DRAFT FOR COMMENTS:

Guideline on the Presentation of Labeling Information, PIL and SPC

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Guideline on the Presentation of Labeling Information, PIL and SPC

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Acronyms:

PIL	Patient Information Leaflet
SPC	Summary of Product Characteristics
INN	International Non-proprietary Name
BN / Lot	Batch Number (or Lot Number) identifying a production batch
API	Active Pharmaceutical Ingredient
I.V.	Intravenous route of administration
I.M.	Intramuscular route of administration
S.C.	Subcutaneous route of administration
OTC	Over-the-counter (non-prescription medicine)
Rx	Prescription-only medicine
PR	Prolonged-release
XR/ER	Extended-release
IR	Immediate-release

Definitions

SPC	Summary of Product Characteristics, the technical document for health professionals describing how to use a medicinal product safely and effectively
PIL	Patient Information Leaflet, the document for patients/end-users giving plain-language instructions and information about the medicine.
Marketing Authorization Holder (MAH)	A legal entity that has been granted the marketing authorization to place a medicinal product on the market, and who is legally responsible for marketing that medicine and post marketing activities.
Active Pharmaceutical Ingredient (API)	A substance in a finished pharmaceutical product that provides pharmacological activity or directly affects disease diagnosis, treatment, or prevention, or alters physiological functions in humans.
Pharmaceutical Form	The form in which the medicine is produced and administered (e.g. film-coated tablet, sustained-release tablet, injection, etc.)
Batch Number (Lot)	The identifier of the specific production batch — must be on packaging (labeling) and sometimes on blister/strip units.
Expiry Date (Exp)	The date after which the medicinal product should not be used — must appear on labeling/packaging
Outer Packaging	The secondary packaging (e.g. carton/box) containing the finished product; must carry the required labeling information per the guidance.
Immediate Packaging (Primary Packaging)	The packaging that directly contains the medicinal unit (e.g. blister pack, strip, container) — must also carry minimum particulars if required.
Small Immediate Packaging Units	Very small containers (e.g. less than ~10 ml) where full labeling may be challenging; the guideline provides “minimum particulars” for such units.

CHAPTER ONE

Introduction

The Summary of Product Characteristics (SPC) is the primary source of information for healthcare professionals on the safe and effective use of a medicinal product. The Patient Information Leaflet (PIL) must be prepared in alignment with the SPC.

This guideline outlines the principles for presenting SPC, PIL, and labeling information. Applicants must ensure that each section contains only information relevant to its heading. Where necessary, cross-references may be made to other sections containing related information.

Applications for registration, renewal, or variation must comply with this guideline. Products with different strengths must have distinct packaging color codes to differentiate between strengths. An Arabic translation of the outer packaging information is required for all medicines except those intended solely for hospital use.

Following the approval of the SPC, PIL and labeling contents, such contents cannot be changed without the authority approval (refer to guideline for variation requirements).

Applicants are required to submit SPC, PIL and labeling documents in searchable, readable PDF format that is clean from all stamps, watermarks, signatures, headers or footers.

Purpose

This guideline is intended to guide applicants on how to present the information required by the Drug Safety Center (DSC) for the following:

- Summary of Product Characteristics (SPC)
- Patient Information Leaflet (PIL)
- Labeling

Scope

It is applicable to medicinal products intended for human use when submitting a new application for registration, renewal or variation.

Structure

This is the first version of this guideline and is organized into four chapters. Chapter one covers the Introduction, Purpose, Scope, and Structure. Chapter two outlines the detailed procedures. Chapter three defines responsibilities in relation to this guideline. Chapter four includes the document history and version control table, references, and the Annex.

CHAPTER TWO

Procedure

Applicants must follow a clear and consistent format when presenting the Summary of Product Characteristics (SPC), Patient Information Leaflet (PIL), and labeling. The structure should ensure that information is easy to understand, well-organized, and aligned with regulatory requirements. The following structure must be observed:

I. Labeling:

The data shall be presented in accordance with the template provided in the appendix below, irrespective of their sequence on the actual labeling, their placement, or any repetition on the individual sides or flaps of the packaging (e.g. top flap, front, back, etc.).

A separate text for outer and inner packaging labeling should be completed per strength and per pharmaceutical form.

The applicant shall provide an Arabic translation for specific labeling information components, as outlined in Appendix 5.

A. Particulars to appear on the outer packaging and the immediate packaging

1. **Name of the medicinal product**

   1.1 A standard packaging box has six faces on which information can be displayed. If it is feasible, display a product description on more than three non-opposing faces.

   1.2 Use blank space to emphasize critical information such as the medicine name, generic name and strength.

2. **Statement of active substance(s)**

2.1 Expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight. Where the active substance is present as a salt, this should be clearly indicated.

3. List of excipients

3.1 Express qualitatively those excipients known to have a recognized action or effect. However, if the medicinal product is a parenteral, a topical or an eye preparation or if used for inhalation, all excipients must be stated.

4. Pharmaceutical form and contents

4.1 Contents by weight, by volume or by number of doses or number of units of administration of the medicinal product (e.g. 28 tablets, 100 mL, ...).

For injectable medicine:

4.2 The strength of injectable medicines should be expressed in quantity/unit volume (mg/ml) e.g. : 5mg/ml.

4.3 Include a representation of the full volume strength, e.g.: total quantity in total volume (mg/ml). This should be emphasized for single-dose containers.

4.4 Display concentration in total quantity/total volume, even if other units of concentration such as percentage and ratios are present e.g. (2 %) (20 mg/ml).

5. Method and route(s) of administration

5.1 Method of administration: directions for proper use of the medicinal product, e.g. “Shake well before use”, “Do not chew” and “Shake well before use”. In all cases, and especially if full details cannot be included on the outer packaging itself, a reference to the patient information leaflet must be made: Read the patient information leaflet before use.

5.2 Use positive statements if possible - use “DO” rather than “DO NOT”, e.g. if the drug given for intravenous, use: (For intravenous infusion), rather than (NOT for I.M).

6. Special warning that the medicinal product must be stored out of the reach and sight of children

7. Other special warning(s), if necessary

8. Manufacturing and Expiry dates

8.1 Dates should be expressed with the month given as 2 digits or 3 characters and the year as 4 digits. e.g.: 02/2010, Feb 2010.

8.2 Where applicable, the shelf life after reconstitution, dilution or after first opening the container should be included.

9. Special storage conditions

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

10.1 E.g. radiopharmaceuticals, cytostatics.

10.2 A reference to any appropriate collection system in place should be included on the outer packaging.

11. Manufacturer name

12. Name and address of the marketing authorization holder

13. Batch number

14. General classification for supply

15. Data matrix

16. Global Trade Item Number (GTIN)

17. Serial number

B. Minimum particulars to appear on blisters or strips

1. Name of the medicinal product

1.1. The name and strength of the product should appear over each blister pocket, if the size of the pockets is too small, the information should be repeated in a pattern across the entire strip.

2. Name of the marketing authorization holder

3. Manufacturing and Expiry dates

3.1. Dates should be expressed with the month given as 2 digits or alphabetic characters and the year as 4 digits. e.g.: 02/2010, Feb 2010.

4. Batch number

4.1. Batch number and Expiry date should be at the end of each blister strip, if technically possible this could be applied to both ends.

5. Other

5.1. Space permitting, any other information necessary for the correct use and administration of the product can be included here, e.g. calendar days may be included if the product is taken as a single dose and that is packaged in blister strips that comprise multiples of seven.

C. Minimum particulars to appear on small immediate packaging units

Small immediate packaging units are defined as containers sized up to and including 10 ml. On a case-by-case basis the minimum particulars could also be considered for other containers where it is not be feasible to include all the information. Such exceptional cases have to be justified, discussed and agreed upon with the Authority.

18. Name of the medicinal product and route(s) of administration

19. Method of administration

19.1. Method of administration: directions for proper use of the medicinal product, e.g. “Shake well before use”.

19.2. Use positive statements if possible - use (DO) rather than (DO NOT), e.g. if the drug given for intravenous, use: (For intravenous infusion), rather than (NOT for I.M).

19.3. If full details cannot be included on the immediate packaging itself, a reference to the patient information leaflet should be made, e.g. “Read the patient information leaflet before use”.

20. Manufacturing and Expiry dates

20.1. Dates should be expressed with the month given as 2 digits or 3 characters and the year as 4 digits. e.g.: 02/2010, Feb 2010.

20.2. Where applicable, the shelf life after reconstitution, dilution or after first opening the container should be included.

21. Batch number

22. Contents by weight, by volume or by unit

For injectable medicine:

22.1. The strength of injectable medicines should be express in quantity /unite volume (mg/ml) e.g. : 5mg/ml.

22.2. Include a representation of the full volume strength , e.g. : total quantity in total volume (mg/ml). This should be emphasized for single-dose containers.

22.3. Display concentration in total quantity/total volume, even if other units of concentration such as percentage and rations are present e.g. (: 2 %) (20 mg/ml).

23. Special storage conditions

23.1. If drug requires refrigeration, highlight storage conditions.

24. Other

24.1. Space permitting, any other information necessary for the correct use and administration of the product can be included here.

25. Data matrix

26. Global Trade Item Number (GTIN):

27. Serial number (SN)

II. Patient Information Leaflet (PIL)

A separate patient information leaflet should be provided for each medicinal product presentation and per strength. In case if the patient information leaflet was common for multiple strengths/pack sizes, the strength/pack sizes should be clearly indicated.

The patient information leaflet must include the elements specified in this guidance. In exceptional circumstances, alternative headings may be used—particularly those involving <take> or <use>, if different wording is more suitable for the specific product or better aligns with how the end user will engage with it. Any changes in headings must not alter the required content of the corresponding section. Applicants should provide justification for using alternative headings, such as evidence from user-testing. For certain medicinal products, some items may not apply; in such cases, the irrelevant heading should be omitted.

It is important that the PIL can easily be tracked for updates and review. Each PIL should be given a reference number along with the date the leaflet was issued and a suitable review date. Each PIL should be reviewed every 5 years or when necessary.

Bracketing convention:
{text}: Information to be filled in.
<text>: Text to be selected or deleted as appropriate.

Patient Information Leaflet (PIL)

{Invented name strength pharmaceutical form}

{Active substance(s)}

The invented name of the medicinal product (referred to as X throughout this document) followed by the strength and pharmaceutical form (i.e. as it appears in the SPC) should be stated here in bold. This should be followed by the active substance(s) (as stated on the label section 1), which may be written on the line below.

<**Read all of this leaflet carefully before you start <taking> <using> this medicine>.**

- Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your <doctor, health care provider> <or> <pharmacist>.

- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor, health care provider> <or> <pharmacist>.

In this leaflet:

1. What {product name} is and what it is used for

– Pharmacotherapeutic group:

The pharmacotherapeutic group or type of activity should be stated here using patient understandable language.

– Therapeutic indications:

The therapeutic indications should be stated here, using patient understandable language. If appropriate, specify that:

<This medicine is for diagnostic use only.>

2. Before you <take> <use> {product name}

a. Do not <take> <use> {product name}

– <if you are allergic (hypersensitive) to {active substance(s)} or any of the other ingredients of {product name}.>

– <if ...>

b. Take special care with {product name}

– <if you ...>

– <when ...>

– <Before treatment with {product name},…>

c. <Taking> <Using> other medicines, herbal or dietary supplements

– Describe the effects of other products on {product name} and vice versa.

<Please tell your <doctor, health care provider> <or> <pharmacist> if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.>

d. <Taking> <Using> {product name} with food and drink

– Interactions not related to medicinal products should be mentioned here. Where relevant, guidance should always be included to clarify if the medicine must be taken with food, during/before meals, or clearly state if food/meals have no influence, etc.

e. Pregnancy and breast-feeding

– Where the information is significantly different, pregnancy and breast-feeding information can be presented under separate headings.

– Include conclusion summary of the information given in the SPC, in addition to the following optional statement:

<Ask your <doctor, health care provider> <or> <pharmacist> for advice before taking any medicine.>

f. Driving and using machines

– <Do not drive <because...>.>

– <Do not use any tools or machines.>

g. Important information about some of the ingredients of {product name}

– If appropriate, details of those excipients knowledge of which is important for the safe and effective use of the medicinal product, including relevant warnings for residues from the manufacturing process.

3. How to <take> <use> {product name}

<Always <take> <use> {product name} exactly as your doctor or health care provider has told you. You should check with your <doctor, health care provider> <or> <pharmacist> if you are not sure.> <The usual dose is...>

– You may include the following sub-headings within the headings given below if needed to increase readability:

- Instructions for proper use
- Dosage
- Method and/or route(s) of administration
- Frequency of administration
- Duration of treatment

a. If you <take> <use> more {product name} than you should

- Describe how to recognize if someone has taken an overdose and what to do.

b. If you forget to <take> <use> {product name}

- Make clear to patients what they should do after irregular use of a product; e.g.

<Do not take a double dose to make up for a forgotten <tablet> <dose> <…>.>

c. If you stop <taking> <using> {product name}

- Indicate any effects of interrupting or ending the treatment early, if applicable.
- Indicate withdrawal effects when the treatment ends, when necessary.
- As appropriate, close this section with:

<If you have any further questions on the use of this product, ask your <doctor, health care provider> <or> <pharmacist>.>

4. Possible side effects

– Describe the side effects and whenever possible, an estimate of frequency should be provided, expressed in standard category of frequency (Appendix 2).

– Begin this section with: "Like all medicines, {product name} can cause side effects, although not everybody gets them".

– Describe, if necessary, the actions to be taken. If the patient needs to seek help urgently, the use of the term <immediately> is recommended; for less urgent conditions, <as soon as possible> can be used.

– Close this section with: "If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor, health care provider> <or> <pharmacist>".

5. How to store {product name}

– Keep out of the reach and sight of children.

– <Do not store above ºC>, <Store in the original <container><carton>>

– Do not use {product name} after the expiry date which is stated on the <label> <carton> <bottle> <...> <after {abbreviation used for expiry date}.> <The expiry date refers to the last day of that month.>

– <Do not use {product name} if you notice {description of the visible signs of deterioration}.>

– <Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.>

6. Further information

a. What {product name} contains

– The active substance(s) (expressed qualitatively and quantitatively) and the other ingredients (expressed qualitatively) should be identified.

- The active substance(s) is (are)…
- The other ingredient(s) is (are)...

b. What {product name} looks like and contents of the pack

– The pharmaceutical form should be stated.

– It is recommended to include a physical description e.g. shape, color, texture, imprint.

– All pack sizes for this pharmaceutical form and strength should be detailed here; if appropriate indicate that not all pack sizes may be marketed. A cross-reference to other pharmaceutical forms and strengths may be included.

c. Marketing Authorization Holder and Manufacturer

{Name and address}

<{tel}>

<{e-mail}>

For any information about this medicinal product, please contact the local representative of the Marketing Authorization Holder:

{Name}

<{Address} {City}>

Tel: + {telephone number}

<{e-mail}>

d. This leaflet was last approved in {MM/YYYY}; version number { }

e. To report any side effect(s):

Pharmacovigilance Department
Drug Safety Center
Ministry of Health, Sultanate of Oman
Phone Nos. 22357687 / 22357690
Fax: 22358489
Email: pharma-vigil@moh.gov.om
Website: www.moh.gov.om

f. Council of Arab Health Ministers

The following statements issued by the Council of Arab Health Ministers should be printed in the PIL.

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

III. Summary of Product Characteristics (SPC)

Applicants are required to provide a separate SPC for each strength and each pharmaceutical form, including all pack sizes relevant to that specific strength and form. However, applicants may present SPCs for multiple strengths within a single document, provided that the different strengths or presentations are clearly identified wherever alternative text elements apply.

Bracketing convention:

{text}: Information to be filled in.

<text>: Text to be selected or deleted as appropriate.

1. Name of the medicinal product

The name should be followed by both the strength and the pharmaceutical form.

{Invented name strength pharmaceutical form}

2. Qualitative and quantitative composition

- Full details of the qualitative and quantitative composition in terms of the active substance(s) and excipients.
- A standard statement should be included at the end of the section, i.e. For a full list of excipients, refer to section 6.1.

3. Pharmaceutical form

- Full description of the pharmaceutical form should be provided.
- It is recommended that a visual description of the appearance of the product (color, markings, etc.) is given, including information on pH and osmolarity as required e.g.:

  'Tablet White, circular flat bevelled-edge tablets marked '100' on one side'.

- In case of tablets designed with a score line, information should be given whether or not reproducible dividing of the tablets has been shown. e.g.:

  <The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.>

<The tablet can be divided into equal halves.>.

4. Clinical particulars

4.1 Therapeutic indications

– The indication(s) should be stated clearly and concisely and should define the target disease or condition distinguishing between treatment (symptomatic, curative or modifying the evolution or progression of the disease), prevention (primary or secondary) and diagnostic indication. When appropriate it should define the target population especially when restrictions to the patient populations apply.

– When the product is indicated in a specific age group such as children/adolescents, the indication should state the age limit e.g., X is indicated in <children> <adolescents> from the age of X <months><years >.

4.2 Posology and method of administration

– In case of restricted medical prescription start this section by specifying the conditions.

– The route of administration and concise relevant instruction for correct administration and use should be given here.

– Instructions for preparation are to be placed under section 6.6 or 12, and cross- referenced here.

Posology

– The dosage should be clearly specified for each method/route of administration and for each indication, as appropriate.

– Dose recommendations (e.g. mg, mg/kg, mg/m2) should be specified per dose interval for each category where appropriate (specify age/weight/body surface area of subsets of the population as appropriate). Frequency of dosing should be expressed using time units (e.g. once or twice daily or every 6 hour) and, to avoid confusion, abbreviations e.g. OD or BID should not be used.

– Where appropriate, the following points should be addressed:

  - the maximum recommended single, daily and/or total dose,

- the need for dose titration,
- the normal duration of use and any restrictions on duration and, if relevant, the need for tapering off, or advice on discontinuation,
- advice on action to be taken if one or more dose(s) is (are) missed, or e.g. in case of vomiting (the advice should be as specific as possible, taking into consideration the recommended frequency of dosing and relevant pharmacokinetic data)
- advice on preventive measures to avoid certain adverse drug reactions (e.g. administration of antiemetics),
- the intake of the product in relation to drink and food intake, e.g. with alcohol, grapefruit or milk,
- advice regarding repeat use, with any information on intervals to be observed between courses of treatment, as appropriate,
- interactions requiring specific dose adjustments with cross-reference to other appropriate sections of the SPC, and
- it may also be relevant to recommend not to prematurely discontinue a treatment in case of specific non-serious adverse reaction(s) that are frequent but transient or manageable with dose-titration.

Special populations

– Dosage adjustments or other posology related information on special populations should be presented here, in well-defined sub-sections ordered by importance, e.g. regarding: elderly population; pediatric population; renal impairment; hepatic impairment, patients with a particular genotype; other relevant special population (e.g. patients with other concomitant disease or overweight patients).

Paediatric population

– The specific sub-section ‘paediatric population’ should always be included and the information given should cover all subsets of the paediatric population, using a combination of the possible situations presented below as appropriate.
– If the product is indicated in the paediatric population, posology recommendations should be given for each of the relevant subsets. The age limits should reflect the benefit-risk

assessment of the available documentation for each subset.

- If the posology is the same in adults and children, then a statement to this effect is sufficient; the posology does not need to be repeated.
- Where a product is indicated in children and no adequate paediatric formulation can be developed, detailed instructions on how to obtain an extemporaneous preparation shall be included in section 6.6 with a cross-reference in section 4.2.
- If there are more appropriate strength(s) and/or pharmaceutical form(s) for administration in some or all subsets of the pediatric population (e.g. oral solution for infants), these can be mentioned in section 4.2 of the SPC of the less appropriate one(s). E.g.: Other pharmaceutical forms/strengths may be more appropriate for administration to this population.

Method of administration

- The route of administration and concise relevant instruction for correct administration and use should be given here.
- When supportive data are available, information on alternative method(s) to facilitate administration or acceptability should be given as explicitly as possible (e.g. possibility of crushing tablet, cutting tablet or transdermal patch, pulverising tablet, opening capsules, mixing with food, dissolution in drinks – specifying if a proportion of the dose can be given) particularly for administration via feeding tubes.
- For parenteral formulations, information on the rate or speed of injection or infusion should be provided.
- For hazardous drugs, statements to indicate that it is a hazardous drug and to follow applicable special handling and disposal procedures in section 6.6.

4.3 Contraindications

- Situations where the medicinal product must not be given for safety reasons, i.e. contraindications, are the subject of this section. Such circumstances could include a particular clinical diagnosis, concomitant diseases, demographic factors (e.g. gender, age) or predispositions (e.g. metabolic or immunological factors, a particular genotype and prior adverse reactions to the medicine or class of medicines). The situations should be

unambiguously, comprehensively and clearly outlined. Only if pregnancy or breastfeeding is contraindicated, should it be mentioned here. Hypersensitivity to the active substance or to any of the excipients or residues from the manufacturing process should be included, as well as any contraindication arising from the presence of certain excipients.

– Lack of data alone should not lead to a contraindication. Where for safety reasons, the product should be contraindicated in a specific population, e.g. paediatric or a subset of the paediatric population, it should appear in this section with a cross-reference to the section giving detailed information on the safety issue. A contraindication in the paediatric population should be listed without a sub-heading.

4.4 Special warnings and precautions for use

– The order and content of warnings and precautions should reflect the clinical importance of the safety information and be tailored to the specific medicinal product and its therapeutic indication. Section 4.4 should include only those risks that require precautions for use or warrant specific warnings to healthcare professionals. Contraindicated patient populations should be addressed exclusively in section 4.3 and not repeated.

– Where relevant, this section should describe:

- conditions under which the product may be used subject to specific precautions or risk minimisation measures, including those required as part of a Risk Management Plan;
- patient populations at increased risk of adverse reactions (e.g. elderly, paediatric patients, or those with renal, hepatic, cardiac or other impairments), with cross-reference to section 4.8 where appropriate;
- serious adverse reactions requiring awareness, preventive measures, or specific clinical action;
- risks associated with treatment initiation or discontinuation, including required preventive measures;
- measures for identifying patients at risk and for early detection or prevention of adverse outcomes, including symptom awareness and monitoring recommendations;
- requirements for clinical or laboratory monitoring, with cross-reference to posology adjustments in section 4.2 where applicable;
- warnings related to excipients, residues, transmissible agents, ethanol content (for

herbal products), genetic or phenotypic factors affecting response or safety, and risks linked to incorrect routes of administration;

- clinically relevant interference with laboratory tests, clearly identified under an appropriate subheading.

– Adverse reactions described in this section should also be included in section 4.8. In exceptional cases, particularly critical safety information may be highlighted using boxed or bold text.

– Information relating to pregnancy and lactation, effects on ability to drive or use machines, and interactions should generally be presented in sections 4.6, 4.7, and 4.5 respectively, with cross-references included where major clinical relevance justifies repetition.

Paediatric population:

– Warnings and precautions specific to paediatric patients or subgroups should be presented under a dedicated subheading. This includes information on long-term safety, required monitoring, potential effects on growth, development, behaviour, learning ability, appetite or sleep, and acknowledgement of any gaps in long-term safety data.

4.5 Interaction with other medicinal products and other forms of interaction

– If no interaction studies have been performed, this should be clearly stated.
<No interaction studies have been performed.>
<Interaction studies have only been performed in adults.>

– This section should describe clinically relevant interactions based on the pharmacodynamic properties and in vivo pharmacokinetic data of the medicinal product, with emphasis on interactions that result in practical recommendations for use. This includes clinically meaningful in vivo interaction data that allow extrapolation to other medicinal products with similar pharmacokinetic characteristics.

– Interactions affecting the use of the medicinal product should be presented first, followed by those affecting the use of concomitant medicines. Interactions referenced elsewhere in the SmPC should be fully described in this section and cross-referenced accordingly. The order of presentation should be: contraindicated combinations, combinations not recommended, and other clinically relevant interactions.

- For each interaction, the following information should be provided:
  - clear recommendations (e.g. contraindication, concomitant use not recommended, or precautions such as dose adjustment or monitoring, with cross-references to sections 4.2, 4.3 or 4.4 as appropriate);
  - relevant clinical consequences, including effects on exposure (e.g. plasma concentrations, AUC), active metabolites, or laboratory parameters;
  - the underlying mechanism, where known, with cross-reference to section 5.2 for in vitro data.
- Predicted interactions based on in vitro studies or other evidence should be included when they impact clinical use, with appropriate cross-reference. The duration of interactions following discontinuation of interacting medicines (e.g. enzyme inhibitors or inducers), the need for dose adjustment, and any required washout periods should be addressed.
- Relevant interactions with food, alcohol, herbal products, smoking, or non-medicinal pharmacologically active substances should be described, including any clinically significant pharmacodynamic potentiation or additive effects. Absence of interaction should only be reported when clinically important. If no interaction studies have been performed, this should be clearly stated.
- Additional information should be provided for special populations where the magnitude or clinical impact of interactions may be increased (e.g. patients with renal impairment, paediatric patients, elderly), including the influence of genetic polymorphisms where relevant.

Paediatric population:

- Where indicated, paediatric-specific interaction information should be included, recognising that exposure and clinical consequences may differ from adults. Any treatment recommendations (e.g. dose adjustment, enhanced monitoring or therapeutic drug monitoring) should be specified. If interaction studies were conducted only in adults, this should be stated, along with whether the relevance to paediatric populations is known. Food interaction recommendations should clarify applicability to paediatric diets, particularly in neonates and infants.

- Overall, section 4.5 should be presented clearly and pragmatically, focusing on interactions that lead to actionable recommendations. Tabulated presentation may be used where interactions are numerous or complex.

4.6 Fertility, Pregnancy and lactation

- Efforts should be made by the Marketing Authorization Applicant or Holder to provide the reasons for the recommendations for use in pregnant or lactating women and in women of childbearing potential. This information is important for the healthcare professionals informing the patient.
- In the overall assessment, all available knowledge should be taken into account, including clinical studies and post-marketing surveillance, pharmacological activity, results from non-clinical studies, and knowledge about compounds within the same class.
- Efforts should be made to update the recommendations for use during pregnancy and lactation on the basis of increasing human experience in exposed pregnancies which eventually supersede the animal data.
- The following should be mentioned:
    - Women of childbearing potential / Contraception in males and females.
    - Pregnancy
    - Breastfeeding
    - Fertility
- [For Pregnancy and lactation statements refer to appendices 3 & 4]

4.7 Effects on ability to drive and use machines

- On the basis of the pharmacodynamic profile, reported Adverse Reactions and/or specific studies on a relevant target population addressing the performance related to driving or using machines, specify whether the medicinal product has:
    a. no or negligible influence;
    b. minor or moderate influence, or

c. major influence on these abilities.

Effects of the disease itself on these abilities should not be discussed.

<{Invented name} has <no <or negligible> influence> <minor or moderate influence> <major influence> on the ability to drive and use machines.>

<No studies on the effects on the ability to drive and use machines have been performed.>

<Not relevant.>

4.8 Undesirable effects

– This section should include all adverse reactions from clinical trials, post-authorization safety studies and spontaneous reporting.

– Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

4.9 Overdose

– Describe acute symptoms and signs and potential sequelae of different dose levels of the medicinal product based on all available information including accidental intake, mistakes and suicide attempts by patients.

– Taking into account all relevant evidence, describe management of overdose in man, e.g. in relation to monitoring or use of specific agonists/antagonists, antidotes or methods to increase elimination of the medicinal product such as dialysis.

5. Pharmacological properties

5.1 Pharmacodynamic properties

– Describe the following:

- Pharmacotherapeutic group: {group}, ATC code: {code}. If an ATC code is not yet available, this should be mentioned as ‘not yet assigned’.
- Mechanism of action (if known).
- Pharmacodynamic effects.

- Clinical efficacy and safety.

5.2 Pharmacokinetic properties

– Pharmacokinetic properties of the active substance(s) relevant for the advised dose, strength and the pharmaceutical formulation marketed should be given in this section. If these are not available, results obtained with other administration routes, other pharmaceutical forms or doses can be given as alternative.

– Basic primary pharmacokinetic parameters, for instance bioavailability, clearance and half-life, should be given as mean values with a measure of variability.

– Pharmacokinetics items, which could be included in this section when relevant, are given below.

a. General introduction, information about whether the medicinal product is a pro-drug or whether there are active metabolites, chirality, solubility etc.

b. General characteristics of the active substance(s) after administration of the medicinal product formulation to be marketed.

- Absorption: complete or incomplete absorption; absolute and/or relative bioavailability; first pass effect; T_{max}; the influence of food; in case of locally applied medicinal product the systemic bioavailability.
- Distribution: plasma protein binding; volume of distribution; tissue and/or plasma concentrations; pronounced multi-compartment behavior.
- Biotransformation: degree of metabolism; which metabolites; activity of metabolites; enzymes involved in metabolism; site of metabolism; results from in vitro interaction studies that indicate whether the new compound can induce/inhibit metabolic enzymes.
- Elimination: elimination half-lives, the total clearance; inter and/or intra-subject variability in total clearance; excretion routes of the unchanged substance and the metabolites.
- Linearity/non-linearity: linearity/non-linearity of the pharmacokinetics of the new compound with respect to dose and/or time; if the pharmacokinetics

are nonlinear with respect to dose and/or time, the underlying reason for the non-linearity should be presented.

– Additional relevant information should be included here.

a. Characteristics in patients

- Variations with respect to factors such as age, gender, smoking status, polymorphic metabolism and concomitant pathological situations such as renal failure, hepatic insufficiency, including degree of impairment. If this influence on the pharmacokinetics is considered to be clinically relevant, it should be described here in quantitative terms (cross-referral to 4.2 when applicable).

b. Pharmacokinetic/pharmacodynamic relationship(s)

- Relationship between dose/concentration/pharmacokinetic parameter and effect (either true endpoint, validated surrogate endpoint or a side effect).
- Contribution (if any) of metabolite(s) to the effect.

5.3 Preclinical safety data

– The findings of the non-clinical testing should be described in brief and qualitative statements as outlined in the following example statements:

<Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.>

<Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.>

<Adverse reactions not observed in clinical studies, but seen in animals at exposure levels similar to clinical exposure levels and with possible relevance to clinical use were as follows:>

– Conclusions on the environmental risk assessment on the product should be included where relevant, with reference to section 6.6.

6. Pharmaceutical particulars

6.1 List of excipients

- A list should be given of the excipients, expressed qualitatively only. All excipients, which are present in the product, should be included, even those present in small amounts, such as printing inks.
- Each to be listed on a separate line according to the different parts of the product.

6.2 Incompatibilities

- Information on physical and chemical incompatibilities of the medicinal product with other products with which it is likely to be mixed or co-administered should be stated.
- Statements concerning compatibility of the product with other medicinal products or devices should not be included in this section but in section 6.6. Statements concerning pharmacological incompatibilities with food should be included in section 4.5.
- If appropriate, the standard statement, 'Not applicable', should be included.
- For certain pharmaceutical forms, e.g. parenterals, either of the following standard statements should be included as appropriate:

<In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.>

<This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.>

6.3 Shelf life

- Information on the finished product shelf life and on the in-use stability after 1st opening and/or reconstitution/dilution should appear here. Only one overall shelf life for the finished product is to be given even if different components of the product may have a different shelf life (e.g. powder & solvent).

<...> <6 months> <...> <1 year> <18 months> <2 years> <30 months> <3 years>

6.4 Special precautions for storage

– General storage conditions of the finished product should appear here, together with a cross-reference to section 6.3 where appropriate:

<For storage conditions of the <reconstituted> <diluted> medicinal product, see section 6.3.>

– [For recommended labeling statements see Appendix 1]

6.5 Nature and contents of container

– The material of construction of the immediate container should be stated (Type I glass vials, PVC/Aluminium blisters, HDPE bottles); and any other component of the product should be listed, e.g. needles, swabs, measuring spoons, inhaler devices, desiccant. The container of any solvent provided with the medicinal product should also be described. Excessive detail, e.g., concerning the color of the stopper, the nature of the heat-seal lacquer, should usually not be included. Examples on the text in this section:

<Volume> ml suspension in a pre-filled syringe (type I glass) with plunger stopper (chlorobutyl rubber) with or without needle in pack sizes of 5 or 10.

'HDPE bottle with a child-resistant closure and a silica gel desiccant. Pack-sizes of 30, 60 or 90 filmcoated tablets.'

– All pack sizes must be listed. Pack sizes mentioned should include the number of units, number of doses (for e.g. multi-dose vaccines, inhalers, etc.), total weight or volume of the immediate container, as appropriate, and the number of containers present in any outer carton. If applicable, add:

<Not all pack sizes may be marketed.>

6.6 Special precautions for disposal and other handling

– Include practical instructions for preparation and handling of the product, where applicable, including disposal of the medicinal product, and waste materials derived from the used medicinal product.

– If applicable, e.g. for cytotoxics, the following standard statement should be included, 'Any unused product or waste material should be disposed of in accordance with local requirements.'

- For hazardous drugs, statements to indicate that it is a hazardous drug and special instructions for handling, manipulation (where applicable), and disposal procedures.
- If there are no special use or handling instructions for the pharmacist or other healthcare professionals, the standard statement, 'No special requirements.' should be included.
- Information on the preparation (e.g. the suspension of a powder for injection, or preparing a dilution) of the medicinal should be included in section 6.6, regardless of who prepares the product (e.g. pharmacist, doctor, other health personnel, patient, parents or careers). In the case of products for reconstitution, the appearance of the product after reconstitution should be stated.
- Statements concerning compatibility of the product with other medicinal products or devices can be given here provided the data have been provided in the dossier.
- In the exceptional cases where a product is indicated in children and where no adequate paediatric formulation can be developed (based on duly justified scientific grounds), information on extemporaneous formulation should appear under a sub-heading "Use in the paediatric population" and should cross-refer to the section 4.2. Detailed instructions for the preparation of the extemporaneous formulation from the appropriate "adult" or other "older children" dosage form and additional information on extemporaneous formulations for use in younger children shall be provided and, where appropriate, the maximum storage time during which such preparation will conform to its specifications. When necessary, the required packaging material and storage conditions should be stated here.

7. Marketing authorization holder

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

8. Marketing authorization number(s)

9. Date of first Authorization/ renewal of the authorization

<{DD/MM/YYYY}> <{DD month YYYY}>

10. Date of revision of the text

{MM/YYYY}

11. <Dosimetry>

– For radiopharmaceuticals, full details of internal radiation dosimetry.

12. <Instructions for preparation of radiopharmaceuticals>

– <Any unused product or waste material should be disposed of in accordance with local requirements.>

– For radiopharmaceuticals, additional detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready- to-use pharmaceutical will conform to its specifications.

CHAPTER THREE

Responsibilities:

Pharmaceutical companies Marketing Authorization Holders (MAHs) Regulatory Affairs Professionals Pharmaceutical Consulting offices	• Prepare, review, and maintain accurate, up-to-date SPC, PIL, and labeling information. • Ensure all documents comply with national and international regulatory requirements. • Guarantee scientific accuracy, clarity, and patient-friendly readability. • Manage regulatory submissions and communication with authorities. • Implement required updates based on new safety data, guideline changes, or regulatory feedback. • Maintain version control and ensure consistent use of approved labeling across all markets. • Ensure proper distribution and use of current, approved labeling materials.
DSC scientific committees	• Review and evaluate SPC, PIL, and labeling submissions. • Ensure scientific validity, safety, and regulatory compliance. • Approve or reject labeling content during assessment.

CHAPTER FOUR

Document History and Version Control

Version	Description	Review Date
1	Initial Release	January 2026
2		
3		

References:

Executive Board of the Health Ministers' Council for GCC States (2011) *The GCC Guidance for Presenting the SPC, PIL and Labeling Information*. Version 2.0.

Saudi Food and Drug Authority (2020) *Guidance for Presenting the Labeling Information, SPC and PIL*. Version 3.0. Riyadh: SFDA.

Annexes

Appendix 1: Recommended labeling statements

- The statements that should be used if supported by the stability studies for finished pharmaceutical products (FPPs) are listed in Table 1.

Table 1: Recommended labeling statements for finished pharmaceutical products (FPPs)

Testing condition under which the stability of the FPP has been demonstrated	Recommended labeling statement
30 °C/65% RH (long-term) 40 °C/75% RH (accelerated)	"Do not store above 30 °C" *
5 °C ± 3 °C	"Store in a refrigerator (2 °C to 8 °C)"
-20 °C ± 5 °C	"Store in freezer"

* "Protect from moisture" should be added as applicable.

- Additional labeling statements that could be used in cases where the result of the stability testing demonstrates limiting factors are listed in Table 2.

Table 2: Additional labeling statements for use where the result of the stability testing demonstrates limiting factors

Limiting factors	Additional labeling statements, where relevant
FPPs that cannot tolerate refrigeration	"Do not refrigerate or freeze"
FPPs that cannot tolerate freezing	"Do not freeze"
Light-sensitive FPPs	"Protect from light"
FPPs that cannot tolerate excessive heat, e.g. suppositories	"Store and transport not above 30 °C"
Hygroscopic FPPs	"Store in dry condition"

Appendix 2: Frequency of adverse drug reactions

- The following standard categories of frequency are recommended:

Adverse effect	Incidence
Very common	>1/10
Common	>1/100 and < 1/10
Uncommon	>1/1000 and < 1/100
Rare	>1/10,000 and < 1/1000
Very rare	< 1/10,000

Appendix 3: Pregnancy statements

1.

- {Generic name} causes/is suspected to cause serious birth defects when administered during pregnancy.
- {Trade name} is contraindicated (only in case of a strict contraindication see section 4.3) in pregnancy.

and if necessary

- Women of childbearing potential have to use effective contraception during (and up to x weeks after) treatment.

2.

- {Generic name} has harmful pharmacological effects on pregnancy and/or the foetus/newborn child.
- {Trade name} should not be used during pregnancy unless clearly necessary (these circumstances should be specified).

3.

- There are no adequate data from the use of {Generic name} in pregnant women.
- Studies in animals have shown reproductive toxicity (see section 5.3). The potential risk for humans is unknown.

  or
- Animal studies are insufficient with respect to effects on pregnancy /and-or/ embryonal/fetal development/ and-or/ parturition/ and-or/ postnatal development (see section 5.3). The potential risk for humans is unknown.
- {Trade name} should not be used during pregnancy unless clearly necessary (these circumstances should be specified where possible).

4.

- For {Generic name} no clinical data on exposed pregnancies are available.
- Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development (see section 5.3) Caution should be exercised when prescribing to pregnant women.

5.

- Data on a limited number (.....) of exposed pregnancies indicate no adverse effects of {Generic name} on pregnancy or on the health of the fetus/newborn child. To date, no other relevant epidemiological data

are available. Animal studies have shown reproductive toxicity (see section 5.3). The potential risk for humans is unknown.

or

- Animal studies are insufficient with respect to effects on pregnancy/ and-or/ embryonal/fetal development/ and-or/ parturition/ and-or/ postnatal development (see section 5.3). The potential risk for humans is unknown.
- Caution should be exercised when prescribing to pregnant women.

6.

- Data on a limited number (.) of exposed pregnancies indicate no adverse effects of {Generic name} on pregnancy or on the health of the foetus/newborn child. To date, no other relevant epidemiological data are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development (see section 5.3).
- Caution should be exercised when prescribing to pregnant women.

7.

- Data on a large number (.....) of exposed pregnancies indicate no adverse effects of {Generic name} on pregnancy or on the health of the foetus/newborn child. To date, no other relevant epidemiological data are available.
- Caution should be exercised when prescribing to pregnant women.

8.

- Well-conducted epidemiological studies indicate no adverse effects of {Generic name} on pregnancy or on the health of the foetus/newborn child.
- {Trade name} can be used during pregnancy.

9.

- In case of interaction with oral contraceptives information should also be given in section 4.5. {Generic name} adversely interacts with oral contraceptives (OCs). Therefore, an alternative, effective and safe method of contraception should be used during (and up to x weeks after) treatment.

or

- The concomitant medication [Generic name} adversely interacts with oral contraceptives (OCs).
- Therefore, an alternative, effective and safe method of contraception should be used during (and up to x weeks after) treatment.

10.

- In case of male-mediated effects on pregnancy outcome information should also be given in section 4.4.
- Both sexually active men and women should use effective methods of contraception during (and up to x weeks after) treatment.

Appendix 4: Lactation statements

1. {Active substance} is not excreted in breast milk. {Invented name} can be used during lactation.

2. {Active substance} is excreted in breast milk. However, at therapeutic doses of {Invented name} no effects on the suckling child are anticipated. {Invented name} can be used during breast-feeding.

3. {Active substance} is excreted in breast milk to such an extent that effects on the suckling child are likely if therapeutic doses of {Invented name} are administered to breast-feeding women.
   - Alternative recommendations (combinations of recommendations may be used):
     - {Invented name} should not be used during breast-feeding.
     - {Invented name} is contraindicated during breast-feeding (must also be contraindicated in 4.3).
     - Lactation should be discontinued during treatment with {Invented name}.
     - A decision must be made whether to discontinue breast-feedingor to discontinue/abstain from {Invented name} therapy.
   - Additional recommendation (if applicable):
     - Due to the long retention time of {substance} in the body, breast-feeding must not be resumed until x (days, months) after {Invented name} therapy is completed.

4. It is unknown whether {Active substance} is excreted in human breast milk. The excretion of {Active substance} in milk has not been studied in animals. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with {Invented name} should be made taking into account the benefit of breast-feeding to the child and the benefit of {Invented name} therapy to the woman.

5. It is unknown whether {active substance} is excreted in human breast milk. Animal studies have shown excretion of (active substance) in breast milk. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with {Invented name}

should be made taking into account the benefit of breast-feeding to the child and the benefit of {Invented name} therapy to the woman.

6. It is unknown whether {Active substance} is excreted in human breast milk. Animal studies have not shown excretion of {Active substance} in breast milk. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with {Invented name} should be made taking into account the benefit of breast-feeding to the child and the benefit of {Invented name} therapy to the woman.

7. There is insufficient/limited information on the excretion of {Active substance} in human or animal breast milk. A risk to the suckling child cannot be excluded. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with {Invented name} should be made taking into account the benefit of breast-feeding to the child and the benefit of {Invented name} therapy to the woman.

8. There is insufficient/limited information on the excretion of (active substance) in human or animal breast milk. Physicochemical and available pharmacodynamic/toxicological data on (active substance) point to excretion in breast milk and a risk to the suckling child cannot be excluded. {Invented name} should not be used during breast-feeding.

9. No effects on the suckling child are anticipated since the systemic exposure of the breastfeeding woman to {Active substance} is negligible. {Invented name} can be used during breastfeeding.
   - *E.g. ear and eye drops and other topical drugs for which negligible systemic exposure has been demonstrated.*

10. No effects on the suckling child are anticipated. {Invented name} can be used during breastfeeding.

11. E.g. most vitamin and mineral formulations.

Appendix 5: Additional information that are required to be translated into Arabic language

- **المعلومات الواجب ترجمتها على الملصق الخارجي للمستحضر الصيدلاني باللغة العربية (بالإضافة للمعلومات التي ذكرت سابقاَ في الدليل الأساسي)**
  1. إسم المستحضر وتركيزه
  2. الشكل الصيدلاني للمستحضر وحجم العبوة
  3. ظروف تخزين المستحضر
  4. التسعيرة- اسم الوكيل / مالك رخصة التسويق - رقم التسجيل

- **المعلومات الواجب ترجمتها على شريط المستحضر الصيدلاني باللغة العربية (بالإضافة للمعلومات التي ذكرت سابقاَ في الدليل الأساسي)**
  1. إسم المستحضر وتركيزه

- **المعلومات الواجب ترجمتها على ملصق العبوات الصغيرة (أقل من 01 مل) باللغة العربية (بالإضافة للمعلومات التي ذكرت سابقاَ في الدليل الأساسي)**
  1. إسم المستحضر وتركيزه
  2. ظروف تخزين المستحضر
  3. التسعيرة- اسم الوكيل / مالك رخصة التسويق - رقم التسجيل

بيانات النشرة الداخلية للمستحضر الصيدلاني (PIL)

معلومات لمستخدم الدواء - النشرة الداخلية للمستحضر الصيدلاني:

{الاسم - التركيز – الشكل الصيدلاني للمستحضر}

{المواد الفعالة}

قم بقراءة هذه النشرة جيداً قبل إستعمال أو تناول هذا الدواء

- إحتفظ بهذه النشرة، لأنك قد تحتاج إليها لاحقاً.
- في حال كانت لديك أي أسئلة تتعلق بهذا المستحضر قم بإستشارة الطبيب أو الصيدلي.
- إن هذا الدواء قد تم صرفه خصيصاً لك بناءاً على وصفة طبية، ولهذا يجب عليك عدم إعطائه لأي شخص حتى وإن كان هذا الشخص يعاني من نفس الأعراض التي سبق وأن عانيت منها.
- قم بالإتصال بطبيبك المعالج أو الصيدلي في حال زيادة حدة الأعراض الجانبية أو الاصابة بعرض جانبي لم يتم ذكره في هذه النشرة.

تحتوي هذه النشرة على:

1. ماهو< إسم المستحضر > وما هي دواعي استعماله.
2. قبل القيام بتناول أو إستعمال < إسم المستحضر >.
3. طريقة إستخدام < إسم المستحضر >.
4. الأعراض الجانبية.
5. ظروف تخزين < إسم المستحضر>.
6. معلومات إضافية.

1. ماهو< إسم المستحضر > وما هي دواعي استعماله

2. قبل القيام بتناول أو إستعمال < إسم المستحضر >

أ- موانع استعمال < إسم المستحضر >

ب- الاحتياطات عند استعمال < إسم المستحضر >

ج- التداخلات الدوائية من أخذ هذا المستحضر مع أي أدوية أخرى أو أعشاب أو مكملات غذائية

د- تناول < إسم المستحضر > مع الطعام والشراب

ه- الحمل والرضاعة

و- تأثير < إسم المستحضر > على القيادة وإستخدام الآلات

ز- معلومات هامة حول بعض مكونات < إسم المستحضر >

3. طريقة إستخدام <إسم المستحضر>

أ- الجرعة الزائدة من < إسم المستحضر >

ب- نسيان تناول جرعة < إسم المستحضر >

ج- التوقف عن تناول < إسم المستحضر>

4. الأعراض الجانبية

5. ظروف تخزين < إسم المستحضر >

6. معلومات إضافية

أ- ماهي محتويات > إسم المستحضر>

ب- ما هو الشكل الصيدلاني > إسم المستحضر > ووصفه وحجم عبوته

ج- اسم وعنوان مالك رخصة التسويق والمصنع

د- تم الموافقة على هذه النشرة بتاريخ { شهر / سنة }، {رقم النسخة}

7. الإبلاغ عن الأعراض الجانبية:

دائرة التيقظ الدوائي
مركز سلامة الدواء
وزارة الصحة، سلطنة عُمان

هاتف: 22357690 / 22357687
فاكس: 22358489
البريد الإلكتروني: pharma-vigil@moh.gov.om
الموقع الإلكتروني: www.moh.gov.om

8. وضع الإرشادات الصادرة من مجلس وزراء الصحة العرب كما يلي:

إن هذا الدواء

- الدواء مستحضر يؤثر على صحتك واستهلاكه خلافاً للتعليمات يعرضك للخطر.
- اتبع بدقة وصفة الطبيب وطريقة الاستعمال المنصوص عليها وتعليمات الصيدلي الذي صرفها لك.
- إن الطبيب والصيدلي هما الخبيران في الدواء وبنفعه وضرره.
- لا تقطع مدة العلاج المحددة لك من تلقاء نفسك.
- لا تكرر صرف الدواء بدون استشارة الطبيب.
- لا تترك الأدوية في متناول أيدي الأطفال.

مجلس وزراء الصحة العرب
واتحاد الصيادلة العرب

ملاحظة:

يجب أن تكون النشرة الداخلية للمستحضر الصيدلاني:

- مترجمة بطريقة احترافيه (من حيث استخدام المصطلحات العلمية)
- مدققة إملائياً ولغوياً
- مكتوبة بلغة سهلة ومفهومة للمريض.

Appendix 6: Readability of the label and patient information leaflet (PIL)

Introduction

The main purpose of this document is to provide guidance on how to ensure that the information on the labelling and patient information leaflet (PIL) is accessible to and can be understood by those who receive it, so that they can use their medicine safely and appropriately.

This document is written to assist applicants and marketing authorizations holders when drawing up the labeling and PIL and preparing the mock-ups or specimens of the sales presentations[1].

The document is intended to apply to all marketing authorization procedures and to all medicinal products.

[1] A **mock-up** is a copy of the flat artwork design in full colour, presented so that, following cutting and folding where necessary, it provides a replica of both the outer and immediate packaging so that the three dimensional presentation of the labelling text is clear. This mock-up is generally referred to as a paper copy and not necessarily in the material of the sales presentation. A **specimen** is a sample of the actual printed out outer and immediate packaging materials and PIL (i.e. the sales presentation).

A. Patient Information Leaflet (PIL) – General principles

- PILs must be designed for patients/users, including those with low literacy, visual impairment, older children and adolescents.
- Clear wording, good information design, and usability are essential; specialist input in information design is encouraged.

1. Font and type size

- Use clear, easily readable fonts; avoid stylised fonts.
- Minimum type size: 9-point (Times New Roman equivalent), adequate line spacing (≥3 mm).
- Use lower case for body text; avoid extensive use of capitals.
- Avoid italics and underlining (except Latin terms).
- Use different text sizes to highlight key information and headings.

2. Design and layout

- Avoid justified text; maintain clear line spacing (≈1.5× word spacing).
- Ensure high contrast between text and background; avoid background images.
- Use columns where helpful; ensure clear separation and logical text flow.
- Clearly separate languages in multilingual PILs.

3. Headings and navigation

- Use consistent, clearly distinguishable headings (e.g. bold or color).
- Maintain consistent spacing and formatting.
- Limit heading levels (ideally no more than two).
- Use lines or spacing to separate sections where helpful.

4. Use of color

- Ensure sufficient contrast (dark text on light background preferred).

- Reverse text may be used selectively for emphasis, with larger or bold type.
- Avoid similar text and background colors that impair legibility.

5. Language and syntax

- Use simple words and short sentences.
- Avoid long paragraphs; use bullet points, especially for side effects (≤5–6 bullets).
- Present side effects by frequency, starting with the most common.
- Highlight serious side effects requiring urgent action.
- Avoid organ/system classifications unfamiliar to patients.

6. Writing style

- Use active voice and direct instructions.
- Provide reasons after instructions.
- Use “your medicine” instead of repeating the product name.
- Avoid abbreviations, acronyms, symbols, and unexplained medical terms.
- Translate medical terminology into plain language consistently.

7. Paper quality

- Use sufficiently thick, uncoated (non-glossy) paper.
- Ensure folds and creases do not impair readability.

8. Symbols and pictograms

- May be used to aid comprehension and navigation, not for promotion.
- Must be clear, well understood, and not replace text.
- Evidence of comprehension may be required.

B. Labeling (outer and immediate packaging) – Key principles

- Labeling must ensure legibility, accessibility, and safe use.
- Minimum character size: 7 points (or x-height ≥1.4 mm).

- PIL principles generally apply to labeling, especially for small packs.

Key labeling elements

- **Name of the medicine:** Full name, strength, pharmaceutical form, target population; INN(s) prominently displayed.
- **Strength and content:** Consistent expression of strengths; avoid decimals and trailing zeros; spell out “micrograms”.
- **Route of administration:** Use standard terms only; avoid negative statements.
- **Design and layout:** Prioritise critical information; ensure adequate type size, spacing, and contrast.
- **Color use:** Avoid confusing color schemes; use color consistently to differentiate strengths.
- **Multilingual packs:** Clearly separate languages.

Blister packs and small containers

- Information must remain legible until the last dose.
- Key particulars should appear frequently across blister packs.
- Use sufficiently large fonts and non-reflective materials where possible.
- For small containers (≤10 ml), minimum particulars may apply; innovative designs are encouraged.