مجلس الصحة
لدول مجلس التعاون
Gulf Health Council

Guidelines for Classifying Legal Status of Veterinary Medicinal Products

Version 1.0

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Registration and Licenses

Central Registration

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ACRONYMS & GLOSSARY

Legal Status	The conditions and restrictions under which the veterinary medicinal product are available to animals/consumers.
Over the counter (OTC) product	A veterinary medicinal product subject to GHC authority that could be obtained by consumers in GCC Member States without a veterinarian prescription.
Prescription only medicine (POM)	A veterinary medicinal product that is subject to GHC authority and that is available to animal / consumers in GCC Member States based on a licensed veterinarian prescription in GCC Member States.

1. INTRODUCTION

1.1.Scope

This guidance addresses the criteria that are followed by Gulf Health Council (GHC) when setting the legal status of veterinary medicinal products in GCC Member States.

It is also describes the criteria and process for changing the classification of the legal status of veterinary products in GCC Member States.

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 is applicable to medicinal products intended for animal use in GCC Member States.

1.2.Legal base:

The legal base of this document 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 GCC Member States.

1.3.Related documents

This guideline must be considered along with the following documents:

- Veterinary Products Law In Arab Gulf Cooperation Council Countries
- Veterinary Products Act and Regulation in GCC
- The Data Requirements for veterinary Drugs 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 GHC 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 consumer for animal without supervision of a pharmacist or veterinary and not subject to veterinary medical prescription.
3. Restricted Medicines dispensed under a prescription: Veterinary Medicines subjected to control according to special terms and conditions
4. Products dispensed under a controlled prescription: narcotics and psychotropic substances under Tables attached to 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 applies, this is considered sufficient for the veterinary medicinal product to be classified as 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 may result in any of the following:
  - A lack of timely diagnosis and treatment
  - A significant worsening of the underlying disease; or
  - Otherwise putting at risk the chance of 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 general population cannot easily understand the drug information.
- The drug has a narrow margin of safety: For some drugs, the difference between a therapeutic dose and toxic dose is very small, so it is critical that the animal precisely receive the right amount of drug to prevent serious consequences.
- The drug has a potential or is known to cause serious adverse reactions or serious interactions at normal dosage level would be typically subject to veterinary medical prescription.
- 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 resistance to the product, 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 expertise 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 only 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 animal, 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 associated with 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 necessary:**

- Diseases or symptoms can be easily and correctly diagnosed, treated, and monitored by the public with respect of the medicine recommended for use:
    - 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 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 proper veterinary medicinal product and dosing should be easily and correctly achieved by 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 a guidance of veterinarian.
    - Monitoring parameters for the effective/safe use of the veterinary medicinal product must be assessed by 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 danger arising 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 pose a Narrow Therapeutic Index.
- 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, 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 GHC'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 GHC. At the time of the

submission, applicants encouraged to indicate their proposal for Legal Status in Part 1 application form (Refer to *The Data requirements for veterinary Drugs Submission Drugs*).

5. APPLICATION SUBMISSION CONSIDERATIONS

In addition to GHC data requirements for drug submission, the followings 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 animal (e.g., to be prescribed by 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 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 with respect of 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 pose a Narrow Therapeutic Index.
- The veterinary medicinal product should have a minor risk to 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 changed by submitting a variation application via Taawon System.

6.2.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. 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 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 subjected to 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.

- 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 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 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.