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Change history

| Version | Valid and binding as of: | Description, comments (by author) | Author's initials |
|---------|--------------------------|---|-------------------|
| 4.1 | 01.03.2022 | Addition re. registered trademark symbol; one addition (h) to section 13.2 | lac |
| 4.0 | 28.01.2022 | Adaptations due to new structure of changes for VMP (early revision of VMP regulations) | fg/ps |
| 3.1 | 01.03.2021 | Formal adjustments to the header and footer No content adjustments to the previous version. | dei |
| 3.0 | 07.10.2019 | New section concerning the implementation of an already approved design change | lac |
| 2.0 | 16.08.2019 | Further explanations re making changes on own initiative, and new section on type IB variations | lac |
| 1.0 | 01.01.2019 | Implementation of TPO4 | lac |

1 Definitions, terms, abbreviations

1.1 Definitions and terms

1.1.1 Packaging

Packaging refers to the container/containers in which the product (medicinal product) is packed. It refers to both the primary and, if applicable, the secondary packaging.

1.1.2 Primary packaging

Primary packages/primary packaging materials are packaging materials that are, or potentially may be, in direct contact with the medicinal product. Instead of primary packaging, the term (primary) container (e.g. bottle, blister, ampoule, pre-filled syringe, tube) is also used.

1.1.3 Secondary packaging

Secondary packages/secondary packaging materials are outer packages that are not in direct contact with the object to be packed and that usually have a protective and control function. Folding cartons are an example of secondary packaging for medicinal products. Instead of secondary packaging, the term packaging material is also used.

1.1.4 Packaging texts

These refer to the texts and particulars on the packaging, including graphic elements.

1.1.5 Medicinal product information, Information for healthcare professionals and package leaflet

The term medicinal product information refers to the Information for healthcare professionals and package leaflet as a whole.

The package leaflet for a veterinary medicinal product contains information for the animal owner and should be enclosed with the medicinal product. Information for healthcare professionals is also published electronically and is intended primarily for the veterinarian. Information for healthcare professionals need not be prepared for veterinary medicinal products in dispensing category E, veterinary medicinal products that can be dispensed in pet and bee-keeping shops, or homeopathic preparations without an indication. On application and subject to agreement with Swissmedic, information for healthcare professionals does not have to be prepared for other veterinary medicinal products in dispensing category D, in particular where the following veterinary medicinal products are concerned: disinfectants, veterinary medicinal products with a predominantly physical mode of action, and veterinary medicinal products for promoting digestion and for treating deficiency symptoms.

1.1.6 The requirements relating to the product information for veterinary medicinal products are defined in the guidance document with the same name. Dosage form

Dosage form refers to the delivery form (e.g. metered dose spray) including the pharmaceutical form (e.g. suspension).

1.1.7 Combination pack

Combination packs (combi-packs) are packages containing various, separately arranged elements (two medicinal products or a medicinal product with a medical device), which are intended to be used together for the same use.

1.2 Abbreviations

| | |
|--------|--|
| Ann. | Annex |
| Art. | Article |
| NarcCO | Ordinance of 25 May 2011 on Narcotics Control (SR 812.121.1) |
| Para. | Paragraph |
| TPA | Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21) |
| TPO | Ordinance of 21 September 2018 on Therapeutic Products (SR 812.212.21) |
| TPLO | Ordinance of the Swiss Agency for Therapeutic Products of 22 June 2006 on the Simplified Licensing of Therapeutic Products and the Authorisation 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) |

2 Introduction and objective

This guidance document explains how primary and secondary packages for veterinary medicinal products must be labelled and how they may be designed. As this is a guidance document aimed at administrative bodies, it does not directly specify the rights and obligations of private individuals. Swissmedic uses the document as a resource for implementing the legal provisions on requirements pertaining to information on packaging in a uniform and equitable manner. The guidance document is

intended to clarify the specific requirements that must be fulfilled so that corresponding applications can be processed as quickly and efficiently as possible.

3 Scope

This guidance document is valid for the Authorisation division of Swissmedic and is applicable to the labelling and design of packaging for veterinary medicinal products.

It does not apply to veterinary medicinal products authorised by the notification procedure according to Art. 39 TPLO.

4 Legal basis

The requirements relating to the texts on containers and packaging materials for veterinary medicinal products are based on the following legislative texts:

TPO

- Art. 26 Language

TPLRO

- Art. 12 Information and texts on containers and packaging materials
- Art. 14b Declaration of active substances and pharmaceutical excipients.
- Art. 17 Transmission of texts to the Agency
- Ann. 6
 - 1: General remarks
 - 2: Declaration of active substances and pharmaceutical excipients
 - 3: Requirements relating to texts on containers and packaging materials

5 Assessment principles

5.1 General principles

In accordance with the general provisions of Art. 1 TPA, packaging that jeopardise drug safety, mislead consumers (or animal owners), lead to inappropriate or excessive use or distort information about the medicinal product are not approved.

As a general rule, packaging texts may only display information that is useful, necessary, clear and not misleading and that correlates with the particulars on the Information for healthcare professionals/package leaflet. The information should be presented in clearly legible writing (there are no legal specifications regarding font size). From the standpoint of drug safety therefore, the graphic design of the packaging must be such that the information required by Ann. 6 TPLRO is easily identifiable and dominant and such that this information is not displaced by other statements.

Other information, texts and illustrations are permitted only if they are directly connected with the use of the medicinal product, important for providing health-related information, do not conflict with the particulars on the medicinal product information and are not misleading. Medicinal product advertising on containers or packaging materials is not permitted.

The appearance of a medicinal product should not lead to any trivialisation or confusion with a consumer product (food or tobacco product, drink or cosmetic) or to drug abuse.

5.2 Language

According to Art. 26 TPO, in the packaging texts must be in at least two official Swiss languages. The marketing authorisation holder may also include other languages, provided the mandatory information in the required languages is clearly legible.

Swissmedic approves the packaging texts in the correspondence language; the marketing authorisation holder is responsible for ensuring that the information in other languages is correct. Swissmedic does not check this.

The composition of the medicinal product can be provided in the national languages, in Latin or using internationally accepted abbreviated designations such as the International Nonproprietary Name (INN) issued by the World Health Organisation.

6 Texts on the primary packaging

Primary packaging must always include the following information:

- Name of the medicinal product, followed by the dosage strength (if several strengths exist) and the pharmaceutical form
- Active substance(s) by type and quantity
- Target animal species
- Administration route route, unless this is already obvious from the name of the medicinal product
- Batch number and expiry date (plus use-by period if applicable)

The following information can be omitted from the primary packaging **only** if its inclusion is not possible for technical reasons (e.g. very small primary containers). In this case, secondary packaging bearing the information in question must also exist.

- Marketing authorisation holder
- The statement “ad us. vet.”
- Contents of the package
- The instruction “Note the information on the package leaflet.”
- if applicable, special precautions for storage
- If applicable, withdrawal periods (waiting periods)
- If applicable, special precautions for disposal
- Authorisation number, packaging code and Swissmedic licence symbol
- Warning regarding children
- If applicable, other safety-related information

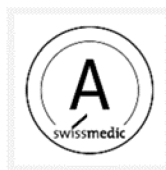
If secondary packaging is used, the last three points can also be stated on that packaging only.

7 Texts on the secondary packaging

7.1 General

If outer packaging exists, it must carry all of the details specified in section 6 regardless of the container. In order to avoid confusion, secondary packages for differing dosage strengths must be clearly distinguishable from each other visually, for example by using different colours.

To indicate the dispensing category ordered by Swissmedic, the corresponding Swissmedic licence symbol (“vignette”) should be shown on the secondary packaging or, if this does not exist, on the primary packaging. Although the font size is not specified, the dispensing category must be clearly legible.



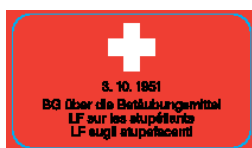
7.2 Additional code on the folding carton

An additional company-specific code is accepted, provided Lot./Exp. cannot be confused with this code and the identifiability of the information required by Ann. 6 TPLRO is not adversely affected. A data matrix or Radio Frequency Identification (RFID tag) may be affixed to the packaging. The authorisation holder is responsible for the content of the data matrix or RFID tag. No promotional claims or references to websites may be included, and this must be ensured by the authorisation holder. The producers and operators of RFID systems are responsible for taking the precautions required for ensuring that these are used in compliance with data protection requirements.

7.3 Labelling of narcotics

According to the Narcotics Control Ordinance (Art. 55 para. 4 NarcCO), a vignette provided by Swissmedic (“narcotics vignette”) must be affixed to the outer packaging of medicinal products

containing narcotics in Lists a or d (see Narcotics Lists Ordinance, SR 812.121.11) . Alternatively, an overprint that corresponds in all parts to the vignette can be affixed to the packaging. There is no standard specification of size and shape, but the writing must be clearly legible.



Furthermore, according to Art. 55 para. 3 NarcCO, the labelling of medicinal products containing controlled substances must satisfy the legal provisions applicable to therapeutic products, and information about the precautions and warnings required to ensure user safety must be included in the Information for healthcare professionals.

8 Texts on blisters

The following should be shown on the blister as a minimum:

- Name of the medicinal product, followed by the dosage strength if several strengths exist
- The expiry date and batch number
- The statement “ad us. vet.” or the target animal species (as text or pictogram)

The lot and EXP details must be placed at the edge of the blister and may not be printed transversely across the blister as this ensures readability even after the blisters are opened. Individual pocket lettering is excluded from this rule.

The perforation of blisters is permitted if all the particulars (incl. batch number and expiry date) are stated on each individual pocket.

9 Explanations of the requirements for the packaging

9.1 Medicinal product name

The registered trademark symbol ® or ™ may be included on the packaging. However, it is not permitted to state “(name of the medicinal product) is a trademark of (company name)” (or license of....) as such information does not meet the criteria stipulated in Annex 6 section 3 para. 3.1.6 TPLRO. In particular, this is not information/these are not illustrations that are directly connected with the use of the medicinal product, and the information is not important for providing health-related information.

9.2 Declaration of composition

The primary and (if it exists) secondary packaging must carry at least a declaration of the full composition of active substances, including quality and quantity.

Negative declaration for the composition

Excipients that are not contained in the medicinal product may not be listed, e.g. “no preservatives”, “no flavouring”.

9.3 Batch number

The batch number may not be stated as a number on its own (risk of confusion with expiry/manufacturing date), but must be accompanied by prefixes such as “Batch no.:...”, “Bat.no.:...”, “Bat. ref.:...”, “B:..”, “BN:...” “Lot:...” , “Lot no.:...”, “Lot:...” , etc.

9.4 Expiry date and use-by period

The expiry date may not be stated as a number on its own (risk of confusion with batch number/manufacturing date), but must be preceded by e.g. “EXP:”, “Expiry:”, “Use by:” etc.

The expiry date must be stated as a month and year: e.g. 10.2001 or OCT 2001

The presentation *EXP/Lot: (date)/(number)* is permitted, provided the authorisation holder ensures that the information is clearly identifiable for the users.

If a use-by period after opening needs to be taken into account according to the medicinal product information, this should also be stated on the packaging (particularly for liquid pharmaceutical forms such as solutions for injection, etc., but also for divisible tablets, for example).

9.5 Authorisation number and the packaging code

The authorisation number, incl. packaging code, is usually integrated in the EAN code, in which case the authorisation number should be bracketed off with the lettering "Swissmedic". The figures in the authorisation no., incl. the packaging code, must be highlighted by being printed in bold or larger than the rest of the EAN code.



If an EAN code is not used, "Swissmedic" should appear before the authorisation number and packaging code (e.g. Swissmedic 41557 036).

9.6 Marketing authorisation holder

The marketing authorisation holder must be stated on the secondary packaging with the following title:

| | | |
|---|---|---|
| German: Marketing authorization holder: ... Zul-Inh.: | French: Titulaire de l'autorisation: ... Tit.de l'AMM | Italian: Titolare dell'omologazione: ... Tit. omol. |
|---|---|---|

This title may be omitted only if the product is distributed and manufactured by the same company.

Division

Stating a "Division" is acceptable if the company can be shown to constitute a subgroup of the marketing authorisation holder (extract from the commercial register).

Stating a "Division" is unacceptable if the company is at the same level as, or a higher level than, the marketing authorisation holder.

9.7 "Ad us. vet."

The statement "ad us. vet." (ad usum veterinarium = for veterinary use) indicates that the medicinal product is a veterinary medicine. If necessary, it can be replaced on foreign packaging by statements such as "(Only) for animals" or "Only for the treatment of animals".

9.8 Storage instruction

If special storage precautions are to be heeded for a particular medicinal product, then these must also be stated on the packaging material as they appear on the IHP/PL. If no special storage instructions exist for the medicinal product, no information about storage need be stated on the packaging material.

9.9 Medically essential information for use

This information should be kept to a minimum, and may not be of a promotional nature or interfere with the other essential information required on the packaging.

Examples of medically essential information for use include "Strictly for i.v. administration" or "Do not use on cats!"

Section titles (e.g. Dosage/Administration) may be stated only if they are followed by the **full** text as stated on the package leaflet. Stating the title followed by "see package leaflet", "follow package leaflet before administration" or similar is not permitted.

9.10 Manufacturer

Stating the manufacturer is optional. If the marketing authorisation holder wants the manufacturer to be stated, then the manufacturer should be clearly identified as such:

| | | |
|---|---|--|
| German: Herstellerin: ... | French: Fabricant: ... Titulaire de l'AMM | Italian: Fabbricante: ... |
| Herstellung: Herstellung durch: ... | Fabrication: ... fabriqué par: ... | Fabbricazione: ... prodotto da: ... |

If all manufacturing steps (incl. quality controls) are carried out by the same company, this company can be listed as the manufacturer. If the manufacturing steps are carried out by various companies, only the company stated as the manufacturer is allowed to issue the batch certificate. If several companies are registered as being responsible for batch release, either no company or all companies must be stated.

9.11 Supplier company

The supplier company (Répartiteur, Fornitore) may be stated on application. The marketing authorisation holder must confirm that the supplier company possesses a corresponding wholesale trading licence. It must be stated as follows: *Supplier: Name of company, place*
 Stating "under license of" on the packaging is not permitted.

10 Use of foreign packaging/"Blue Box"

It is possible to use foreign packaging for distribution in Switzerland provided this satisfies the general requirements (e.g. at least two national languages) and has been approved by Swissmedic. In this case, the information specific to Switzerland should be shown in the "Blue Box", which can be used on the packaging for country-specific information. The fact that the information applies to Switzerland should be indicated in this "blue box area" ("CH"). The following information for distribution in Switzerland must be shown:

- Swiss marketing authorisation holder (see section 9.5)
- Swiss authorisation number, incl. packaging code (see section 9.4)
- Swissmedic licence symbol (dispensing category; see section 7.1)

This information can either be printed in an empty "blue box area" or affixed to the packaging by means of a sticker.

While the simultaneous listing of the approved foreign marketing authorisation holder, the foreign authorisation number and the foreign requirements for dispensing the medicinal product (prescription-only, etc.) can be tolerated on the packaging for distribution in Switzerland, such information does not possess any validity for Switzerland.

11 Pictograms, illustrations and logos on packaging

11.1 Pictograms

Pictograms are permitted only if their meaning is clearly defined and self-explanatory. If this is not the case, the pictogram must be accompanied by appropriate text. The following points should be observed:

- The mandatory text on the naming of the approved target animal species can be replaced by a pictogram/pictograms, particularly on small primary packaging, if the species is/are identifiable beyond doubt. In this context, Swissmedic would refer to the pictograms used in the EU: <https://www.ema.europa.eu/en/grd-guidance-use-approved-pictograms-packaging-veterinary-medicinal-products-authorised-centralised>
- The selective illustration of individual target animal species is not permitted.
- If pathogens are represented with pictograms, these must be identifiable beyond doubt and fully correspond with the particulars on the approved medicinal product information.

- Other examples of acceptable pictograms:
 - Cat crossed out on medicinal products that may be used on dogs, for example, but that may not be used on cats
 - Thermometer as an addition to the storage instruction
 - Pictograms as an addition to the warning regarding children and the instruction to note the information on the package leaflet
 - Recycling pictograms recognised by the Swiss Association for Standardisation
 - GHS hazard pictograms

11.2 Illustration of the primary packaging and pharmaceutical form

Illustrations of the primary packaging (e.g. injector) and pharmaceutical form are permitted if the actual appearance is correctly reproduced (e.g. tablet with/without score line; a scaled-down representation is acceptable provided the proportions are correct).

11.3 Illustration of target animal species

The illustration of the target animal species approved for a medicinal product on the packaging is permitted (no selective illustration of individual target animal species). Avoid using any breed that is considered to result from “torture breeding” and ensure that the illustration of the animal species is neutral.

11.4 Illustrations of plants or active substances

Illustrations of plants may appear on the packaging material for herbal medicinal products, provided the plant or plant part can be considered as contributing to the efficacy of the medicinal product. Illustrations of plants on synthetic medicinal products is not permitted, except as a graphical element in a form that is so highly stylised that the plant cannot be directly identified as such. The graphical highlighting of individual active constituents is not permitted. The principle of completeness applies, i.e. either all of the plants or active substances contained in the medicinal product or no plant or active substance should be illustrated.

11.5 Logos

Logos are permitted provided that the following points in particular are observed:

- The packaging must be designed in such a way that the information required by Annex 6 remains easily identifiable and dominant.
- If company logos are used, the company name of the marketing authorisation holder for the respective medicinal product must be stated as it appears in the commercial register.
- Logos of other companies may also appear, provided these can be connected with the medicinal product (e.g. manufacturer). Ensure that the logo of the marketing authorisation holder is presented in at least the same size. The textual note “Developed in cooperation with xxx AG” is not permitted.
- The statement “Swiss made” or the Swiss cross on packaging is not permitted.

12 Information on special packs

12.1 Information on combination packs

The following applies to combination packs:

- A combi-pack is issued with an authorisation number and an Information for healthcare professionals/package leaflet
- The dispensing category is the strictest of the individual components.
- LOT – has a separate LOT number.
- The individual component that expires first determines the stated expiry date

Combination packs are subject to authorisation and are issued with a separate 8-character number consisting of the authorisation number and packaging code/EAN code.

12.2 Packaging not placed on the market

Packaging not placed on the market is subject to the same requirements as packaging placed on the market, i.e. colour laser printouts (incl. confirmation of identity) of the packaging should be submitted for first authorisation/new authorisation.

No packaging will be approved for medicinal products that are authorised exclusively for export.

13 Annex Changes to packaging

13.1 General

The following rules specify what changes marketing authorisation holders can make to packaging on their own initiative (without an application). The lists are not exhaustive.

13.2 Minor changes on own initiative

The "editorial" changes to packaging listed below can be made by the marketing authorisation holders on their own initiative without having to submit an application to Swissmedic. This concerns the following changes for example:

- a) Minor adaptations to the lettering (colour change, font, size within the range +/- 10%): It should be borne in mind that the marketing authorisation holder is responsible for the unambiguous identification of the medicinal product.
- b) Discreet changes to the packaging, e.g. slight reduction or increase in the size of the folding carton (without any changes to the packaging texts).
- c) Inclusion/omission of Braille
- d) Updates to existing approved pictograms or photos of the pharmaceutical form (same size and placement).
- e) Updates to existing approved illustrations of a plant (new photo of the same plant) for complementary and herbal medicines (roughly the same size and placement), provided the requirements concerning the illustration of plants are fulfilled.
- f) Inclusion of a data matrix
- g) Deletion of redundant information (e.g. name of the medicinal product and dosage strength on one side of the folding carton)
- h) Inclusion or deletion of the superscripted R ("Registered") or TM ("Trademark") in the brand name
- i) Replacement of the superscripted R ("Registered") in the brand name with TM ("Trademark")
- j) Modification of placement of EXP./LOT.:
- k) Modified placement of Swissmedic licence symbol and EAN code
- l) Switching around two sides of a folding carton with no other changes (i.e. no change to text, font size and colour, size of the folding carton or design)
- m) Rotating the printing (landscape <-> portrait) with no other changes (i.e. no change to text, font size and colour, size of the folding carton or design)
- n) Replacement of the German title *Absetzfristen* ("withdrawal periods") by *Wartezeiten* ("waiting times").
- o) Replacement of the male German forms of the nouns *Zulassungsinhaber* ("marketing authorisation holder") and *Hersteller* (manufacturer) with the female forms of the nouns (*Zulassungsinhaberin*, *Herstellerin*).

13.3 Variations requiring an assessment

Any change to packaging which the authorisation is not allowed to make on its own initiative must be submitted as an administrative variation with assessment E.100 "Change in the product information and/or packaging texts without submission of scientific data" (see Annex 7a TPLRO). Examples of this type of variation are:

- a) Change to the fixed text for the expiry statement on the packaging elements ("EXP" instead of "use by", or "use by" instead of "EXP").
- b) Deletion, inclusion or modification of the name of the supplier company
- c) Addition to the active substance name (without further changes)
- d) Deletion of non-mandatory information (e.g. company logo, illustration, photo or pictogram of the pharmaceutical form, brief description)
- e) Changes to the corporate identity (usually associated with a major change to the lettering in respect of size, shape, colour and/or a change to the background design)
- f) Other major and conspicuous changes to the design (new visual appearance)
- g) Inclusion of, or distinct change to, the company logo (not covered by 13.2.a)

- h) First inclusion of a pictogram or photos of the pharmaceutical form or modification of a pictogram or photo of the pharmaceutical form that does not correspond to the requirements of 13.2.d.
- i) First inclusion of an illustration (e.g. plant illustration for complementary and herbal medicines) or a modification of an illustration that does not correspond to the requirements of 13.2.e.
- j) Inclusion or modification of the indications or brief description
- k) Inclusion or deletion of the manufacturer

13.4 Implementation of design changes (corporate identity) as a variation not requiring an assessment

Once the first pack has been submitted as an administrative variation with assessment E.100 and subsequently approved, the implementation of the design change (corporate identity) may be notified as an administrative variation without assessment A.100 as of the second pack, provided no further changes are made.

13.5 Changes to the packaging in connection with other applications

Changes to the information on packaging that are directly connected to the processing of another variation application do not need to be submitted as a separate application, nor are they billed separately, e.g. when storage conditions are changed.