1 Is it no longer necessary to notify Swissmedic if it is more than two years since a 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No. Provided the product was withdrawn on purely commercial grounds, there is no longer any requirement to notify Swissmedic.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 Arts. 61 and 62 TPO. In such cases, Swissmedic has to be notified of the withdrawal. Consequently, a medicinal product may be withdrawn in another country for entirely market-related reasons without the withdrawal affecting its authorisation status in Switzerland.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 product of 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 The final report on readability testing has been inserted as section 1.3.4 of the reference country's Module 1. Does this report also have to be submitted?

Yes, the documentation submitted to Swissmedic has to be identical to that on which the reference authority based its authorisation of the medicinal product (see also Chapter 5.1 of guidance document *Authorisation of human medicinal products under Art. 13 TPA*).

4 If pharmacovigilance planning or other updated documents are available for an application for authorisation of or for a variation to a medicinal product under Art. 13 TPA, 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 medicinal product or a variation to the product (final version). 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 module in question, or it can be submitted separately. The variations must be referred to in the cover letter, and a comparison showing the changes (old/new) must be appended to the corresponding final assessment report (see also Chapter 5.1 of guidance document *Authorisation of human medicinal products under Art. 13 TPA*).

5 When applying for authorisation of a 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 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.

6 If a medicinal product was approved under Art. 13 TPA, can variations also only be submitted under Art. 13 TPA? Revised November 2026

No, once a 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. Similarly, for medicinal products authorised by Swissmedic without reference to Art. 13 TPA, applications for variations can be submitted according to Art. 13 TPA. This requires that the documentation of the reference authorities (before authorisation of the variation/extension) and the documentation for Switzerland are identical (Modules 2.4, 2.5, 2.6, 2.7, 4 and 5) and any deviations regarding Module 2.3 and Module 3 correspond to the deviations described in full in the Guidance document *Authorisation human medicinal product under Art. 13 TPA*.

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7 How does Swissmedic deal with variations in the procedure according to Art. 13 TPA that are submitted to Swissmedic after 1 February 2026, but that were approved in the EU according to the "old" catalogue of variations? New from March 2026

For variations that were approved by the EMA according to the "old" catalogue, but that are submitted to us after 1 February 2026 in the procedure according to Art 13 TPA, the company must submit the corresponding variation using the new *Variations and extensions HMP* form. The EMA decision is accepted. The number (e.g. B.II.b.1.c) under which the variation was submitted to the EMA and approved is irrelevant, what matters is the EMA's Assessment Report on the variation. However, the company must check the box for the appropriate variation number in the new Swissmedic form (e.g. Q.II.b.1.c).

8 Can applications for the authorisation of herbal and complementary medicinal products be submitted under Article 13 TPA?

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

9 Is it possible to have orphan drugs authorised under Art. 13 TPA using the EU dossier as the reference dossier?

We are planning to submit an application for rapid authorisation in Switzerland of a chemical NAS. The substance has Orphan Drug Designation for the indication in question in Switzerland, the EU and the USA. The EMA has issued a positive opinion recommending authorisation, and the EU Commission is expected to approve the medicinal product soon. This raises the following questions:

a) *Is it possible to have the product authorised under Art. 13 TPA using the EU dossier as the reference dossier?*

Yes, a medicinal product with a new active substance or an indication extension of that product is eligible for a reduced assessment under Art. 13 TPA if the product has been classified and authorised as an orphan drug by the EMA Committee for Orphan Medicinal Products (COMP) or under the FDA Orphan Drug Act (see also Chapter 7.1 of guidance document *Authorisation of human medicinal products under Art. 13 TPA*).

b) *How much time does submitting under Art. 13 TPA save?*

The processing times for authorisation procedures under Art. 13 TPA are those set out in guidance document *Time limits for authorisation applications* for the relevant application type. The procedure for applications under Art. 13 TPA will be shorter if no List of Questions has to be issued and the preliminary decision can be issued straight away.

10 Can authorisation of a medicinal product (NAS) with orphan drug status in Switzerland and the USA but not in the EU be applied for in application of Art. 13 TPA with reference to the EMA authorisation?

Yes, the reference country for the status (ODS) and that for the authorisation (in the procedure according to Art. 13 TPA) do not have to be the same.

What is important is that the medicinal product notified in Switzerland under Art. 13 TPA is the same product (or the same active substance) as that recognised or authorised abroad (in this case, in the USA and EU).

11 Are medicinal products with a new active substance (NAS) that have orphan drug status in Switzerland but not in the EU or USA, but which are nevertheless authorised in the EU and/or USA, eligible for Article 13 TPA?

No. Art. 13 TPA can only be applied to an application for authorisation of a medicinal product with a new active substance if the product in question has been granted orphan drug status by the EMA or FDA. In addition, the medicinal product must have been authorised by the EMA or FDA and an

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application for orphan drug status in Switzerland must already have been approved before the application for authorisation is submitted.

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

Swissmedic does not "approve" assessments under Art. 13 TPA. Article 13 TPA states that Swissmedic will factor the results of foreign authorities' assessments into its own review. Arts. 16–20 TPO specify which documents have to be submitted to Swissmedic to ensure that the Agency considers the results of assessments carried out abroad in its authorisation decision. Swissmedic examines whether the criteria set out in Arts. 16–20 TPO for the application of Art. 13 TPA have been fulfilled. If they have not, 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 of 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.

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

No. When completing the form *New authorisation of human medicinal products* or the form *Variations and authorisation extensions*, 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. The appropriate additional forms (e.g. form *Information for application Art.13 TPA*) should then be completed in full and returned to Swissmedic in accordance with guidance document *Authorisation of human medicinal products under Art. 13 TPA*.

14 Are oncologicals also eligible for a reduced assessment under Art. 13 TPA for medicinal products with a new active substance (NAS)?

Yes, provided the product has been granted orphan drug status by the EMA COMP or by the US FDA under the Orphan Drug Act and the product has been authorised by the EMA or FDA. In addition, an application for orphan drug status in Switzerland must already have been approved.

15 Are applications for the authorisation of biosimilars under Art. 13 TPA subject to additional requirements?

The criteria for applying Art. 13 TPA to applications for the authorisation of biosimilars are geared to the requirements in Chapter 6 of guidance document *Authorisation of human medicinal products under Art. 13 TPA*. If the criteria for applying Art. 13 TPA are not fulfilled, an interim decision to refuse application of Art. 13 TPA will be issued and the application for authorisation of the biosimilar will be reviewed in a normal authorisation procedure.

16 If Swissmedic has rejected an indication for a biosimilar, is it possible to submit this indication as an indication extension under Art. 13 TPA?

Yes. Since Swissmedic has rejected the indication in question, however, the reference authority's Assessment Report will have to be evaluated. If this evaluation does not resolve the concerns that led to Swissmedic rejecting the indication, the Agency will inspect the basic documentation, but limit this inspection to its major concerns.

17 Is the CHMP opinion sufficient for an application for authorisation under Art. 13 TPA or is it necessary to wait for the Commission Decision? Revised November 2026

The CxMP / HMPC opinion can be submitted to Swissmedic for first submissions that are based on the EMA's Centralised Procedure. Once the European Commission's decision is available, this should be submitted.

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18 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 under Art. 10 FeeO-Swissmedic are reduced by 60%.

19 Do major objections in the foreign authority's List of Questions count as major concerns?

If the foreign authority has authorised the 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.

20 Can 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 medicinal product, on which the EU hybrid authorisation is based, to also be authorised in Switzerland. Otherwise, a 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)) to which it could refer as necessary (see Chapter 5.3 of guidance document *Authorisation of human medicinal products under Art. 13 TPA*).

21 Does the Swiss Information for healthcare professionals have to be referenced in the documentation submitted for applications according to Art. 13 TPA? New from March 2023

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.

22 Can authorisation of a medicinal product according to Art. 13 TPA be applied for with reference to a "marketing authorisation under exceptional circumstances" by the EMA? New from March 2023

No. Authorisation of a medicinal product according to Art. 13 TPA based on an EMA decision with "marketing authorisation under exceptional circumstances" is not possible, as there is no comparable authorisation procedure in Switzerland.

23 Is it possible to reference a marketing authorisation from an authority outside of the EU for authorisation of a combination product according to Art. 13 TPA? New from October 2023

No, Switzerland is aligned with the requirements of the European Union's (EU) conformity and certification system for the assessment of medical devices and medical device components in combination products. The authorisation/certification systems for medical devices outside of the EU differ from the currently valid certification system applied in the EU and Switzerland. Other authorisations (e.g. FDA) are currently not valid in respect of the current legislation in Switzerland.

24 What documents (decisions and additional documentation) have to be submitted for a repeat use procedure? (clarification on section 5.2 of the Guidance document on Art 13) New from December 2024

For an authorisation based on a repeat use procedure (RUP) of an EU MRP or DCP, an Assessment Report (AR) of the original procedure from the RMS must also be submitted in addition to an updated dossier with all variations approved since first authorisation.

If the RUP is based on an MRP, the subsequent variations must be commented on in the updated AR of the original procedure from the RMS. If the RUP is based on a DCP, the updated AR of the original procedure from the RMS must also include the result and full procedure history of the DCP.

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Basis for foreign decision:
Letter end of procedure of RUP

Additional documentation:
Updated Assessment Report (AR) including comprehensive list of variations or changes made in updating the dossier for the RUP
Approvals/Assessment Reports of all variations included in the updated dossier

25 May parts of the reference dossier containing confidential information, e.g. composition of a cell culture medium, be submitted via third parties? New from December 2024

With the exception of the restricted part of a DMF, all documentation included in the reference dossier, including those containing confidential information, must be provided by the marketing authorisation holder and be available in the consolidation sequence, because the submission of the consolidation sequence must confirm that Modules 2-5 of the reference dossier submitted to Swissmedic have been adopted unchanged and that there are no variations (see also section 5.1 of Guidance document *Authorisation of human medicinal products under Art. 13 TPA*: The documentation submitted to Swissmedic must be identical to that on which the reference authority based its authorisation of the medicinal product).

26 Until what point in the current authorisation procedure under Art 13 TPA can acknowledgements / approvals of variations approved by the reference authority be submitted? New from March 2026

Acknowledgements and approvals are accepted without fees or additional time up to and including the response to the preliminary decision in the current authorisation procedure under Art 13 TPA, as the consolidation sequence must be submitted by this point at the latest. These must correspond to the approved documentation. If the consolidation sequence and/or the acknowledgements / approvals are submitted later than the response to the preliminary decision, additional fees and time may apply.

27 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? New from March 2026

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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