1 Is it no longer necessary to notify Swissmedic if it is more than two years since a veterinary medicinal product was last marketed in the countries in which it was authorised?

No. Provided the product was withdrawn on purely commercial grounds, there is no longer any requirement to notify Swissmedic. However, if sale of the product has been restricted or stopped in other countries because of safety signals, these signals are subject to the mandatory notification requirement under Art. 59 TPA and Art. 61 and 62 TPO. In such cases, Swissmedic has to be notified of the withdrawal. Consequently, a veterinary medicinal product may be withdrawn in another country for entirely market-related reasons without the withdrawal affecting its authorisation status in Switzerland.

2 Is it possible to apply for authorisation of a co-marketing medicinal product based on a medicinal product that has been authorised under Art. 13 TPA, and, if so, are the requirements the same as for applications for medicinal products authorised under the regular procedure?

Yes, the requirements are identical.

3 If pharmacovigilance planning or other updated documents are available for an application for authorisation of or for a variation to a veterinary medicinal product under Art. 13TPA, should applicants provide the documents submitted to the reference authority for the original procedure or the updated versions of those documents? And in what form should they submit the documents?

The documentation submitted to Swissmedic must be identical to that on which the reference authority based its authorisation of the veterinary medicinal product or a variation to the product. In parallel with the application, the variations and/or additions approved since the reference authority granted authorisation must also be submitted to Swissmedic. This additional or replacement documentation can either be integrated within the application documentation or the part in question (updated dossier), or it can be submitted separately. The variations since authorisation must be referred to in the cover letter and be submitted with the associated final Assessment Report (see section 5.1 of guidance document *Authorisation veterinary medicinal product under Art. 13 TPA*.)

4 When applying for authorisation of a veterinary medicinal product that has been authorised in over 20 EU states under a DCP, do the decisions of all 20 states have to be submitted?

Any application for a veterinary medicinal product under Art. 13 TPA that is based on an EU DCP only needs to include the assessment results and authorisation decision of the Reference Member State (RMS). The decisions and authorisation certificates of the Concerned Member States (CMS) no longer have to be submitted to Swissmedic.

5 If a veterinary medicinal product was approved under Art. 13 TPA, can variations also only be submitted under Art. 13 TPA?

No, once a veterinary medicinal product has been authorised under Art. 13 TPA, applications for variations can be submitted either with or without a request for application of Art. 13 TPA.

6 Can applications for the authorisation of herbal and complementary medicinal products be submitted under Art. 13 TPA?

Yes, Art. 13 TPA can also be applied to applications for the authorisation of herbal and complementary medicinal products.

7 How much time does submitting under Art. 13 TPA save?

The processing times for authorisation and variation procedures are those set out in guidance document *Time limits for authorisation applications* for the relevant application type. If Swissmedic can take the results of a recognised foreign reference authority into consideration for applications

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under Art. 13 TPA, the assessment workload is reduced, which generally leads to a shorter first assessment phase. Usually in these cases, no List of Questions is compiled, rather the preliminary decision is issued directly.

8 Are veterinary medicinal products with a new active substance (NAS) that have MUMS status in Switzerland but not in the EU, but which are nevertheless authorised in the EU, eligible for Art. 13 TPA?

Yes, it is the MUMS status in Switzerland that is relevant in this case.

9 What is the further procedure if an assessment under Art. 13 TPA is not "approved"?

If the criteria for the application of Art. 13 TPA have not been met, the applicant will be notified accordingly by means of a preliminary decision *Rejection of application to apply Art. 13 TPA*. The applicant then has the option of responding to the preliminary decision or withdrawing its application. Swissmedic will examine the applicant's response and decide if Art. 13 TPA can be applied. Unless informed otherwise, and assuming the application is not withdrawn, the Agency will review the documents under the regular procedure, i.e. conduct its own scientific review.

10 Is prior notification of submission (a letter of intent) needed for procedures under Art. 13 TPA?

No. When completing the form *New authorisation of veterinary medicinal products* or the form *Variations VMP*, applicants should instead answer "yes" to the question of whether they want to request consideration of the results of foreign authorities' assessments in accordance with Art. 13 TPA, and the *Form for application under Art. 13 TPA VMP* must be submitted.

11 Is the CVMP opinion sufficient for an application for authorisation under Art. 13 TPA or is it necessary to wait for the Commission Decision?

The CVMP opinion can be submitted to Swissmedic for first submissions that are based on the EMA's Centralised Procedure.

12 By how much are fees reduced if an application is made to switch a regular authorisation procedure to Art. 13 TPA?

If there are parallel procedures, and Swissmedic permits the application of Art. 13 TPA, and the results of the foreign reference authority's assessment provide a suitable basis, the flat-rate fees applicable to individual cases are reduced by 60% according to Art. 10 FeeO-Swissmedic.

13 Do major objections in the foreign authority's List of Questions count as major objections for Swissmedic?

If the foreign authority has authorised the veterinary medicinal product, it can be assumed that the case made by the applicant and/or the data it has supplied have been sufficient to resolve the major objections.

14 Can veterinary medicinal products that have been authorised in the EU with hybrid authorisation be authorised under Art. 13 TPA?

The assessment of the reference authority must be plausible for Swissmedic. This requires the veterinary medicinal product on which the EU hybrid authorisation is based to also be authorised in Switzerland. Otherwise, a veterinary medicinal product would be authorised without Swissmedic having full documentation (in particular also concerning certain aspects regarding safety and efficacy in the indication applied for (incl. clinical trials)).

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15 Does the Swiss Information for healthcare professionals have to be referenced in the documentation submitted for applications according to Art. 13 TPA?

No, referencing of the Information for healthcare professionals is not required because Swissmedic bases its review on the decision of the foreign authority and the approved foreign Information for healthcare professionals or, in the case of KAS without innovation, on those of the Swiss reference product.

16 Can authorisation of a veterinary medicinal product according to Art. 13 TPA be applied for with reference to a "marketing authorisation under exceptional circumstances" by the EMA? New from September 2026

Yes, although this authorisation procedure does not exist in Switzerland, authorisation of a veterinary medicinal product according to Art. 13 TPA based on an EMA decision with "marketing authorisation under exceptional circumstances" is possible. Provided that the requirements in terms of documentation and criteria according to Art. 18–23 TPLO are met, as a rule, a temporary authorisation under Art. 9a TPA can be issued.

17 What documents have to be submitted for a repeat use procedure? (clarification on section 5.2 of the Guidance document *Authorisation veterinary medicinal product under Art. 13 TPA*) New from September 2026

For an authorisation based on a repeat use procedure (RUP) of an EU MRP or DCP, the foreign dossier of the original procedure (if available, as an updated dossier) with all variations approved since the first authorisation must be submitted, as it was submitted for the RUP.

Basis for foreign decision:
Letter end of procedure of RUP

Documentation from the RUP:
Consolidated List of Questions and Assessment Reports from the RUP
List of all variations after the RUP
Approvals/Assessment Reports of all variations after the RUP

18 May parts of the reference dossier containing confidential information, e.g. composition of a cell culture medium, be submitted via third parties? New from September 2026

Yes.

19 What needs to be submitted as a minimum when the studies submitted as part of a procedure according to Art. 13 TPA do not comply with the currently valid guidelines?

If the details of clinical and/or pharmacokinetic studies refer to outdated guidelines, this must be stated and discussed in a justification in the cover letter.

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