swissmedic

Guidance document

Authorisation of immunological veterinary medicinal products in the event of an epizootic outbreak

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1 Abbreviations

CVMP	Committee for Veterinary Medicinal Products of the European Medicines Agency
EzDA	Epizootic Diseases Act of 1 July 1966 (SR 916.40)
EzDO	Epizootic Diseases Ordinance of 27 June 1995 (SR 916.401)
FDHA	Federal Department of Home Affairs
FSVO	Federal Food Safety and Veterinary Office
LoQ	List of Questions
MPLO	Ordinance of 14 November 2018 on Licensing in the Medicinal Products Sector (SR 812.212.1)
TPO	Therapeutic Products Ordinance of 21 September 2018 (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 (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)
WL	*Wegleitung* = guidance document

2 Definitions

Epizootic disease
Under Art. 1 EzDA, epizootic diseases must be either combated or monitored at federal level. Epizootic diseases are classed as “highly contagious” or “other” (Art. 1 para. 2 EzDA).

Highly contagious epizootic diseases
Transmissible animal diseases that spread widely and quickly, including from country to country. They have extensive consequences on health, society and the economy (Art. 1 para. 2 EzDA).

3 Introduction and objective

In the exceptional situation of an impending or existing outbreak of an epizootic disease, especially a highly contagious one such as avian flu, Swissmedic can offer applicants a range of options in order to expedite authorisation applications for immunological veterinary medicinal products that serve to mitigate and prevent the epizootic disease. The measures are designed to ensure that these veterinary medicinal products can be supplied as quickly as possible. The review of authorisation applications for immunological veterinary medicinal products aimed at mitigating and preventing epizootic diseases is based on scientific criteria pursuant to Art. 10 TPA in conjunction with Art. 9 TPO. Authorisation is granted if the quality, efficacy and safety of the immunological veterinary medicinal product have been proven. The additional authorisation for use required for epizootic diseases is based on Art. 48 of the Epizootic Diseases Ordinance (EzDO).
This guidance document (WL) is primarily intended for administrative bodies and does not directly specify the rights and obligations of private individuals. Swissmedic uses this WL mainly as a resource for deciding on possible authorisation procedures in the exceptional situation of an impending or existing outbreak of an epizootic disease in a consistent and equitable manner. For applicants, its publication is intended to elucidate the specific preconditions and requirements that must be fulfilled so that procedures can be used and applications processed as quickly and efficiently as possible.

4 Scope

This WL applies to new authorisations and variations with assessment for immunological veterinary medicinal products that are used to mitigate and prevent an impending or existing outbreak of epizootic diseases, especially those that are highly contagious. The use of immunological veterinary medicinal products is based in particular on Art. 48 EzDO and is not in the scope of this WL.

5 Legal framework

The procedures for the authorisation and variation of immunological veterinary medicinal products for especially highly contagious epizootic diseases are based on the following legal provisions in particular:

- TPA
- Art. 9 Marketing authorisation
- Art. 9a Temporary authorisation

- Art. 10 Conditions for granting a marketing authorisation
- Art. 11 Application for a marketing authorisation
- Art. 13 Medicinal products and procedures authorised in foreign countries
- Art. 16 Authorisation decision and period of the marketing authorisation
- Art. 17 Official batch release
- TPO
- Art. 9 Marketing authorisation
- Art. 16 to Art. 20 Medicinal products and procedures authorised in foreign countries (Art. 13 TPA)
- Art. 25b and Art. 25c Change in authorisation for veterinary medicinal products
- Art. 1 Epizootic diseases

and the provisions of the relevant ordinances, particularly the Therapeutic Products Licensing Requirements Ordinance (TPLRO), Medicinal Products Licensing Ordinance (MPLO) and the 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 (TPLO), and the Epizootic Diseases Ordinance (EzDO).

6 National and international collaboration on epizootic outbreaks

In general, the organisation of epizootic disease control and the specific control measures are defined in the Epizootic Diseases Ordinance (Art. 1 para. 1 EzDO). Vaccinations against highly contagious epizootic diseases are prohibited in Switzerland (Art. 81 EzDO). However, the Federal Department of Home Affairs (FDHA) can require vaccinations in emergency situations.
In the event of an impending outbreak or actual epizootic disease outbreak, there is close cooperation at national level with the Food Safety and Veterinary Office (FSVO) and other stakeholders. Further details on national and international collaboration are published on the Swissmedic website.

7 Advice and authorisation procedures

Swissmedic assigns priority to authorisation applications for immunological veterinary medicinal products used to mitigate and prevent especially highly contagious epizootic diseases and will expedite the process in accordance with the epidemiological situation in order to make effective, safe veterinary medicinal products available as quickly as possible.

7.1 Scientific advice

Applicants are advised to request a preliminary discussion of the available data material and development programme in the form of a Scientific Advice Meeting. The documents to be submitted are based on the provisions of the WL *Meetings for applicants held with the Authorisation sector*.
Within the scope of this WL, Swissmedic can waive the fee for the Scientific Advice (Art. 12 FeeO-Swissmedic).

7.2 Presubmission meeting

During a presubmission meeting, the potential procedures described below for the authorisation of immunological veterinary medicinal products used to mitigate and prevent the spread of especially highly contagious epizootic diseases, and the submission methods, must be clarified in advance (see WL *Meetings for applicants held with the Authorisation sector*). Provided the planned authorisation application is being conducted in parallel with a foreign authority, the applicant will be asked during the presubmission meeting to let Swissmedic know whether it will provide Swissmedic with the review results (correspondence, assessment reports and LoQs) of the foreign partner authority, or whether it will allow Swissmedic to share information about the ongoing application with the foreign authority. Within the scope of this WL, Swissmedic can waive the fee for the presubmission meeting (Art. 12 FeeO-Swissmedic).

7.3 Rolling submission

In the exceptional situation of an impending or existing outbreak of an epizootic disease, especially one that is highly contagious, upon the applicant's request during a presubmission meeting, the authorisation application can be filed as a “rolling submission”. The rolling submission procedure represents a special form of a first authorisation procedure or a variation procedure and was introduced during the COVID pandemic. The rolling submission procedure is also available for applications for authorisation and variation of immunological veterinary medicinal products in exceptional cases of impending or existing outbreaks of an epizootic disease, especially one that is highly contagious. In contrast with a standard procedure under Art. 11 TPA, upon initial submission of the application for authorisation, the applicant does not already need to provide Swissmedic with a complete dossier or complete documentation on the variation application for the immunological veterinary medicinal product. The data required for the authorisation of the medicinal product will be collected and compiled continually by the applicant and submitted to Swissmedic as soon as possible. In a presubmission meeting, the applicant must provide Swissmedic with a plan showing how it expects to submit the data packages within a reasonable deadline and on what schedule. This ensures that the rolling submission procedure is constructive, and that Swissmedic can arrange for the required staff resources to perform the review. The review will then be started as soon as Swissmedic has received a data package. On completion of the partial review, the applicant will be sent a List of Questions (LoQ) to clarify any issues and an appropriate deadline will be set to answer the questions. This review cycle will be used for each individually submitted documentation package. As soon as all the questions have been fully answered and the documentation required to evaluate the authorisation application has been received, Swissmedic will inform the applicant of the scheduled decision as a preliminary decision. Based on the discussion with the applicant during the presubmission meeting, the submitted data material and the results of the evaluation, Swissmedic decides whether the veterinary medicinal product can be authorised under Art. 11 TPA, or whether temporary authorisation can be granted on the basis of Art. 9a TPA (see “Temporary authorisation on request” (Article 9a TPA)).

7.4 Rolling questions

Like the rolling submission procedure, “rolling questions” represents a special form of a new authorisation or variation procedure. At the request of the applicant during a presubmission meeting,

Swissmedic decides whether this procedure is possible. In the rolling questions procedure, the applicant possesses complete documentation. The authorisation application must include the information and documents listed in Article 11 TPA in conjunction with Article 2 and Articles 7 to 11 TPLRO. The review is started as soon as the formal check has been concluded with a positive result. In contrast with the standard procedure, Swissmedic will ask its questions that must be answered by the applicant within the specified time limit on an ongoing basis. The classical LoQ milestone of the standard procedure does not apply. As with the rolling submission procedure, based on the discussion with the applicant during the presubmission meeting, the submitted data and the result of the evaluation, Swissmedic decides whether the veterinary medicinal product can be authorised under Art. 11 TPA or whether temporary authorisation can be granted on the basis of Art. 9a TPA (see “Temporary authorisation on request” (Art. 9a TPA)).

7.5 Authorisation under Art. 13 TPA

Applications under Art. 13 TPA are subject to the requirements of the WL *Authorisation of veterinary medicinal products under Art. 13 TPA*. Under Art. 13 TPA, Swissmedic assigns priority to authorisation applications for immunological veterinary medicinal products used to mitigate and prevent especially highly contagious epizootic diseases, and will expedite the process in accordance with the epidemiological situation once all requirements have been met and the required documents, including a positive authorisation decision from the foreign authority or positive opinion of the CVMP, are submitted.

7.6 Temporary authorisation on request (Art. 9a TPA)

Even during an outbreak of an epizootic disease, great importance is attached to the submission of the necessary clinical data, particularly on the safety and efficacy. Temporary authorisation of immunological veterinary medicinal products to treat or prevent life-threatening illnesses is possible under the following conditions:

- The veterinary medicinal product is expected to have a major therapeutic benefit;
- There is no equivalent veterinary medicinal product authorised in Switzerland, or no comparable veterinary medicinal product is available;
- It would take so long to compile all the required data and to process and evaluate the data that irreversible damage would result or worsen or this would cause the affected animals severe suffering (see Art. 18 TPLO).

If temporary authorisation is to be granted for a veterinary medicinal product, a corresponding request must be submitted to Swissmedic before filing the authorisation application. The process is described in more detail in the WL *Temporary authorisation of veterinary medicinal products*. This can be expedited appropriately depending on the epidemiological situation. During the review of an immunological veterinary medicinal product that is the subject of an application for ordinary authorisation, Swissmedic is permitted at any time to grant an “ex officio” temporary authorisation.

8 Time limits

The procedures described under “Advice and authorisation procedures” will not be processed according to the time limit schedule described in the WL *Time limits for authorisation applications*. Swissmedic will prioritise and fast-track the review given the exceptional situation and taking account of the available staff resources. The applicant can help expedite the authorisation procedure by replying promptly to the questions posed by Swissmedic and by delivering the documents required for processing an application as quickly as possible.

9 Fees

The fees are based on the FeeO-Swissmedic.

Change history

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1.0	First version	zai, ps, fg