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Change history

Version	Valid and binding as of	Description, comments (by author)	Author's initials
3.0	01.04.2022	Adaptations arising from the new structure of the changes for VMPs (early revision of regulations for VMPs), section on Publication of the product information inserted, as well as other minor editorial and content-related clarifications and corrections.	fg/ps
2.1	01.03.2021	Formal adjustments to the header and footer No content adjustments to the previous version.	dei
2.0	01.01.2020	Alignment with current practice according to the publication dated 08.10.2019 (new section 5.4), as well as general content-related and editorial clarifications and corrections.	ps
1.0	01.01.19	Implementation of TPO4	ps

1 Abbreviations

ATCvet — **A**natomical **T**herapeutic **C**hemical classification system for **vet**erinary medicinal products

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FeeO-Swissmedic	Ordinance of 14 September 2018 on the Fees charged by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic; SR 812.214.5)
FO MI:	Form: Manufacturer information
HMP	Human medicinal product
IHP	Information for Healthcare Professionals
MP	Medicated premix
PI	Product information = Information for healthcare professionals and package leaflet
PL	Package leaflet
PM	Packaging materials = primary and secondary packaging
SPC	Summary of Product Characteristics
TPLO	Ordinance of the Swiss Agency for Therapeutic Products on the Simplified Licensing of Therapeutic Products and the Licensing of Therapeutic Products by the Notification Procedure (SR 812.212.23)
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)
VMP	Veterinary medicinal product
VMPC	Veterinary medicinal products compendium = publication platform for veterinary medicinal product information
WHO	World Health Organization

2 Introduction and objective

This guidance document describes the requirements pertaining to the product information for veterinary medicinal products according to Article 26 TPO and Articles 13 and 14 TPLRO in conjunction with Annex 6 TPLRO. Additional notes can be found in the templates for the "Information for healthcare professionals for veterinary medicinal products with notes" and "Package leaflet for veterinary medicinal products with notes".

Since this guidance document involves an Administrative Ordinance document aimed at the administrative bodies, it does not directly specify the rights and obligations of private individuals. Swissmedic uses this document first and foremost as a resource for applying the legal provisions on authorisation in a uniform and equitable manner. The publication of the guidance document is designed to make it clear to third parties what requirements must be fulfilled according to the practice of Swissmedic.

3 Scope

The guidance document is valid for the Authorisation division of Swissmedic and is applicable to veterinary medicinal products, excluding medicinal products authorised in the notification procedure according to TPLO, Art. 39.

4 Legal framework

The requirements relating to the product information for veterinary medicinal products are based on the following legislative texts:

TPO, Section 4: Labelling and medicinal product information

- Art. 26 Language

TPLRO

- Art. 13 Information for healthcare professionals

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- Art. 14 Package leaflet
- Art. 14b Declaration of active substances and pharmaceutical excipients.
- Art. 16 Exceptions
- Annex 6

1 General remarks
2 Declaration of active substances and pharmaceutical excipients
3 Requirements for the veterinary medicinal product Information for healthcare professionals
4 Requirements for the veterinary medicinal product package leaflet

5 Requirements for veterinary medicinal product information

5.1 Other valid European documents

1. DIRECTIVE 2001/82/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to veterinary medicinal products (EU Directive 2001/82/EC)
2. Notice to Applicants Veterinary Medicinal Products, Volume 6C - Summary of Product Characteristics SPC - Pharmaceuticals (2006) (NtA VMP Vol 6C – SPC)
3. Quality Review of Documents veterinary product-information template version 8.2
4. Declaration of storage conditions: 1. in the product information of pharmaceutical veterinary medicinal products, 2. for active substances (Annex)

5.2 General remarks

- The requirements specified in TPLRO relating to the veterinary medicinal product information for Switzerland are based on the requirements specified in the repealed EU Directive 2001/82/EC [1] and, in respect of the Information for healthcare professionals, fleshed out in the NtA Veterinary Medicinal Products, Vol. 6C - SPC [2].
- The specified order of sections in the IHP and PL must be followed.
- For the correct drafting of the IHP and PL Swissmedic provides templates, based on the European template [3], in German, French and Italian. If these templates are used to prepare the IHP and PL without the deletion of any section headings, the correct section headings and their sequence according to this WL will automatically be guaranteed. The section headings in the IHP and PL correspond to the requirements specified in the German, French and Italian versions of the document "Quality Review of Documents veterinary product-information template version 8.1" [3] but diverge partially from those in appendix 6 TPLRO. For example, the document "Quality Review of Documents veterinary product-information template version 8.2" "waiting times" (Wartezeiten) is used instead of the term commonly used in Switzerland (Absetzfristen – "withdrawal periods"). Swissmedic recommends using the terminology according to the document "Quality Review of Documents veterinary product-information template version 8.1" already now as this terminology will be taken up into the Swiss ordinances at the next best opportunity. Differences between the term used in the PI adapted to the new format and non-updated packaging materials will be tolerated.
- For ease of legibility, at least a 7-point font should be used in the printed versions of the IHP and PL supplied with the VMP.
- The text of the product information should be submitted to Swissmedic in an official Swiss language for review, together with references to the documentation underlying the statements. For variation applications, the new information should be clearly identified (changes visible in "Track changes" mode) and should also be referenced.
- Swissmedic approves the manuscript of the product information, incl. all graphical elements in the reviewed language (= definitive version of the product information). The authorisation holder is

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responsible for the correct translation of the approved product information into the two other official languages and for incorporating the graphical elements in the translated texts.

5.3 Technical requirements for the Information for healthcare professionals and package leaflet

- The IHP contains the information on the use of the veterinary medicinal product that has been approved by Swissmedic on the basis of the outcome of the assessment. All statements in the IHP must be verified by the information in the authorisation documentation. Accordingly, any changes in content made by the authorisation holder are subject to application to, and approval by, Swissmedic.
- The purpose of the IHP is to provide a clear and unambiguous description of the approved conditions of use for a veterinary medicinal product in a standardised format.
- The IHP contains detailed and objective information about the authorised medicinal product. It is not promotional in nature, nor does it represent a summary of the assessment of the veterinary medicinal product.
- The IHP should be drafted in clear, unambiguous technical language. In particular, all information concerning indications, contraindications, precautions for use and warnings per target animal species must be defined precisely.
- The individual sections in the IHP and PL should contain only the information that is relevant to the heading. If certain aspects must be mentioned in more than one section (e.g. Contraindications and Interactions), the individual statements must be referenced such that the information in the concerned sections is mutually complementary.
- The sections in the IHP and PL should be listed in full unless they are explicitly classed, in the templates, as "Headings that may be deleted". Certain headings may not be deleted even if the corresponding sections do not include any content. If no content is entered in a section, the standard formulations specified in the templates should be used.
- While the statements in the PL are based on those in the Information for healthcare professionals, the PL should be understandable for laypersons, i.e. the text should be simplified and medical terms should be translated or reformulated.

5.4 When is a specific information text required?

An IHP and a PL are not mandatory for every authorised VMP, but the following applies (see also the online publication dated 8.10.2019):

IHP and PL required:

- Veterinary medicinal products authorised for pets, or for pets and livestock, and which may be dispensed by the veterinarian to the animal owner and therefore frequently administered to animals by the veterinarian.

IHP not required:

- Veterinary medicinal products in dispensing category E
- Veterinary medicinal products that can be dispensed in pet and bee-keeping shops
- Homeopathic preparations without an indication
- On application and subject to the agreement of Swissmedic, usually veterinary medicinal products in dispensing category D, particularly disinfectants, veterinary medicinal products with a predominantly physical mode of action, veterinary medicinal products for promoting digestion and for treating deficiency symptoms

PL not required (veterinary medicinal product can be distributed with IHP):

- Veterinary medicinal products in dispensing category A and narcotics
- Veterinary medicinal products in dispensing category B, authorised exclusively for livestock
- On application and subject to the agreement of Swissmedic, veterinary medicinal products for pets, provided these are usually administered by the veterinarian

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If a PL is not issued and the IHP is enclosed with the packs to be distributed instead, useful information for the user that is normally included in the PL can be added to the IHP in addition to the required information. Example: the "Warning regarding children" stated under section 6.4 "Special precautions for storage". If there is no space in the existing (usually folding carton) for a trilingual IHP, a bilingual IHP can, by way of exception, be enclosed with the packaging with the consent of Swissmedic. Irrespective of this option, however, it must be published in the VMPC in the 3 official languages.

For veterinary medicinal products for which the PL is not mandatory, the PL may nevertheless still be produced and submitted to Swissmedic for approval. The approved PL should be enclosed in the packs to be distributed.

VMP authorised for distribution abroad (export licence)

- For VMP in dispensing categories A and B, the IHP is sufficient.
- For VMP that can be dispensed in pet and bee-keeping shops, homeopathic preparations without an indication and VMP in dispensing category E, the PL is sufficient.
- For all other VMP in dispensing category D, the PL is sufficient provided Swissmedic approves the corresponding application. Otherwise, the IHP is sufficient.

For VMP authorised for distribution abroad, the approved text in the correspondence language does not need to be translated into other languages. However, like all other approved PI, the approved text must be forwarded to the relevant agency for publication.

5.5 Special remarks for the product information for medicated premixes (MP)

5.5.1 Sections on Amounts to be administered and administration route (Information for healthcare professionals), and on Dosage for each species, route(s) and method of administration (package leaflet)

On the one hand, the dosage should be stated in grams of MP per 100kg body weight and, on the other, in milligrams of active substance per kilogram body weight.

The number of feeds over which the daily dosage is to be distributed should be stated.

The product information for MP should include detailed instructions on the preparation and administration of the medicated feed.

The following information should be considered:

- Specify the feeds (suitable feed types) in which the MP can / is meant to be administered.
- State whether the MP can / is meant to be administered via the drinking water.
- Specify the conditions (temperature, pH, etc.) under which the MP should be added to the feed / water.
- Specific remarks on feeding. For example, state how quickly the feed must be given after the MP is added.
- If relevant, state any specific active substance-related precautions. For example, "Divalent and trivalent cations can lead to decreased absorption and efficacy of chlortetracycline!"

The product information for MP should include information about dosing guide values for preparing a medicated feed:
formula for calculating the admixing rate in kilograms of MP per tonne of feed or grams of MP per litre of drink.

- Practical sample calculations should be stated here so that the prescribing veterinarian has a rough indication of the dosage per tonne of feed for the prevailing situation.

A measuring device for the MP must be enclosed with packs ≤ 1kg.

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5.5.2 Special precautions for storage section

The shelf-life after preparation of a medicated feed should be verified and listed for each suitable medicated feed for admixing.

5.5.3 Section headings to be used in the IHP, incl. additional remarks on section content

See template for "Information for healthcare professionals for veterinary medicinal products with notes" on the Swissmedic website

https://www.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl000_00_043d_vl_fachinformationtierarzneimittelhmv4.docx.download.docx/ZL000_00_043d_VL_Fachinformation_Tierarzneimittel_HMV4.docx

5.6 Section headings to be used in the package leaflet and additional remarks on section content

See template for "Package leaflet for veterinary medicinal products with notes" on the Swissmedic website)
https://www.swissmedic.ch/dam/swissmedic/en/dokumente/zulassung/zl_hmv_iv/zl000_00_044d_vl_packungsbeilage_tam_hmv4.docx.download.docx/ZL000_00_044d_VL_Packungsbeilage_Tierarzneimittel_HMV4.docx

The PL is based on the entries in the IHP and should be drafted in a language that can be understood by laypersons.

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6 Adjustment of product information to the new format

6.1 Background

Adjustments to the existing structure of product information in line with the new format will be made per Art. 25b TPO as a change with evaluation and "standard" time limit. The change and the documentation that must be submitted in this context are described in the form *Variations VMP HMV4* as a regulatory change E.106. The same fee as for a variation with evaluation and "shortened" time limit (= previous type IB variation) is payable.

The application for the adjustment to the product information must be submitted to Swissmedic separately in accordance with Art. 23c TPLRO not later than the next applications for renewal of authorisation. In the case of medicinal products whose authorisation expires before 1 January 2020, the application must be submitted not later than 1 year after the next renewal.

Substantial changes to the product information, for example additional indications or changed waiting times that go beyond the adaptation to the new structure/the adaptation to the EU SPC e.g. concerning additional warnings and that require the submission of additional documents (see also section 6.2), should be submitted as separate variation applications.

6.2 Application procedure

The authorisation holder must incorporate the text of the veterinary medicinal product information approved by Swissmedic unchanged and in its entirety in the new structure of the Information for healthcare professionals and – with the exception of the "Pharmacokinetics" section – in the new structure of the package leaflet (preferably using the templates supplied by Swissmedic for product information and PL). If any additional statements are requested (e.g. adaptation to the approved EU SPC), these must be accompanied by documentation/references and the changes tracked. Any other changes, such as corrections to the declaration, harmonisation of the wording with the EU standard and purely linguistic corrections (note: technical language in product information vs. laypersons' language in PL) should also be tracked. The process is confirmed by checking the "YES" box on the form *Variations VMP HMV4*, section 6.6.

Drafts of the Information for healthcare professionals and of the package leaflets and, if applicable, the adapted packaging materials must be submitted to Swissmedic together with the documentation required by the form *Variations VMP HMV4*, regulatory change E.106. Note that corrected packaging materials only need to be submitted if substantial deviations arise as a result of adaptations to the product information, e.g. because the storage instruction is to be changed or the declaration is switched from "per unit" to "per millilitre".

Swissmedic will examine the applications submitted for compliance with the current regulations (especially Annex 6 TPLRO), the present Guidance document and the Guidance document *Packaging texts for veterinary medicinal products HMV4* as well as for consistency with the statements in the Information for healthcare professionals and the package leaflet. At the same time, Swissmedic is endeavouring – as part of the adaptation of veterinary medicinal product information to the new format – to eliminate any existing shortcomings (e.g. in the declaration on comparable medicinal products).

7 Publication of the product information

In accordance with Art. 67 para. 3 et seq. TPA, the product information is published in the VMPC. To this end, the marketing authorisation holders are asked to send to the VMPC the approved medicinal product information (after changes without evaluation and changes with evaluation with "shortened time limit" at least partially without approval stamp) together with their translations required by therapeutic products legislation within the following time limits:

- Safety-relevant changes: at the latest 20 calendar days after the official decision
- Changes: at the latest 60 calendar days after approval of the change

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- New authorisations: at the latest when the corresponding veterinary medicinal product is first placed on the market (Art. 29 TPO)

In connection with changes, please note that the time limit for submitting the medicinal product information to the VMPC should be observed and should not be confused with the implementation of the change (see also the Swissmedic publication 05/2021).

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