



To:  
Director General of Royal Hospital  
Director General of Khoula Hospital  
Director General of Medical Supplies, MOH  
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Health Institutions)  
Director General of Primary Health Care, MOH  
Director General of Specialized Medical Care, MOH  
Director General of Quality Assurance Centre, MOH  
Director General of Health Services in all Governorates  
Director of Rational Use of Medicine (MOH)  
Hospital Director (Al Nahda Hospital)  
Hospital Director (Al Massara Hospital)  
Hospital Director (Sultan Qaboos Hospital)  
The Head of Medical Services in SQU Hospital  
The Head of Medical Services in Royal Oman Police  
The Head of Medical Services in Ministry of Defence  
Director General of the Public Authority for Civil Defence & Ambulance  
The Head of Medical Services in The Diwan  
The Head of Medical Services in The Sultan's Special Force  
The Head of Medical Services in Internal Security Services  
The Head of Medical Services in Petroleum Development of Oman  
The Head of Medical Services in LNG Oman  
Director of Pharmacy of Qaboos Comprehensive Cancer Care & Research Center  
Director of Pharmacy & Medical Stores in all Governorates (for distribution pls.)  
Marketing Authorization Holders & Pharmaceutical Companies  
All Private Pharmacies & Drug Stores

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After Compliments,

Please find attached our Circular No. 189 Dated 3/9/23 regarding the **Monitored Medicines (MM)**

This has reference to our previous circular no. 162/2023 dated 25/07/2023, this is to inform you that the list and regulations of the monitored medicines (MM) were recently revised by this directorate. The revised list and regulations are attached.

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Head of Narcotic Drugs & Psychotropic Substances committee
- Head of Narcotic Drugs & Psychotropic Substances Inspection Team
- Section Head (Controlled Drugs)
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Medical Device Control, DGPA&DC
- Director of Central Quality Control Lab, DGPA&DC



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المديرية العامة للصيدلة والرقابة الدوائية  
Directorate General of Pharmaceutical  
Affairs & Drug Control





### **Sub: Monitored Medicines**

Definition: monitored medicines (MM) are prescription only medicines (POM) that are being monitored particularly closely by the Directorate General of Pharmaceutical Affairs and Drug Control. These medicines undergo additional restrictions on their import, prescribing, dispensing, storage and records. The revised list is attached in (Annexure 1) and the following regulations will be binding for these medicines with immediate effect. The restrictions are described as follow:

#### **1. IMPORT**

- 1.1. Import will be allowed against a 'no objection certificate' (NOC) issued in advance by this directorate on request only for the following consignments:
  - Samples for registration purpose.
  - Samples for government tenders.
  - Consignments to supply the private market, government and semi-government institutions.
- 1.2. NOC letter will be issued against submission of an online application through MOH e-portal. A copy of the institution's LPO should be submitted along with the online application, if the consignment is for government tenders/a specific private health institution.
- 1.3. The NOC is only granted to government health institute and/or medical stores.
- 1.4. NOC letter can be used for multiple imports and valid for one year only.
- 1.5. Applications for samples for government tenders/registration purpose, do not require LPOs.
- 1.6. Imports of 'free medical samples' for (MM) will not be allowed.
- 1.7. Approval to release a shipment containing (MM) is only against an e-portal request supported with necessary documents including the NOC and one clearance invoice for each request.
- 1.8. A copy of the delivery note signed by the receiving party should be maintained and submitted to MOH upon request.



## 2. PRESCRIPTION & DISPENSING

All (MM) should be dispensed only against prescription as follows:

2.1. White prescription

2.2. Prescription should clearly show the:

- Name of patient
- Patient ID number
- Patient registration file number
- Age
- Sex
- Department
- Health institution/establishment stamp
- Treatment details:
- Drug generic name
- Quantity to be dispensed (in numbers and letters)
- Dose & frequency for use.
- Date of prescription
- Name, stamp & signature of prescriber.

2.3. For prescriptions issued by private health establishments, the dispensed quantities should not exceed the dose of 30 days.

2.4. For prescriptions issued by government health institutions, full prescribed quantities can be dispensed.

2.5. Validity of the prescription is 10 days from the date of issue.

2.6. Pharmacist should mention the total quantity dispensed, the date and his / her stamp with the pharmacy seal on the prescription.

2.7. Dispensed prescriptions should be kept for a period of 6 months and presented to MOH upon request.



**3. STORAGE & RECORDS:**

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- 3.1. All medical stores, pharmacies and local pharmaceutical manufacturers should maintain separate registers of the MM as follows
- Stocks in medical stores (Annexure 2).
  - Stocks in pharmacy (Annexure 3).
  - Registration/tender samples in medical store (Annexure 4).
- 3.2. The register should be reviewed, approved by this directorate before any data entries are made.
- 3.3. The dispensed prescriptions should be entered in the relevant registers within 24 hours from the dispensing date.
- 3.4. Submission of (MM) quarterly statements is no longer required.
- The in/out stocks of (MM) will be reviewed by inspection team.
- 3.5. The register should be kept for 12 months from the last day of entry.
- 3.6. Each institution should contract with specialized company to destruct unusable/expired medicines according to para 17/article 37 & para 6/article 34 from the *ministerial decision 113/2020* issuing the executive regulation of the law governing the practice of the pharmacy profession and pharmacy enterprises.

**4. OTHERS:**

Preparations containing Ephedrine, Pseudoephedrine, Phenylpropanolamine, whether they are in plain or combination formulations like, (Pseudoephedrine/Tripolidine or Ephedrine/Chlorpheniramine), are not included in the list of MM and they can be dispensed against normal doctor's prescriptions. They should be imported/exported only against NOC letter issued by this directorate.

All correspondence on this subject be directly addressed to the director of drug control, DGPA&DC. This circular will be effective from the date of its issue and it supersedes all previous circulars in this regard.

Yours faithfully,

AS

**Dr. Mohammed Hamdan Al Rubaie**  
Director General



**PADDC**  
المديرية العامة للصيدلة والرقابة الدوائية  
Directorate General of Pharmaceutical  
Affairs & Drug Control



## Annexure (1)

**List of Monitored Medicines**

S/No.	Description	Remarks
1	Vaccines	Medical stores should distribute vaccines to the private health establishment that are qualified by the Directorate General of Disease Surveillance and Control. The list will be available on the MOH website and updated on regular basis.
2	Biologicals	Biological products derived from blood. Plasma certificate should be provided upon clearance.
3	Dextromethorphan	To be dispensed against a valid prescription.
4	Xanthine derivatives in Paed. Syrup form only (e.g. Caffeine, Theophylline, Theobromine)	To be dispensed against a valid prescription.
5	Isotretinoin	To be dispensed only against prescription issued by Specialist/Consultant in Dermatology.
6	Novatrein	To be dispensed only against prescription issued by Specialist/Consultant in Dermatology.
7	Tretinoion	To be dispensed against a valid prescription.
8	Misoprostol	Prescriptions from private health establishments, should be strictly prescribed by Specialist/Consultant (Obstetric/Gynecologist) for in-patients at private health establishments with labor services.
9	Carisoprodol containing products	To be dispensed against a valid prescription.
10	Mycophenolate	To be dispensed only against prescription issued by Specialist/Consultant.
11	Anabolic steroids (Nandrolone, Oxandrolone, Mesterolone)	To be dispensed against a valid prescription.
12	Growth Hormone	To be dispensed against a valid prescription.
13	Hydroxychloroquine	Allowed to be prescribed by Specialist/Consultant at private health institutions strictly, only for the treatment of Rheumatoid Arthritis, Systemic and Discoid Lupus Arrhythmia.

14	<p>Topical preparations containing plain/combination:</p> <ul style="list-style-type: none"> <li>• Clobetasol</li> <li>• Diflucortolone</li> </ul>	To be dispensed only against the prescriptions issued by Specialist/Consultant (Dermatologists, Clinical Immunologist, Allergist).
15	<p>Topical Preparations containing plain/combination:</p> <ul style="list-style-type: none"> <li>• Alclometasone</li> <li>• Beclomethasone</li> <li>• Betamethasone</li> <li>• Clobetasone</li> <li>• Fluocinonide</li> <li>• Flucortolone</li> <li>• Fluocinolone</li> <li>• Fluticasone</li> <li>• Mometasone</li> </ul>	To be dispensed against a valid prescription.
16	Hydroquinone topical preparations in any concentration	To be prescribed by Specialist/Consultant Dermatologist.
17	Ethyl Chloride Spray	To be dispensed against a valid prescription.
18	Tropicamide	To be dispensed only against prescriptions issued by Ophthalmologist.
19	Heberprot-P	Restricted to health establishments providing diabetic foot care/treatment.
20	Ketamine	To be dispensed against a valid prescription.
21	Esketamine	To be used in hospital with Psychiatry Specialty.





