الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Classifying Legal Status of Veterinary Medicinal Products Guideline

Version 1.0

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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

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ACRONYMS & GLOSSARY

Legal Status	The conditions and restrictions under which the veterinary medicinal products are available to animals/consumers.
Over the counter (OTC) product	A veterinary medicinal product subject to SFDA authority that consumers could obtain in Saudi Arabia without a veterinarian prescription.
Prescription only medicine (POM)	A veterinary medicinal product that is subject to SFDA authority and that is available to animals / consumers in Saudi Arabia based on a licensed veterinarian prescription in Saudi Arabia.

1. INTRODUCTION

1.1.Scope

This guidance addresses the criteria that are followed by the Saudi Food and Drug Authority (SFDA) when setting the legal status of veterinary medicinal products in Saudi Arabia.

It also describes the criteria and process for changing the classification of the legal status of veterinary products in Saudi Arabia.

This guideline is divided into four main sections:

- Classification of the legal supply status.
- Criteria for classification of legal supply status
- Criteria for the legal status re-classification.
- Submission process and requirements for the re-classification.

This guidance applies to medicinal products intended for animal use in Saudi Arabia.

1.2.Legal base

This document's legal base is Article 12 of the Registration Rules of Veterinary Pharmaceutical Manufacturers and their products, which lays down the classification of legal status for the supply of veterinary medicines marketed in the Kingdom of Saudi Arabia.

1.3.Related documents

This guideline must be considered along with the following documents:

- Veterinary Products Law In the Arab Gulf Cooperation Council Countries
- Veterinary Products Acts and Regulations in GCC
- The Data Requirements for veterinary Drug Submission.
- Labeling Information and Package Leaflet for Veterinary Medicinal Products.
- Summary of the Product Characteristics (SPC) for Veterinary Pharmaceutical Products.

- Law of Combating Narcotic Drugs and Psychotropic Substances.
- Procedures and controls of narcotics and psychotropic substances.
- Circular No. E/2391 "update on procedures and controls of controlled products according to special terms and conditions".
- Registration Rules of Veterinary Pharmaceutical and Manufacturers and their products.
- any other document issued by the SFDA in this regard

2. CLASSIFICATION OF LEGAL SUPPLY STATUS

The veterinary medicinal products are classified according to the following categories:

1. Prescription Only Medicines (POM): available only on a Veterinary prescription.
2. Over-the-Counter (OTC): obtained by a consumer for the animal without supervision of a pharmacist or Veterinarian and not subject to veterinary medical prescription.
3. Restricted Medicines dispensed under a prescription: Veterinary Medicines are subjected to control according to special terms and conditions
4. Products dispensed under a controlled prescription: narcotics and psychotropic substances under the Tables attached to the Law of Combating Narcotic Drugs and Psychotropic Substances.

3. CRITERIA FOR CLASSIFICATION OF LEGAL SUPPLY STATUS

The Criteria for the supply of veterinary medicine are outlined below:

3.1. Prescription only medicine (POM) Criteria

If any of the criteria apply, this is considered sufficient for the veterinary medicinal product to be classified as a prescription-only-medicine (POM).

1. Supervision by an animal healthcare practitioner is necessary

- The drug is used in the treatment of a serious disease not easily diagnosed by the public. In these situations, the involvement of a veterinarian in the diagnosis, treatment, and monitoring of the disease, including selecting and monitoring the use

of the drug, can help decrease the chances of harm occurring, as well as increase the benefits.

- The use of the drug may mask other diseases, and result in:
  - A lack of timely diagnosis and treatment
  - A significant worsening of the underlying disease; or
  - Jeopardize the chances of a more successful therapy.
- The use of the drug requires complex or individualized instructions: When the use of a drug needs to be tailored to an animal specific circumstances or when the public cannot easily understand the drug information.
- The drug has a narrow margin of safety: For some drugs, the difference between a therapeutic dose and a toxic dose is very small the animal must receive the right amount of drug to prevent serious consequences.
- The drug has the potential or is known to cause serious adverse reactions or interactions at normal dosage level.
- The use of the drug may lead to direct or indirect danger to animal health, even when used correctly, if used without medical supervision. A veterinary medicinal product would increase the risk of product's resistance, in particular in the general population, to such an extent that the usefulness of any veterinary medicinal product is likely to be compromised e.g., Antibiotic.
- Practitioner experience is necessary to administer the drug or oversee the drug's administration.

2. Limited marketing experience

- Recent authorization/limited marketing experience of the drug can leave some uncertainties regarding its safety and efficacy:
  - Further investigation may be necessary when a veterinary medicinal product has recently been granted a marketing authorization or because of limited experience/use of the product.
  - Even if animal clinical trial data are extensive and reassuring, it is important to have post-marketing experience in veterinary field, which may be imposed by the design of clinical trials.

- New strength, dose, route of administration, indication, new target species and/or combination of substances.
    - A drug may have been on the market but is now 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 of the new use. In these cases, legal status would help to ensure practitioner oversight.

3.2. OTC Criteria

A veterinary medicinal product, which does not meet any of the criteria for supply subject to medical prescription, may be classified as an OTC, if:

1. **Supervision by a veterinarian is not required:**

- The public can easily and accurately diagnose, treat, and monitor diseases or symptoms with respect to the recommended medicine:
    - The risks associated with a misdiagnosis of symptoms, and/or a delay in using the appropriate treatment or use of sub-optimal treatment should be addressed.
    - Any collateral measures that might be needed for effective use of the treatment should be usable without veterinarian intervention.
- The utilization, administration and/or monitoring of the veterinary medicinal product should not require complex or individualized instructions:
    - The selection of a proper veterinary medicinal product and dosing should be easily and correctly achieved by the public.
    - Product information can be easily understood and followed by the public.
    - Self-administration must be done without veterinarian supervision.
    - Benefit can be achieved when utilized without the guidance of a veterinarian.
    - Monitoring parameters for the effective/safe use of the veterinary medicinal product must be assessed by the public without veterinarian intervention.

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

- The product should not lead to direct or indirect danger when used without veterinarian 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 hazards that arise from drug interactions with food or other drugs.
- Examples on indirect danger may include:
  - When symptomatic treatment might mask an underlying condition requiring medical attention.
  - Increased risk of development of bacterial resistance in the community because of the wide use of antibiotics without veterinarian supervision.

- The veterinary medicinal product should not have a narrow therapeutic index.
- The consequences of misuse of the product are minor:
  - The risk to health is Limited if the consumer uses the product when it is not indicated, exceeds the recommended dose or recommended length of treatment, or fails to read the contraindications or warnings.
  - The risk of intentional and unintentional misuse or accidental overdose should be addressed.
- The use of the product does not lead to abuse/dependence.

3.3.Restricted Medicines dispensed under a prescription

Refer to Circular No. E/2391 "update on procedures and controls of controlled products according to special terms and conditions" here.

3.4.Products dispensed under a controlled prescription

Refer to the SFDA's website for Tables attached to Law of Combating Narcotic drugs and Psychotropic Substances here.

4. IMPLEMENTATION OF THE LEGAL STATUS

The classification of the legal status of veterinary medicinal products takes place following the full assessment of products undergoing registration by the SFDA. At the time of the submission, applicants are encouraged to indicate their proposal for Legal Status in the Part

1 application form (Refer to *The Data requirements for veterinary Drugs Submission Drugs*).

5. APPLICATION SUBMISSION CONSIDERATIONS

In addition to SFDA data requirements for drug submission, the following are special considerations:

- Summary of Product Characteristics (SmPC): Wherever appropriate, the SPC will include an explanation on how the veterinary medicinal product should be supplied to the animal (e.g., to be prescribed by a specialist only, or any specific type of care during the treatment).

- For OTC products:
    - Product Information

The product Information Leaflet (PIL) 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 the duration of treatment or the need to consult a veterinarian in certain situations, should be provided as appropriate.

- A cautionary statement on the product label could be included, e.g. after a certain period, if symptoms /signs continue in the animal, a veterinarian should be consulted.

6. LEGAL STATUS RECLASSIFICATION

Veterinary medicinal products can be reclassified from POM to OTC if they meet the criteria for OTC as set out below:

- Diseases or symptoms can be easily and correctly diagnosed, treated, and monitored by the public concerning the drug recommended for use.
- The utilization, administration and/or monitoring of the Veterinary medicinal product should not require complex or individualized instructions.
- The veterinary medicinal product should have an adequate margin of safety.
- The veterinary medicinal product should not have a narrow therapeutic index.
- The veterinary medicinal product should have a minor risk of misuse.
- The use of the veterinary medicinal product must not lead to abuse / dependence.

- No Limited Market Experience with the Use of the Drug.

6.1.Reclassification Application

The legal classification status of veterinary medicinal products may be changed by submitting a variation application via the Saudi Drug Registration System (SDR)[1].

6.2.Requirements

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

1. Cover letter
2. Non-clinical and/or clinical overview (expert reports)

In all cases, a non-clinical and/or 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 the OTC criteria should be addressed and supporting documentation submitted when applicable.

3. Non-clinical and/or clinical safety
   - A pre-clinical and/or clinical overview and the non-clinical and/or clinical summaries, or references to studies on target species that show low general toxicity and no relevant reproductive toxicity, genotoxic or carcinogenic properties relevant to the experience/exposure of the veterinary medicinal product should be given.
   - Experience in terms of animal exposure to the substance needs to be considerable and should be outlined. However, active substances permitted for supply without a veterinary medical prescription will be subject to a medical prescription if limited knowledge exists about the consequences of long-term drug use.
   - Information on adverse reactions should be provided, including experience of use without veterinarian supervision.

[1] Please refer to SFDA Guidelines for Variation Requirements to determine the type of variation required to reclassify legal status.

- 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.
- The application should consider the consequences of the use of the product by a consumer who has incorrectly assessed his animal condition or symptoms.
- The application should consider the consequences of incorrect or delayed diagnosis of an animal condition or symptoms due to self-medication with the product by the consumer.

4. Product information (PI)
   - For a medicinal product classified for supply as OTC, the proposed 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.
   - The outer packaging should include instructions for use in the case of non-prescription medicinal products.
   - Contraindications and warnings, such as advice limiting the duration of treatment or the need to consult a veterinarian in certain situations, should be provided as appropriate.
   - This product information, on the label and in the leaflet, should be readable, see *the Guidance for Presenting the Labeling Information, SPC, and PL.*

References:

1. Guidance Document: Determining Prescription Status for Human and Veterinary Drugs, Health Canada, December 2013.