Guidance document

Notification procedure for veterinary medicinal products

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List of contents

Notification procedure for the authorisation of non-prescription veterinary medicinal products for ornamental fish, songbirds or exotic birds, carrier pigeons, reptiles, amphibians or small mammals.

1 Introduction and objective

According to the Ordinance on the Simplified Licensing of Therapeutic Products and the Licensing of Therapeutic Products by the Notification Procedure (TPLO; SR 812.212.23), non-prescription veterinary medicinal products for ornamental fish, songbirds or exotic birds, carrier pigeons, reptiles, amphibians or small mammals can be authorised purely on the basis of notification. This guidance document provides an overview of the general conditions to be observed, the sequence of the authorisation procedure, the documents to be submitted and other important background information.

2 Scope

The guidance document is valid for the Authorisation division of Swissmedic and is applicable to non-prescription veterinary medicinal products that satisfy the requirements of Art. 39 TPLO.

3 Legal basis

3.1 The notification procedure as a greatly simplified authorisation procedure

Pursuant to Art. 15 para. 1 b of the Therapeutic Products Act (TPA; SR 812.21), Articles 39 and 40 of the TPLO describe the procedure for the authorisation of the specified veterinary medicinal products by the notification procedure. This procedure is designed to simplify and accelerate market access for non-prescription veterinary medicinal products for ornamental fish, exotic birds or songbirds, carrier pigeons, reptiles, amphibians or small mammals. Accordingly, the requirements pertaining to the volume of documentation to be submitted and its evaluation have been minimised by Swissmedic. The details concerning the required documents can be found in section 4.

The simplified authorisation procedure should help avoid bottlenecks in the supply of veterinary medicinal products in the stated category without adversely affecting the relevant basic requirements for safety, efficacy and quality.

3.2 Art. 39 TPLO Principle

In accordance with Art. 32 para. 1, Art. 39 limits the specific veterinary medicinal products that can be authorised by the notification procedure. Only non-prescription (dispensing categories D or E) veterinary medicinal products for ornamental fish, songbirds or exotic birds, carrier pigeons, reptiles, amphibians or small mammals which contain the active substances included in the list in Annex 2 of the TPLO may be authorised by the notification procedure. If an active substance is not included in this list, according to Art. 39 TPLO a veterinary medicinal product can be authorised purely on the basis of notification if the latest scientific findings indicate that the risk potential of the active substance is low.

During the authorisation of veterinary medicinal products by the notification procedure, Swissmedic takes account of the following points in particular:

- The medicinal products may not contain any antibiotic, anaesthetic, narcotic or psychotropic active substances. Individual sedatives can be approved after they have been evaluated by Swissmedic.
- The medicinal products must be administered orally or topically, excluding preparations applied to the eye or ear.
- For fish, administration via the addition to water is possible.
- The medicinal products may only be sold in packs designed for a single treatment cycle.
- The medicinal products must be manufactured in accordance with the Good Manufacturing Practice (GMP) guidelines.

3.3 Art. 40 TPLO Notification

An authorisation application may be submitted only by a company that satisfies the authorisation preconditions stated in Art. 10 para. 1 b and c TPA.

When submitting the authorisation application, the applicant does not need to include documentation on the quality, safety or efficacy of the veterinary medicinal product according to Art. 2 c of the Ordinance on the Licensing Requirements for Therapeutic Products (TPLRO; SR 812.212.22). The applicant merely needs to demonstrate, by means of the entries in the form *Application for New authorisation by notification procedure veterinary medicinal products*, that the medicinal product satisfies the basic requirements relating to the target animal species, dispensing category and active substances.
In specific cases, Swissmedic can request additional documents, particularly if there is doubt about the low risk potential of an active substance not listed in Annex 2 of TPLO.

3.4 Art. 42 TPLO Reclassification

For safety reasons, veterinary medicinal products that have been authorised by the notification procedure may not be reclassified in accordance with Art. 6 of the Veterinary Medicinal Products Ordinance (VMPO; SR 812.212.27), i.e. they may not be used for the treatment of other animal species and/or other indications. Since the documentation requirements for preparations authorised by the notification procedure are reduced, there is no information or experience about their use in other animal species or other indications.

4 General requirements and assessment principles

4.1 New authorisation

4.1.1 Administrative documents

- Covering letter confirming that Art. 39 TPLO is fulfilled
- Form *Application New authorisation by notification procedure veterinary medicinal products*
- Proof of authorisation if the preparation is already authorised in another country
- If the notified preparation contains an active substance that is not listed in Annex 2 of TPLO, further documentation should be submitted:
  - documents showing that the risk potential of the active substance is low according to the latest scientific and technical findings
  - additional information deemed to be useful for the assessment

4.1.2 Product information texts for the veterinary medicinal products authorised by the notification procedure

The packaging texts intended for distribution in Switzerland do not need to be submitted to Swissmedic, and these are neither checked nor approved by Swissmedic. The marketing authorisation holder is responsible for ensuring that the packaging texts comply with the relevant requirements, and this is checked as part of market surveillance.

- **Packaging texts of marketable, foreign veterinary medicinal products that are drafted in at least two official Swiss languages:**
  It is usually sufficient to stick an extra label on the outer packaging, per section 4.1.4, with the relevant information that is specific to Switzerland. If the foreign packaging texts do not mention that the veterinary medicinal product may not be used in food-providing animals, this missing warning should be included on the added label.

- **Packaging texts of marketable, foreign veterinary medicinal products that are drafted in only one official Swiss language:**
  As well as the extra label mentioned in section 4.1.4 – if applicable with a warning concerning the non-use in livestock (see above) – the veterinary medicinal product must be accompanied by a translation of the package leaflet in a second official language (e.g. packed in the carton).
- **Packaging texts produced specifically for Switzerland:**
  The information mentioned under section 4.1.4 must exist in at least two official Swiss languages.

4.1.3 Documentation on quality

Quality documentation does not need to be submitted together with the authorisation application. Instead, the applicant must confirm, on the form *New authorisation by notification procedure veterinary medicinal products*, that the following requirements are satisfied:

- The manufacturing process is defined and validated
- The quality and the manufacturer of the active substance are defined
- The primary container is defined (dimensions and materials)
- The specifications and test methods for batch release are defined
- The shelf life (including shelf life after opening or reconstitution) and storage instruction have been verified by corresponding investigations

The manufacturer must be in possession of the quality documentation concerning the aforementioned points. This documentation should be submitted to Swissmedic on request – e.g. in the event of safety signals.

Documents to be submitted:
A copy of GMP certificate/s for the manufacturer of the ready-to-use medicinal product, which must be no older than three years or a copy of the manufacturing authorisation(s). Alternatively, a risk assessment can be submitted (for details see the guidance document on *the GMP conformity of foreign manufacturers*).

4.1.4 Application process for the authorisation procedure

The notification procedure is a greatly simplified authorisation procedure involving a significantly reduced volume of authorisation documentation and a summary risk assessment. This risk assessment is based, in particular, on the entries made in the form *New authorisation by notification procedure veterinary medicinal products*, and also on the confirmation that the required quality requirements are satisfied. After an application is received, a formal check is carried out. If the criteria for the notification procedure are not fulfilled or if incomplete documentation is not completed on time, this will result in a ‘Non-approval’ decision.
If the criteria are fulfilled the preliminary decision is issued. The procedure is concluded with an official decision.
If the application can be approved, the applicant is informed accordingly by means of the preliminary decision on the Swissmedic licence symbol for the preparation (= Swissmedic authorisation number with pharmaceutical code and the dispensing category (D or E)).

The authorisation number and dispensing category should be supplemented by the note ‘Authorised by the notification procedure’ and the details of the authorisation holder (company name and registered office according to the entry in the Commercial Register), and should appear on the outer

packaging of the preparations. Stating the pharmaceutical code is optional. Alternatively, these details can be stated on an extra label:

Authorisation number, reference to dispensing category*
Authorised by the notification procedure
If sufficient space is available: Authorisation holder:
If space is insufficient: MA holder:
Company name, legally registered office of the company (location)

*  or 

The following information, at least, must appear on the outer packaging:

- Product name and target animal species
- Details concerning the indication
- Pack size (quantitative information about the contents)
- Batch number, expiry date and storage instructions
- Note stating that the product should be kept out of the reach of children
- Note stating that the product may not be used in food-providing animals

In addition to the aforementioned details, the package leaflet should also include at least the following information:

- Complete list of indications
- Name and quantity of the active ingredient / ingredients
- Administration route and recommended dosage
- If necessary, information about contraindications, precautions and interactions
- Instructions on disposal

The authorisation holder is responsible for ensuring that the packaging texts comply with the requirements, and this is checked as part of market surveillance.

4.2 Change to an existing authorisation

Any change to the information on the most recently submitted form *New authorisation by notification procedure veterinary medicinal products* should be reported by means of a correspondingly updated form and, if necessary, documented accordingly.

4.3 Renewal of the authorisation

According to Art. 16 para. 3 TPA, the authorisation of a medicinal product by the notification procedure is valid for an unlimited period and does not need to be renewed.

5 Time limits

The time limits specified in Guidance document *Time limits for authorization applications* apply.

6 Miscellaneous

6.1 Market surveillance

Measures should be in place to ensure that adverse drug reactions (ADR) are reported in connection with market surveillance. The pharmacovigilance requirements are specified in articles 60 – 65 of the Therapeutic Products Ordinance (TPO; 812.212.21). Pharmacovigilance refers to a system for recording, evaluating and classifying information on suspected adverse drug reactions.

The following reactions must be reported:

- Serious and/or hitherto unknown ADR, and also quality defects (Art. 59 TPA and Art. 62 TPO)
- Adverse reactions in the user
- Lack of efficacy
- Hypersensitivity, misuse, ecotoxicity

Reports can be sent to the Swissmedic reporting office for Veterinary Pharmacology and Toxicology of the Vetsuisse faculty in Zurich (see www.vetvigilance.ch). In addition to the options on this website for submitting reports electronically or in writing or for contact the office by phone, an ADR report can also be sent to the Veterinary Medicines Division at Swissmedic.
As part of its market surveillance activities, Swissmedic can check the quality of medicinal products at any time (Art. 58 TPA).

6.2 Advertising

Veterinary medicinal products authorised by the notification procedure may be advertised to the public (see Art. 31 para. 1 b TPA). The provisions of the Therapeutic Products Advertising Ordinance (TPAO; SR 812.212.5) must be observed.
These include the following requirements in particular:

- All information included in advertising for the public must be factually correct and in accordance with the medicinal product information.
- Medicinal products in dispensing categories C and D must be clearly identified as medicines in the advertising.

6.3 Waiving of fees

As a rule, fees can be waived only if the applicant requests the MUMS status (MUMS: minor use, minor species) for the veterinary medicinal product and this has been approved by Swissmedic.
Veterinary medicinal products to be authorised by the notification procedure according to Art. 39 TPLO can be granted the status of an important medicine for rare diseases (MUMS), but only if the applicant provides Swissmedic with scientific documentation for authorisation that satisfies the requirements of Art. 26 TPLO.

- Of course, the relevant applicants can, during the course of the procedure for status recognition by analogy with Art. 25 TPLO, obtain a corresponding evaluation by Swissmedic concerning the specific scope and content of the studies and trials to be submitted in order demonstrate the quality, safety and efficacy of their preparation.
- Art. 5 TPLO ("The status can be linked to restrictions and conditions") can be cited as the legal basis for this condition since this provision also applies to veterinary medicinal products according to Art. 8 para. 3 TPLO.

Change history

Version	Change	sig
2.0	Addition of the option of a risk assessment in section 4.1.3 Deletion of suffix HMV4	hul stb
1.4	New layout, no content adjustments to the previous version.	hem
1.3	Incorrect section reference corrected; addition under section 4.1.4: indicating the pharmaceutical code is optional	lac
1.2	Formal adjustments to the header and footer No content adjustments to the previous version.	dei
1.1	Section 4.1.3 Documentation on quality: Explanation regarding the documents to be submitted.	lac
1.0	Implementation of TPO4	lac, stb