swissmedic

Guidance document
Authorisation of veterinary medicinal products

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1 Terms, definitions, abbreviations

1.1 Definitions and terms

1.2 Abbreviations

CVMP	Committee for Veterinary Medicinal Products
DMF	Drug Master File
EDQM	European Directorate for the Quality of Medicines and Healthcare
EU Regulation 2019/6	Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC
FDA	Food and Drug Administration
FeeO-Swissmedic	Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products of 14 September 2018 (SR 812.214.5)
INN	International Nonproprietary Name
Ph. Eur.	European Pharmacopoeia
Ph. Helv.	Pharmacopoea Helvetica
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, SR 812.21)

TPLRO	Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the Licensing Requirements for Therapeutic Products (SR 812.212.22)
TPO	Ordinance of 21 September 2018 on Therapeutic Products (Therapeutic Products Ordinance, TPO) (SR 812.212.21)
TSE	Transmissible Spongiform Encephalopathy
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
VMPI	Veterinary medicinal product information = Information for healthcare professionals and/or package leaflet
VMPO	Veterinary Medicinal Products Ordinance of 18 August 2004 (SR 812.212.27)

2 Introduction

This guidance document describes the requirements pertaining to the documents to be submitted when applying for authorisation of veterinary medicinal products in Switzerland.

2.1 Legal framework

The requirements pertaining to the submission of authorisation applications are based on the following legal provisions:

TPA

Art. 9 Marketing authorisation
Art. 10 Conditions for granting a marketing authorisation
Art. 11 Application for a marketing authorisation

TPO

Art. 1
Art. 2 Authorisation requirement
Art. 3 Application for a marketing authorisation
Art. 6 Application for authorisation of a medicinal product with GMO
Art. 9 Marketing authorisation

TPLRO

Section 1: General Provisions

Art. 1 Scope
Art. 2 General preconditions

Section 3: Documentation requirements for the authorisation of medicinal products for use in veterinary medicine (veterinary medicinal products)

Art. 7 Documentation of analytical, chemical and pharmaceutical investigations
Art. 8 Documentation of innocuousness
Art. 9 Additional documentation of safety and residues in investigations on livestock
Art. 10 Admissibility of pharmacologically active substances and proposed withdrawal periods
Art. 11 Documentation of preclinical and clinical trials

Section 4: Labelling and product information requirements

Art. 12 Information and texts on containers and packaging materials
Art. 13 Information for healthcare professionals
Art. 14 Package leaflet
Art. 16 Exceptions

Annex 6: Requirements pertaining to labelling and product information for veterinary medicinal products

3 Objective

Swissmedic uses this guidance document first and foremost as a resource for applying the legal provisions on the authorisation of veterinary medicinal products in a uniform and equitable manner. For applicants, the document is intended to make clear the specific requirements that must be fulfilled so that corresponding applications can be processed by Swissmedic as quickly and efficiently as possible.

4 Scope

This guidance document is applicable in the Veterinary Medicines department, Authorisations division, to the authorisation of veterinary medicinal products in accordance with Article 11 TPA. The description of the documents to be submitted is not final. Swissmedic reserves the right to request additional documents if necessary.

5 Description

5.1 General remarks

This guidance describes the requirements relating to the documentation for the submission and authorisation of veterinary medicinal products
The application documents must correspond to the current state of science and technology, *EU Regulation 2019/6*, the latest versions of the relevant pharmacopoeias (primarily EP and Ph. Helv.), and the relevant guidelines issued by the *International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products* (VICH) or the European *Committee for Veterinary Medicinal Products* (CVMP). In justified cases, reference can be made to other guidelines, such as those issued by the US Food and Drug Administration (FDA). Other requirements that Swissmedic publishes in the Swissmedic Journal or on its website are also relevant. Deviations must be scientifically justified. Relevant scientific literature should be discussed in the corresponding section and be enclosed, fully referenced, with the documentation.
The quality, efficacy and safety claimed for the veterinary medicinal product in the application should be evaluated and justified (benefit-risk evaluation).
Swissmedic will accept documentation structured in accordance with the current recommendations of the European Union. The provisions concerning language and formal requirements must be observed.
Medicinal product samples for analytical investigation should be submitted only if requested by Swissmedic.

New efficacy- and safety-related findings that come to light while the application is being processed should be submitted continually and voluntarily. However, except in special cases such as in the event of an epizootic outbreak (cf. WL ZL000_00_986 Authorisation of immunological veterinary medicinal products in the event of an epizootic outbreak), this requirement must not be applied to the delayed rectification of documentation that was incomplete when first submitted ("rolling submission"). In this context, clinical trial data that had not been finalised at the time of submission is not regarded as a subsequent submission. Accordingly, if such data is submitted and the original application has to be re-evaluated as a result, additional time will generally be required to process the application[1] and a charge may be made for the extra time involved[2].
Authorisation applications that do not satisfy the following requirements either in whole or in part will be rejected and returned for improvement.

In the case of immunological veterinary medicinal products containing GMO (genetically modified organisms), documentation as per Art. 28 of the Release Ordinance (RO, SR 814.911) must be submitted over and above the requirements of therapeutic products legislation. According to Art. 43 RO, Swissmedic must submit the documentation accompanying the authorisation application to the specialist bodies (Federal Office for the Environment, Federal Office of Public Health, Federal Food Safety and Veterinary Office, Federal Office for Agriculture, Swiss Expert Committee for Biosafety and Federal Ethics Committee on Non-Human Biotechnology) for assessment. This means that Swissmedic may only approve a veterinary medicinal product with GMO if it meets the conditions of the Release Ordinance in addition to the requirements of therapeutic products legislation. The decision regarding the former is made by the specialist bodies listed above.
The following in particular are required by the specialist bodies: Part I C Expert Reports, Part II Documentation on quality and Part III Documentation on innocuousness and residues.

5.2 Part I Forms, packaging texts, Expert Reports

5.2.1 I A + B Administrative requirements and product information

Specific requirements governing the form in which the application documentation must be submitted can be found in the guidance document *Formal requirements* and the associated Directory *Overview of documents to be submitted*.

Veterinary medicinal product information and packaging texts must be submitted to Swissmedic in one of the three official Swiss languages. Swissmedic accepts the other administrative documents, the Expert Reports (Part I C) and Parts II-IV in English. The original language version of studies translated from languages other than those just mentioned should be submitted with the translation.

All text elements must comply with the requirements stated in Annex 6 of the TPLRO (Requirements pertaining to labelling and product information for veterinary medicinal products).

The requirements applicable to product information are also described in the guidance document *Product information for veterinary medicinal products* and in templates to be used for information for healthcare professionals for veterinary medicinal products and for the package leaflet for veterinary medicinal products.

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1 See guidance document *Time limits for authorisation applications*
2 See guidance document *Time limits for authorisation applications* and Fee-O Swissmedic

5.2.2 I C Expert Reports

An Expert Report (Detailed and Critical Summary) should be prepared for each part of the submitted documentation (Parts II to IV).
The Expert Reports should consist of a critical evaluation of all the submitted documents. They should be of a manageable volume and provide the reader with a comprehensive evaluation of the quality, safety and efficacy of the veterinary medicinal product, as well as its advantages and disadvantages. All important data should additionally be compiled and presented in a supplement in tabular and graphical form.
All statements in the Expert Reports and enclosed tables or graphical presentations should be referenced in accordance with the guidance document *Formal requirements* and the guidance document *Guidance eDOK*. It should be possible to locate the literature underlying the statements as directly as possible via the references (ideally with a single mouse click).
The Expert Reports must be prepared, signed and dated by an experienced specialist with appropriate qualifications. The name, activity and qualifications of this specialist should be stated in a dated curriculum vitae.

5.3 Part II Documentation on quality

The quality requirements are set out in detail in Annex II, Title I, Part 2 for non-immunological veterinary medicinal products and in Annex II, Title II, Part 2 for immunological veterinary medicinal products of REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2018.
Reasons must be given for any deviations and, where necessary, agreed with Swissmedic prior to submission. The documentation must take account of Switzerland-specific stipulations and particularities.

5.4 Part III Documentation on safety and residues.

The requirements regarding safety and residues are set out in detail in Annex II, Title I, Part 3 for non-immunological veterinary medicinal products and in Annex II, Title II, Part 3 for immunological veterinary medicinal products of REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2018.

Reasons must be given for any deviations and, where necessary, agreed with Swissmedic prior to submission. The documentation must take account of Switzerland-specific stipulations and particularities.

5.5 Part IV Documentation on preclinical studies and clinical trials / efficacy tests

The requirements regarding preclinical studies and clinical trials are set out in detail in Annex II, Title I, Part 4 for non-immunological veterinary medicinal products and in Annex II, Title II, Part 4 for immunological veterinary medicinal products of REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2018.

Reasons must be given for any deviations and, where necessary, agreed with Swissmedic prior to submission. The documentation must take account of Switzerland-specific stipulations and particularities.

Change history

Version	Change	sig
2.0	Additions regarding GMO-containing immunological veterinary medicinal products	zai
1.2	New layout, no content adjustments to the previous version.	dei
1.1	Formal adjustments to the header and footer No content adjustments to the previous version.	dei
1.0	Implementation of TPO4	ps/fg