGMS.
## LAB REAGENTS / CHEMICALS / DISPOSABLES
### QUALITY REPORTING FORM

Health Unit : ........................................... Governorate : ...........................................

Item computer code : .................................. Cat No : .................................. Lot No : .................

Item description : ................................................................. Expiry : ...........................................

No. of kits complained : .................................. Mfr Name : ...........................................

No. of kits received : .............. Date of receipt of kits : .............. No. of kits on stock : ..............

Performance : Manual □  Semiautomatic □  Automatic □

Analyzer name : .................................................................

Control(s) used : .................................. Cat.No.: .................................. Lot No: ..................................

Expiry : ...........................................

Target value : ...........................................

Results : ...........................................

Sample material : .................................................................

Comparative test done?  Manufacturer 1/Name: Method 1:

................................................................. Please attach results

No □  Yes □  Manufacturer 2/Name: Method 2:

................................................................. Please attach results

Detailed failure description: (If available attach copies from application, printouts, photos etc.
Give patient’s data, clinical status, former and follow up results, etc...)

.................................................................

Actions and investigations already performed:

Customer’s results confirmed by own testings No Yes □  □ Please attach results

With customer’s reagent No Yes □  □ Please attach results

With fresh stock reagent No Yes □  □ Please attach results

Test procedure checked No Yes □  □ Please attach results

Other actions/investigations done No Yes □  □ Please attach results

Reporters name ................................................................. Designation ..................................................

Signature .................................................................

Date ................................................................. Health Unit stamp

Note: To be filled in by the staff concerned and forwarded through the Director / Supdt. / Head of Pharmacy & Medical Stores to The Head of Quality Management & Medicines Safety, DGMS, MOH, Muscat, Fax: 22358340 / 22358333 with a copy to the Director of Medical Stores, DGMS.
1.0 INTRODUCTION

World Health Organization (WHO) defines pharmaceutical promotion as “all information and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/ or use of medicinal drugs”. Drug promotion has a key role to stimulate prescription and sales of pharmaceuticals. It has also an important negative impact on the rational use of pharmaceuticals, drug price-control mechanisms, availability and use of essential drugs, equity of drug distribution and the cost of health care system. It thus becomes a public health concern when newer more expensive medicines displace older, less costly ones without any evidence of an improvement in therapeutic outcome.

Ministry of Health do appreciate the role that healthcare companies play in assisting health practitioners to provide safe, effective and economic products and services to the patients in their care. Medical Representatives can provide useful information about medicinal products to MOH staff. However it is important that this is provided in a way that does not impact on patient care and the operation of wards and departments and provided in strict adherence to MOH approved codes or policies regulating the promotional activities in Oman.

2.0 SCOPE

Medical Representative’s visits to MOH Health Units.

3.0 PURPOSE

To regulate the activity of Medical Representatives visiting MOH Healthcare facilities to ensure controlled access, patient privacy, formulary management goals.

4.0 DEFINITION

Medical Representatives: Are those individuals employed by commercial enterprises whose responsibility may include the marketing, sale, provision of information, or other form of promotion of drug products, drug related devices and other medical equipment.

5.0 POLICY

5.1 This policy is an internal supportive guideline and not intended to replace any approved national codes or policies regulating the promotional activities in MOH Healthcare Units.

5.2 Medical Representative’s access is prohibited in any patient care area, Laboratories and Pharmacy & Medical Store (drug dispensing areas).

5.3 Medical Representatives are only allowed to visit MOH Healthcare Units to present product information on appointment only. Pharmacy administrative area and education auditorium/classrooms are permitted without prior appointment.
5.4 Appointments will be limited to the working hours (Sunday through Thursday 8:00 AM- 2:00 PM), as per the time specifically scheduled by each individual Health Unit. The Medical Representative should be oriented about the time schedule for visit.

5.5 Any Representative found without an appointment in any restricted access area in violation of the promotion regulations will be subject to the appropriate disciplinary action that may involve banning his visits to MOH Healthcare Units.

5.6 Direct receipt or distribution of breast milk substitutes by baby milk companies is strictly prohibited as per Omani code for marketing of breast milk products as it contradict with MOH policy encouraging breast milk feeding.

6.0 PROCEDURE

6.1 The Medical Representatives will only be allowed to areas which have been previously approved as above policy.

6.2 Medical Representatives may detail staff about formulary medications, and must notify physicians and professional staff when a medication is under restriction.

6.3 The Medical Representatives are generally prohibited from:

- Detailing in any restricted access area without prior approval.
- Leaving samples in unapproved areas.
- Posting or leaving any promotional material in unapproved areas.
- Providing misleading or dishonest impression, suspicion on effectiveness or quality of products purchased by the Ministry of Health from other suppliers i.e., generics.
- Providing any sort of promotion or distribution of Breast Milk Substitutes in any Health Units.

6.4 Free reduced medical samples of approved drugs may be supplied to health care providers in small quantities. e.g., two samples maximum. These samples must not be used for treatment of the patients in the health units.

6.5 Samples of Narcotic & Psychotropic drugs or other controlled should not be distributed.

6.6 Frequency and duration of visits of Medical Representatives should be minimized to avoid disturbance or distraction in work.

6.7 In case of violation, the matter and name of the violating medical representative should be reported to the Hospital / Health unit Director.

7.0 RESPONSIBILITY

All Medical, Pharmacy, Nursing and other MOH healthcare workers (“professional staff”) should:

- To ensure that Medical Representatives abide by the code of practice and MOH regulations and to report any non-compliance while interacting with the Medical Representatives.

8.0 RELATED DOCUMENTS

N/A
## 9.0 REFERENCES

<table>
<thead>
<tr>
<th>Title of book/journal/articles/Website</th>
<th>Author</th>
<th>Year of publication</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASHP Guidelines for Pharmacists on the Activities of Vendors Representatives in Organized Healthcare Settings System</td>
<td>ASHP Board of Directors</td>
<td>1998</td>
<td>2</td>
</tr>
<tr>
<td>Drug Promotion – What we know, What we have yet to learn?</td>
<td>Pauline Norris Andrew, Joel, Peter Mansfield, HAI Europe &amp; WHO</td>
<td>2004</td>
<td>102</td>
</tr>
<tr>
<td>Pharmaceutical Representative Policy &amp; Procedure – New Hanover Regional Medical Center</td>
<td>Albert Meyer Mary Ellen, Mark Allen</td>
<td>2010</td>
<td>4</td>
</tr>
<tr>
<td>Pharmaceutical Representatives Policies and Procedures</td>
<td>Quality and Patient Safety Committee, Royal Hospital for Women, Australia</td>
<td>2015</td>
<td>3</td>
</tr>
<tr>
<td>Guidelines for Medical Representative visiting Trust premises</td>
<td>Chief Pharmacist, Northamptonshire, NHS</td>
<td>2016</td>
<td>5</td>
</tr>
</tbody>
</table>