الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Guideline for Legal Status Classification and Distribution of Human Medicinal Products

Version 1.0

Date of issue	19 January 2026
Date of implementation	21 June 2026

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Saudi Food & Drug Authority

Drug Sector

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Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

Version	Author	Date	Comments
Draft	Executive Directorate of Benefits and Risks Evaluation	10 October 2024	-
1.0	Executive Directorate of Benefits and Risks Evaluation	19 January 2026	Final

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ACRONYMS & GLOSSARY

Legal Status	The classification of medicinal product supply to the patient
Distribution Status	The medicinal product distribution site
Prescription Only Medicine (POM)	Medicinal product that require a written licensed physician's prescription before it can be obtained by patient
Over-the-counter (OTC) medicine	Medicinal product that can be obtained by patient without a medical prescription and are not complementary medicines (i.e. they do not primarily consist of complementary medicine ingredients such as vitamins, minerals and plant material).
SPC	Summary of Products Characteristics
PIL	Patient Information leaflet
SFDA	Saudi Food and Drug Authority

1. INTRODUCTION

1.1. Background

This guideline addresses the criteria of the Saudi Food and Drug Authority (SFDA) for classifying the legal and distribution status of human medicinal products. The guideline also provides information on re-classifying of legal status based on marketing authorization holders' requests.

1.2. Scope

This guideline is applicable to medicinal products intended for human use in Saudi Arabia.

1.3. Related guidelines

This document should be read in conjunction with the following Drug Sector documents:

- The Data Requirements for Human Drugs Submission.
- Guidelines for Variation Requirements

1.4. Legislative Basis

The legal base of this document is the Registration Rules of Pharmaceutical, Herbal and Health Product Manufacturers and their Products Guideline.

2. CLASSIFICATION OF LEGAL AND DISTRIBUATION STATUS

The classification of medicinal product supply to the patient is referred to as "Legal Status" and the medicinal product distribution site as "Distribution Status".

The legal statuses of medicinal products registered in Saudi Arabia are classified into the following:

1. Prescription Only Medicine (POM): Medicinal product that requires a written licensed physician's prescription before it can be obtained by the patient.

2. Over-the-counter (OTC) medicine: also known as non-prescription medicine, which can be obtained by patients without a medical prescription and are not

complementary medicines (i.e. they do not primarily consist of complementary medicine ingredients such as vitamins, minerals, and plant material).

3. Controlled prescription medicine: Controlled substances are regulated under set of regulations available on SFDA website:

- Law of Combating Narcotic drugs and Psychotropic Substances, and attached tables.
- Circulars related to update on procedures and controls of controlled products according to special terms and conditions. (Circulars can be accessed via www.SFDA.gov.sa).

The site of distribution for medicinal products falls under the following categories:

1. Community Pharmacies.

2. Hospitals.

3. Products for sale in food retail store that meet storage conditions. (List of products for sale in food retail store available here on SFDA website).

3. CRITERIA FOR CLASSIFICATION OF LEGAL STATUS

3.1. Prescription only medicine (POM)

Medicinal products shall be subject to medical prescription when they meet any of the following criteria:

1. **Medicinal products are likely to present a danger either directly or indirectly, even when used correctly, if utilized without medical supervision.**

1.1 Direct danger/safety profile

- A direct danger encompasses toxicity, interactions and adverse reactions even when the product is used correctly.
    - The drug has a potential or is known to cause serious adverse reactions or serious interactions with food or other drugs at normal dosage level
    - The drug has relevant reproductive toxicity, genotoxic or carcinogenic properties
    - The drug has a narrow margin of safety.

1.2 Indirect danger/safety profile

- The use of the drug might mask/hide an underlying condition requiring medical attention and supervision. As a result, this might delay diagnosis and definitive treatment and jeopardize the chance of more successful therapy

- Indirect danger also could occur if wider use of a medicinal product would increase the risk of resistance to the product, in particular in the general population, to such an extent that the usefulness of any medicinal product is likely to be compromised (e.g. antibiotics).

1.3 Self-assessment

- The drug is used in the treatment of condition that cannot be correctly assessed by the patient
- The product requires patient monitoring and medical supervision.

1.4 Patient Information

- The use of the drug requires complex or individualized instructions: When the use of a drug needs to be tailored to a patient's specific circumstances or when the general population cannot easily understand the drug information.

1.5 Risk and consequences of incorrect use

- The drug is frequently used incorrectly which could lead to direct or indirect danger to human health.
- A high incidence of conditions listed as contraindications, precautions or warnings, or a high rate of usage of interacting drugs in the population, in case of patients likely to use the medicine, may increase the incidence and risk of misuse
- Several reporting incidences of patient uses the product where it is not indicated, uses it for a longer period than recommended, exceeds the recommended dose or fails to heed warnings or contraindications.

2. Medicinal products shall be subject to medical prescription when they contain substances or preparations thereof the activity and/or side-effects of which require further investigation.

2.1 Recent authorization/limited experience

- Further investigation may be necessary when a medicinal product has only recently been granted a marketing authorization or because of limited experience/use of the product e.g., Orphan drugs.

- It is important to have post-marketing experience in the general population that is evidence of safety when the product is being used without the exclusion of certain groups of patients, which may be imposed by the design of clinical trials e.g. the elderly, children, certain racial or phenotypic groups and those having certain medical conditions.

2.2 New strength, dose, route of administration, indication, new age group or combination of substances.

- A drug may have been on the market but now is being proposed for sale with a change to its conditions of use (e.g., a new use, strength, dose, species, age group, or route of administration). In some cases, there may be gaps in the information regarding the long-term consequences associated with the new use. In these cases, legal status would help to ensure practitioner oversight.

3. Medicinal products shall be subject to medical prescription when they are normally prescribed by a doctor to be administered parenterally.

- Practitioner expertise is necessary to administer the drug or oversee the drug's administration.

3.2. Over-the-counter (OTC) medicine:

A medicinal product that does not meet any of the criteria for supply subject to medical prescription may be classified as over-the-counter medicine if:

1. Supervision by a healthcare practitioner is not necessary:

1.1 There are no risks associated with a misdiagnosis of symptoms, and/or a delay in using the appropriate treatment or use of sub-optimal treatment with respect of the medicine recommended for use

1.2 The utilization, administration and/or monitoring of the medicinal product shall not require complex or individualized instructions:

- The selection of proper medicinal product and dosing shall be easily and correctly achieved by the patient.

- Product information can be easily understood and followed by the public.
- Self-administration must be done without healthcare provider.
- Benefit can be achieved when utilized without a guidance of health care provider.
- Monitoring parameters for the effective/safe use of the medicinal product must be assessed by the patient without practitioner's intervention.

2. The Medicinal Product shall have an adequate margin of safety:

2.1 The product shall not lead to direct or indirect danger when used without medical supervision.

- **Examples on direct danger may include:**
  - Adverse reactions that are important because of their seriousness, severity, or frequency or because the reaction is one for which there is no suitable preventative action such as the exclusion of a clearly identifiable risk group.
  - Serious drug interactions with food or other drugs.
  - The medicinal product has a Narrow Therapeutic Index.
  - The medicinal product has potential to produce serious adverse reactions in particular subpopulation (e.g., children, pregnant and/or elderly).

- **Examples on indirect danger may include:**
  - The use of medicinal product might mask an underlying condition requiring medical attention.
  - Increased risk of drug resistance in the community because of the wide use without medical supervision.

3 The consequences of misuse of the product are minor:

- The risk to health is small if the consumer uses the product when it is not indicated, e.g. exceeds the recommended dose or recommended length of treatment, or fails to read the contraindications or warnings.

4 The use of the product does not lead to abuse / dependence.

4. CONSIDERATIONS

- Wherever appropriate, an explanation on how the medicinal product should be supplied to patients (e.g., to be administered in a hospital setting or prescribed by specialists only, or specific type of care during the treatment of a chronic disease) could be included in the Summary of Product Characteristics (SPC).
- The Patient Information Leaflet (PIL) shall provide information on the appropriate use of the product and the circumstances when referral for medical advice is appropriate. Contraindications and warnings, such as advice limiting duration of treatment or the need to consult a doctor in certain situations, should be provided as appropriate.
- Whenever appropriate, a cautionary statement on the product label could be included, e.g. intravenous use only.

5. DISTRIBUTION STATUS

The distribution status of medicinal products is classified into either:

- Hospitals.
- Community Pharmacies.

During the determination of the appropriate distribution site of a medicine product, the following points should be taking into consideration (safety profile, monitoring parameters, route of administration, pack size and the legal status)

6. IMPLEMENTATION OF THE LEGAL AND DISTRIBUATION STATUS

At the submission stage, applicants should indicate their proposed classification for the legal and distribution status in Module 1 of the application form (Refer to *The Data Requirements for Human Drugs* Submission).

7. RECLASSIFICATION OF LEGAL STATUS

Medicinal products can be reclassified from Prescription-only medicine to over-the-counter if they meet all the following criteria:

- The medicine product is used for condition that can be easily and correctly assessed and managed by the public with respect of the drug recommended for use.
- The utilization, administration and/or monitoring of the medicinal product not require complex or individualized instructions.
- The medicinal product has an adequate margin of safety.
- The medicinal product has wide Therapeutic Index.
- The medicinal product has a minor risk to misuse.
- The use of the medicinal product did not lead to abuse / dependence.
- The medicinal product has adequate market experience

7.1. Reclassification Application

Applicants should submit a variation request to re-classify legal and/or distribution status of medicinal product as per SFDA guideline for variation requirements through the Saudi Drug Registration (SDR) system.

- For reference medicinal products, the applicant requires to submit a Type II variation request for reclassifying the Legal status, and Type IB variation for the distribution site change.
- For generic/biosimilar medicinal products, the applicant requires to submit a Type IB variation request to follow the SFDA approved legal status or distribution site changes of the reference medicinal product.

7.2. Requirements

The documentation concerning safety and efficacy required to support an application for reclassification will vary from application to application and depend on the nature of the active substance. However, all applications should include:

1. **Cover letter**
2. **Completed request** (See request form in Appendix 1)
3. **Clinical overview (Expert Reports)**

- In all cases, clinical overview (expert reports) should be provided with a critical analysis of the proposed availability of the product without a prescription with the dose and indications as stated in the application. All of OTC criteria should be addressed and supporting documentation should be submitted.

4. Non-clinical and/or clinical safety

- A pre-clinical and/or clinical overview and the non-clinical and/or clinical summaries of, or references to, animal studies or studies on humans that show low general toxicity and no relevant reproductive toxicity, genotoxic or carcinogenic properties relevant to the experience/exposure of the medicinal product should be given.
- Experience in terms of patient exposure to the substance needs to be considerable and should be outlined.
- Information on adverse reactions should be provided, including experience of use without medical supervision.
- The safety profile should be summarized, including reports of and data from post-marketing surveillance studies, clinical trials and published literature presenting the issue of drug safety.
- The application should consider the potential for and consequences of drug interactions, in particular with commonly prescribed drugs.
- The application should consider the consequences concerning misuse, e.g. use for longer periods than recommended, as well as accidental or intended overdose and the use of higher doses, should be discussed.
- The application should consider the consequences of the use of the product by a patient who has incorrectly assessed his condition or symptoms.
- The application should consider the consequences of incorrect or delayed diagnosis of a patient's condition or symptoms due to self-medication with the product.

5. Product information (PI)

- For a medicinal product proposed to classify for supply as **over-the-counter medicine**, the labelling and package leaflet are important elements of the application and will be closely examined for comprehensive information and effectiveness in protecting patients from any safety hazards.
- Package leaflets should provide information on the use of the product and the circumstances when referral for medical advice is appropriate.
- Contraindications and warnings, such as advice limiting duration of treatment or the need to consult a doctor in certain situations, should be provided as appropriate.

APPENDIX 1: Request of Re-classification of Legal and/or Distribution Status of Medicinal Products

Product Name		**Active ingredient(s)**	
Dosage form		**Strength and unit of strength**	
Route of administration			
Type of request	☐ Re-classification of legal status ☐ Re-classification of distribution status		
Current legal status	☐ Prescription only medicine ☐Over-the-counter medicine		
Current distribution status	☐ Hospital ☐ Community Pharmacy		
Requested (Proposed) legal status	☐ Prescription only medicine ☐Over-the-counter medicine		
Requested (Proposed) distribution status[1]	☐ Hospital ☐ Community Pharmacy		
Evidence to support the Re-classification request	An overview of evidence should be addressed in support of the reclassification application. A Tabular list including all related study reports and literature references should be submitted in the application form. The reports shall be placed in relevant Modules of the dossier and thus cross-referred as hyperlinked accordingly.		
List of countries with proposed legal/distribution status			

[1] If the request includes only "Re-classification of legal status", skip "Requested (Proposed) Distribution status".