الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Data Requirements for Renewal the Marketing Authorizations of Veterinary Medicinal Products

Draft

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DRAFT

This document is a draft SFDA guideline published for comments and suggestions purposes. It is, therefore, subject to alteration and modification and may not be referred to as SFDA guideline until approved by SFDA

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Drug Sector

Please send your comments or suggestions before January 24, 2020 to: Drug.comments@sfda.gov.sa

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الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

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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1. INTRODUCTION

1.1. Objective

This document initiated to explain and clarify the requirements for the renewal of veterinary drug marketing authorizations.

1.2. Scope

These requirements apply only for veterinary drugs, including Pharmaceutical and Immunological drugs.

1.3. Related Guidelines and Documents

This document should be read in conjunction with the following guidelines and documents published in the SFDA website (Drug Sector page):

- Regulatory Framework for Drug Approvals.
- Guidance for Submission.
- GCC Guideline on the specifications for provision of an electronic submission for a veterinary medicinal product.
- Data Requirements for Veterinary Medicinal Products (Pharmaceutical and Immunological).
- Guidance for presenting the Summary of products characteristics (SPC), package leaflet (PL), and labeling information for veterinary products.

2. DOCUMENTATION

2.1. Data Requirements for the Renewal of Veterinary Pharmaceutical Products

Section	Requirements	Required (R) or Optional (O)
Part 1	**Summary of the dossier**	
1a	**Administrative information**	
1a1	Cover letter	R
1a2	Application form	R
1a3	Pharmacovigilance	O
1a31	Pharmacovigilance system	O
1a32	Risk management plan	O
1a4	Certificates & documents	
1a42	CPP	R
1a5	Pricing	
1a51	Price list	O
1b	**SPC and Product Literature**	
1b1	Summary of Product Characteristics (SPC)	R
1b2	Package leaflet (PL)	R
1b21	Arabic leaflet	R
1b22	English leaflet	R
1b3	Labeling	R
1b4	Artwork (Mock-ups)	R
Part 2	**Quality documentation**	
2f	Stability	R
2f1	Active substances(s)	R
2f2	Finished product	R

2.2. Data Requirements for the Renewal of Veterinary Immunological Products

Section	Requirements	Required (R) or Optional (O)
Part 1	**Summary of the dossier**	
1a	**Administrative information**	
1a1	Cover letter	R
1a2	Application form	R
1a3	Pharmacovigilance	O
1a31	Pharmacovigilance system	O
1a32	Risk management plan	O
1a4	Certificates & documents	
1a42	CPP	R
1a5	Pricing	
1a51	Price list	O
1b	**SPC and Product Literature**	
1b1	Summary of Product Characteristics (SPC)	R
1b2	Package leaflet (PL)	R
1b21	Arabic leaflet	R
1b22	English leaflet	R
1b3	Labeling	R
1b4	Artwork (Mock-ups)	R
Part 2	**Quality documentation**	
2g	Stability tests	R

3. PART 1:

Summary of the Dossier for Pharmaceutical and Immunological Veterinary Medicinal Products

1a Administrative information

1a1 Cover letter

The applicant shall include a cover letter for each submission. A template provided in the SFDA Guidance for Submission.

1a2 Application form

The completed and signed application form printed out from the Saudi Drug Registration (SDR) system (https://sdr.sfda.gov.sa/frmLogin.aspx) should be presented in this section.

1a3 Pharmacovigilance

1a31 Pharmacovigilance system

It shall contain a detailed description of the pharmacovigilance system including the proof that the applicant has the services of a qualified person responsible for pharmacovigilance and the necessary means for the notification of any adverse reaction.

1a32 Risk management plan

A detailed description of the risk management system, which the applicant will introduce, should provide, where appropriate.

1a4 Certificates & documents

1a42 CPP

The CPP should be in accordance with WHO guidelines. However, if the CPP is not available, a marketing authorization (or free sales certificate) from the country of origin (COO) should be submitted. Marketing authorization (or free sales certificate) should include the following:

- Product trade name in the COO
- Number and date of marketing authorization in the COO
- Name of active and inactive substances with their concentrations

- A statement that certifies the product is marketed in the COO. If not, please specify the reasons
- Provide official document demonstrating that the product has registered for no less than one year in the COO
- Provide the Summary of Product Characteristics (SPC)
- Provide a copy of the Package Leaflet (PL)

1a5 Pricing

1a51 Price list

The applicant shall include the price of the product in countries listed in the SFDA Guidance for Submission.

1b SPC and product literature

1b1 Summary of product characteristics (SPC)

Refer to the Guidance for presenting the SPC, PL, and labeling information for veterinary products.

1b2 Package leaflet (PL)

Refer to the Guidance for presenting the SPC, PL, and labeling information for veterinary products.

1b21 Arabic leaflet

1b22 English leaflet

1b3 Labeling

Refer to the Guidance for presenting the SPC, PL, and labeling information for veterinary products.

1b4 Artwork (Mock-ups)

A mock-up is a flat artwork design in full color, presented so that, following cutting and folding, where necessary, it provides a full size replica of both the outer and immediate packaging so that the two dimensional presentation of the label text is clear. The application for a marketing authorization must include one or more mock-ups of the outer packaging and of the immediate packaging of the product. Refer to the Guidance for presenting the SPC, PL, and labeling information for veterinary products.

4. PART 2:

Quality Documentation for Veterinary Pharmaceutical Products

2f Stability Tests

Refer to the VICH stability testing guidelines:
http://www.vichsec.org/guidelines/pharmaceuticals/pharma-quality/pharma-stability.html

2f1 Active substances(s)

Stability data shall be presented to support the defined retest period and storage conditions. The type of stability studies conducted, protocols used, the analytical procedures used and their validation together with the detailed results shall be presented. The stability commitment with a summary of the protocol shall be provided.

2f2 Finished product

A description shall be given of the investigations by which the shelf life, the recommended storage conditions and the specifications at the end of the shelf life proposed by the applicant have been determined.

The type of stability studies conducted, protocols used, the analytical procedures used and their validation together with the detailed results shall be presented.

Where a finished product requires reconstitution or dilution prior to administration, details of the proposed shelf life and specification for the reconstituted/diluted product are required, supported by relevant stability data.

In the case of multi-dose containers, where relevant, stability data shall be presented to justify a shelf life for the product after it has been broached for the first time and an in-use specification shall be defined.

Where a finished product is liable to give rise to degradation products, the applicant shall declare and indicate the identification methods and test procedures for degradation products.

The conclusions shall contain the results of analyses, justifying the proposed shelf life and if appropriate, the in-use shelf life, under the recommended storage conditions and the

specifications of the finished product at the end of the shelf life, and in-use shelf life if appropriate, of the finished product under these recommended storage conditions.

The maximum acceptable level of individual and total degradation products at the end of shelf life shall be indicated.

A study of the interaction between product and container shall be submitted wherever the risk of such interaction is regarded as possible, especially where injectable preparations are concerned.

The stability commitment with a summary of the protocol shall be provided.

5. PART 2:

Quality documentation for veterinary immunological products

2g Stability tests

Description shall be given of the tests undertaken to support the shelf life proposed by the applicant. These tests shall always be real-time studies; they shall be carried out on a sufficient number of batches produced according to the described production process and on products stored in the final container(s); these tests include biological and physicochemical stability tests.

The conclusions shall contain the results of analyses, justifying the proposed shelf life under all proposed storage conditions.

In the case of products administered in feed, information shall also be given as necessary on the shelf life of the product, at the different stages of mixing, when mixed in accordance with the recommended instructions.

Where a finished product requires reconstitution prior to administration or is administered in drinking water, details of the proposed shelf life are required for the product reconstituted as recommended. Data in support of the proposed shelf life for the reconstituted product shall be submitted.

Stability data obtained from combined products may be used as preliminary data for derivative products containing one or more of the same components.

The proposed in-use shelf life shall be justified. The efficacy of any preservative system shall be demonstrated.

Information on the efficacy of preservatives in other similar immunological veterinary medicinal products from the same manufacturer may be sufficient.

Refer to the VICH stability testing guidelines:

http://www.vichsec.org/guidelines/biologicals/bio-quality/stability.html