

Guidance document

Authorisation veterinary medicinal product under Art. 13 TPA

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1 Terms, definitions, abbreviations

1.1 Definitions and terms

1.1.1 Countries with comparable veterinary medicinal product control

- The current list of countries recognised by Swissmedic as countries with comparable veterinary medicinal product control in accordance with Art. 16 para. 4 TPO is published on the Swissmedic website under *Directory List countries with comparable control of veterinary medicinal products HMV4*.

The veterinary medicinal product authorities in these countries are referred to collectively in this guidance document as *foreign authorities*.

1.1.2 Reference authority

The term *reference authority* refers to the foreign authority that has already authorised the veterinary medicinal product concerned and on whose review outcome the applicant is basing its request for authorisation in Switzerland.

1.2 Abbreviations

AI	Additional Indication
AR	Assessment Report
ASMF	Active Substance Master File
CP	Centralised Procedure
CVMP	Committee for Medicinal Products for Veterinary Use of the EMA
DCP	Decentralised Procedure of the EU
DMF	Drug Master File
EFTA	European Free Trade Association
EMA	European Medicines Agency
EU	European Union
EU-SmPC	Summary of Product Characteristics (EU)
FDA	Food and Drug Administration (USA)
FeeO-Swissmedic	Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products of 14 September 2018 (SR 812.214.5)
GCP	Good Clinical Practice
GxP	Good x Practice
IHP	Information for healthcare professionals
KAS	Known active substance
LoQ	List of Questions
LoOI	List of Outstanding Issues
MPI	Medicinal product information
MRP	Mutual Recognition Procedure of the EU
NAS	Medicinal products containing new active substances
NTA	Notice to Applicants
Ph. Eur.	European Pharmacopoeia
Ph. Helv.	Pharmacopoea Helvetica
PL	Package leaflet (information for animal owners)
RMS	Reference Member State of the EU
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21)
TPLO	Ordinance of the Swiss Agency for Therapeutic Products of 22 June 2006 on the Simplified Licensing of Therapeutic Products and the Licensing of Therapeutic Products by the Notification Procedure (SR 812.212.23)
TPO	Ordinance of 21 September 2018 on Therapeutic Products (SR 812.212.21)
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	Guidance document

2 Introduction

If an applicant requests authorisation or an extension or a variation of an authorisation for a veterinary medicinal product for which authorisation has already been granted in a country with comparable veterinary medicinal product control, Swissmedic takes account of the results of the reviews conducted for this purpose if certain requirements are satisfied. The aim of taking into account the outcome of foreign authorisation procedures is to assist in handling the authorisation of veterinary medicinal products in Switzerland in such a way that veterinary medicinal products that are already authorised abroad are made available in Switzerland as quickly as possible and Swissmedic's resources are deployed in a risk-based manner (Art. 1 para. 2 c and Art. 1 para. 3 a TPA).

2.1 Legal framework

The procedure for taking account of review outcomes determined in the course of foreign authorisation procedures is governed in particular by the following legal framework (the provisions of laws and ordinances):

Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA¹):

- Art. 13 Medicinal products and procedures authorised in foreign countries

Ordinance of 21 September 2018 on Therapeutic Products (Therapeutic Products Ordinance, TPO²):

- Section 2: Medicinal products and procedures authorised in foreign countries (Art. 13 TPA), Art. 16 - 20

3 Objective

This guidance document is aimed at administrative bodies and thus does not directly set out the rights and obligations of private individuals. Swissmedic uses this guidance document first and foremost as a resource for applying the legal provisions in a uniform and equitable manner. For applicants, the document is intended to make clear the specific preconditions and requirements that must be fulfilled so that applications for authorisation of veterinary medicinal products as per Art. 13 TPA can be processed as quickly and efficiently as possible.

4 Scope

This guidance document applies in the following cases:

1st To the following types of application for authorisation and variation of veterinary medicinal products and to procedures that are based on Art. 16 – 19 TPA and refer to an authorisation that has already been granted in a country with comparable veterinary medicinal product control:

- a) New authorisation applications for veterinary medicinal products with known APIs
- b) New authorisation applications for veterinary medicinal products with new APIs and their additional indications, provided they fulfil the criteria listed in Chapter 7
- c) New authorisation applications for veterinary medicinal products that, on the basis of Art. 12 para. 4 TPLO, cannot be authorised using the simplified procedure, provided they fulfil the criteria listed in Chapter 7
- d) New authorisation applications for the grant of temporary authorisation for a veterinary medicinal product in accordance with Art. 9 a TPA, provided the criteria listed in Chapter 8 are fulfilled
- e) Applications for variations not requiring assessment, as long as they meet the criteria in section 5.1
- f) Applications for variations requiring assessment (extension of indications for medicinal products with new active substances, provided they fulfil the criteria listed in Chapter 7)

¹ [SR 812.21](#)

² [SR 812.212.21](#)

2nd For parallel procedures in Switzerland and abroad as per Art. 20 TPO

By analogy, for authorisation of processes as per Art. 9 para. 3 TPA.

3rd For authorisation of veterinary medicinal products for which variations are being requested, provided the applicant requests the procedure defined in Art. 13 TPA and all the following requirements are fulfilled:

- a. The submitted documents from the foreign procedure, including all variations, are no older than five years and correspond to the authorisation status in the other country.
- b. The official assessment decisions issued during the foreign authorisation procedure are available, including the related Assessment Reports.
- c. The documents contain all the information required for Switzerland as shown in Chapter 11, particularly the medicinal product information and labelling texts.
- d. The documents are available in an official language, in English or in a translation into one of these languages. If a translation is submitted, the applicant must confirm that it is correct.

4th For variations for veterinary medicinal products that were initially authorised by Swissmedic without reference to Art. 13 TPA, provided the applicant confirms that the status of the dossier is the same and that an Assessment Report by a foreign authority regarding the variation in question is available.

This guidance document is not applicable to veterinary medicinal products in the notification procedure in accordance with Art. 39 TPLO.

5 Description

5.1 Documentation requirements (Art. 16 TPO)

If a veterinary medicinal product has already been authorised in a country with comparable veterinary medicinal product control as defined in Chapter 1.1.1, Swissmedic will take account during the authorisation procedure of the outcome of the reference authority's review, provided the applicant specifically requests this on the form *New authorisation of veterinary medicinal products HMV4* or the form *Variations VMP HMV4*. In this case Swissmedic will at the same time check whether all the documents required for this procedure have been submitted in full.

5.1.1 Documentation submitted to the reference authority

- *Agreement between foreign and Swiss documentation*

The documentation submitted to Swissmedic must be identical to the documentation on the basis of which the reference authority approved the authorisation of the veterinary medicinal product or its variation³.

If authorisation was granted in more than one country with comparable veterinary medicinal product control, the authorisation documentation must be completely identical to that submitted to the reference authority.

The complete documentation should be submitted to Swissmedic with the country-specific Part 1 assessed by the reference authority and the Swiss Part 1. The documents generated in the

³ See Chapter 5.7 and 5.8 for exceptions

course of the foreign procedure (LoQ and responses, Assessment Reports, official authorisation decision, etc.) should be included in the Swiss Part 1.

- **Documentation for variation applications**

An Assessment Report from the reference authority must be available if Art. 13 TPA is to be applied.

For variation applications for veterinary medicinal products that have been authorised by Swissmedic without reference to Art. 13 TPA, confirmation from an authorised signatory that the documentation status with the reference authority (prior to approval of the variation) is identical to that in Switzerland is additionally required. Confirmation of this kind is also required if the authorisation documentation affected by the variation was approved by a reference authority other than the authority stated in the variation application.

- **Variations and / or additions since the foreign official decision**

When the application for new authorisation is submitted, variations and additions approved by the reference authority since the official authorisation decision was issued must be submitted to Swissmedic at the same time. This additional or substituted documentation can either be integrated into the documentation or submitted separately. The variations should be mentioned in the cover letter and a comparison of the variations (old / new) must be enclosed with the related final Assessment Report.

- **Information concerning safety signals**

All relevant information relating to ongoing national and international safety signals should be submitted to Swissmedic, including relevant correspondence with the reference authority, such as letters announcing the opening of a procedure, LoQ letters, Expert Reports, interim results (milestones) and final reports. Updates should be submitted during the authorisation procedure as they arise. For safety signals that have occurred since authorisation was granted in the foreign country and the application was submitted to Swissmedic and have been concluded, only the final report and the medicinal product information, if amended, should be submitted.

- **GLP / GMP / GCP**

Conformity of the veterinary medicinal product for which authorisation is being requested with GLP / GMP / GCP must be demonstrated. Ongoing investigations (e.g. elimination of defects, necessary follow-up inspections) must be stated in the cover letter.

- **Drug Master File (DMF / ASMF)**

If a DMF / ASMF was submitted to the reference authority, the DMF / ASMF holder must submit to Swissmedic an identical copy of the Restricted Part, including the Letter of Access. Furthermore, the Assessment Report, the LoQ and the responses to the Restricted Part must be submitted where available. If the DMF / ASMF has since been modified, the approved modifications and the related Assessment Report should be submitted separately and mentioned in the cover letter with a comparison of the modifications (old / new).

5.1.2 Date of authorisation or last revision of the documentation

The first authorisation or the most recent version of the full documentation approved by the reference authority and updated must not be more than 5 years old when the application is submitted to Swissmedic⁴ (Art. 16 para. 1 TPO).

Differences compared with the currently valid guidelines that were not yet in force when the authorisation was granted in the foreign country are possible. They must be assessed critically and mentioned in the cover letter.

⁴ Date of the official decision on the new authorisation or approval of the variation

5.1.3 Results of the assessment and official decision by the reference authority

Swissmedic must have at its disposal the results of the assessment that enable it to understand the reference authority's decision-making process. The documentation required for the usual European procedures (CP, DCP and MRP) are listed in the Annex as examples. For applications relating to other countries, the equivalent documents from the applicable reference authorities must be provided.

The complete and final Assessment Report from the reference authority must be submitted to Swissmedic in all cases. If the foreign reference authority only provides the applicant in Switzerland with an Assessment Report that is not readable as a continuous document, Swissmedic will accept the submission of this incomplete assessment report. However, in such situations Swissmedic reserves the right to carry out its own scientific assessment of the inaccessible parts of the Assessment Report using the basic documentation. The additional time involved will usually result in a time surcharge⁵ and correspondingly higher fees⁶.

If a veterinary medicinal product has been authorised in several countries with comparable veterinary medicinal product control, only the official authorisation decision and the outcome of the assessment (according to the Annex) by the reference authority cited by the applicant should be submitted to Swissmedic.

A negative authorisation decision on the veterinary medicinal product concerned, withdrawal by the applicant, an ongoing review procedure or a suspension by any foreign authority as described in Chapter 1.1.1 must be listed in the form *Status of authorisation applications abroad HMV4*. The cover letter must describe transparently any deviating authorisation decisions of this type issued by other authorities (rejection of notifications leading to withdrawal of the application, deviations with respect to indications, dosage, storage information, shelf life, and other restrictions or similar).

5.1.4 Other administrative data

The applicant should apply for reviews performed by foreign authorities to be taken into account as per Art. 13 TPA / Art. 16 – 20 TPO using the form *New authorisation of veterinary medicinal products HMV4* or *Variations VMP HMV4*.

All the enclosures and forms required are listed in the *Table of documents to be submitted HMV4*. Documents that are submitted in addition but not listed in the table should be mentioned in the cover letter.

Evidence of compliance with the current requirements of Ph. Eur. / Ph. Helv. can be integrated into Part II or enclosed separately and should be confirmed using the form *Form Information for application Art. 13 TPA HMV4*. If methods other than the respective methods in Ph. Eur. / Ph. Helv. are used, their equivalence with the methods in Ph. Eur. / Ph. Helv. must be demonstrated.

⁷ See guidance document *Time limits for authorisation applications HMV4*

⁶ See FeeO-Swissmedic

5.1.5 Medicinal product information

Swissmedic must ensure specific aspects for Switzerland, such as congruence with the text of the medicinal product information for other veterinary medicinal products with comparable data. It is therefore not generally possible to use the medicinal product information approved by the reference authority unchanged without it being checked by Swissmedic.

The Swiss requirements regarding the information and texts on containers and packaging materials must be fulfilled (Art. 26, 28 and 29 TPO and Art. 12 - 14 and Annex 6 TPLRO).

5.1.6 Language and document translation requirements

The documentation (Parts 1 - IV) and the required documents shown in the Annex (see Chapter 11) must be provided to Swissmedic in an official Swiss language or in English. Translations into these languages will also be accepted provided the applicant confirms the correctness of the translation. The Swiss Part 1 (1A and 1B) and the medicinal product information and packaging texts must be in an official Swiss language.

5.1.7 Deviations from the medicinal product authorised by the reference authority

The veterinary medicinal product authorised in a foreign country must be identical with the product notified in Switzerland. Deviations are possible with respect to the following aspects:

- batch release
- quality control(s)
- secondary packaging or the secondary packager
- pack sizes provided they do not contradict the use of the product
- the name of the veterinary medicinal product authorised in a foreign country.

Since differences relating to the manufacturing site of the finished product and the primary packaging/primary packager must be subjected to a scientific assessment, they are not permitted in connection with an application according to Art.13 TPA.

If there are minor deviations between the authorisation in the foreign country and the application to Swissmedic, the documentation submitted to the reference authority for authorisation should be submitted. The deviations must be described in the cover letter and confirmed on the form *Information for application Art.13 TPA H MV4*. These deviations will be assessed as a variation by Swissmedic but will not result in a longer processing time nor usually to a fee for additional work.

5.1.8 Other authority-specific documentation

The documents from the reference authority that must be submitted are listed in the Annex. In its assessment, Swissmedic refers solely to documentation submitted by the applicant. A direct transfer of the documentation used for the foreign assessment by the authority in that country is not possible. If the Assessment Report on the Restricted Parts of the DMF / ASMF is not readable as a continuous document, the applicant must ensure that the DMF / ASMF holder submits the uncensored documents directly to Swissmedic.

5.1.9 Information and documentation after authorisation by Swissmedic

The enactment of the approval or rejection decision by Swissmedic concludes the authorisation procedure as per Art. 16 - 20 TPO.

The requirements imposed by the reference authority that have not yet been fulfilled by the time Swissmedic issues its authorisation decision are generally imposed by Swissmedic too.

Decisions by the reference authority with respect to fulfilment of requirements that are issued after authorisation has been granted in Switzerland must be submitted to Swissmedic within an appropriate period.

5.2 Application to veterinary medicinal products with known active substances (Art. 17 TPO)

The following statements apply to the assessment of applications for the authorisation of veterinary medicinal products with known active substances as per Art. 17 TPO. The consideration of results of assessments by foreign authorities within the framework of an application for a variation for a veterinary medicinal product with a known active substance is also subject to these provisions, provided the documentation requirements as per Chapter 5 are met.

For applications for authorisation of a veterinary medicinal product with known APIs that has already been granted authorisation in a country with comparable veterinary medicinal product control (see Chapter 1.1.1) and fulfils the requirements for the application of Art. 13 TPA as described in Chapter 3, Swissmedic does not perform its own scientific assessment provided the documentation requirements as per Art. 16 TPO are fulfilled. These applications are evaluated using the following criteria:

Swissmedic checks the following based on the history and context:

- whether safety signals requiring special consideration exist
- whether material differences exist between the authorisation decisions of two authorities (e.g. authorisation by one and rejection or partial rejection by the other, differing indications and / or therapeutic regimen)
- whether major concerns exist in respect of quality, safety and/or efficacy based on an earlier assessment of a veterinary medicinal product carried out by Swissmedic with the same active substance or the same substance class
- whether new findings from the published specialist literature or information arising from cooperation with other regulatory authorities exist.

If the decisions in two or more foreign countries are contradictory, or if assessment of the points listed here gives rise to major concerns about the authorisation decision issued by the foreign authority, the application is assessed on the basis of the Assessment Report of the reference authority. If a review of the Assessment Report cannot eliminate concerns regarding the points listed, a specific review of the basic documentation is performed that is limited to the points mentioned (see flow chart I in the Annex).

5.2.1 Transparency regarding major concerns

The reasons for concerns leading to Swissmedic carrying out an independent assessment will be provided to the applicant with the List of Questions or – in the event that no List of Questions is compiled – with the preliminary decision.

5.3 Application to medicinal products with a new active substance and their additional indications (Art. 18 TPO)

Applications for authorisation of a veterinary medicinal product with a new active substance or for additional indications and applications for authorisation of veterinary medicinal products as per Art. 12 para. 5 TPLO are subjected to a comprehensive scientific assessment by Swissmedic. In justified cases, Swissmedic may reduce the assessment accordingly on application or *ex officio* on the basis of corresponding outcomes of foreign reviews (see flow chart II in the Annex).

5.3.1 Restriction of the assessment on application

Reduced assessment for NAS or their additional indications is possible for the following medicinal products:

1st Veterinary medicinal product that have been classified or authorised as MUMS by a country with comparable veterinary medicinal product control (see Chapter 1.1.1).

2nd Veterinary medicinal products that fulfil the following requirements cumulatively:

- a. Used to identify, prevent or treat a disease that can lead to serious damage or suffering possibly resulting in death or to the death of an animal in the short term;
- b. No alternative and equivalent medicinal product is authorised or available in Switzerland;
- c. Use is likely to be of major therapeutic benefit;

The application for consideration of the outcome of the review by the foreign authority must be scientifically justified in each case.

For MUMS it is sufficient to submit the corresponding classification or authorisation.

Otherwise the scientific justification must address the individual requirements and list the most important references in an Annex.

If there are major concerns as a result of prior assessments carried out by Swissmedic, the Agency may perform its own assessment, drawing on additional documentation, even if the stated criteria are fulfilled.

5.4 Application to veterinary medicinal products with a conditional or temporary authorisation in a foreign country (Art. 9 a TPA, Art. 19 TPO, Art 18 ff TPLO)

For applications for authorisation of a process or a medicinal product for which conditional authorisation with special requirements has been granted in a country with comparable veterinary medicinal product control because of missing data on quality, safety and efficacy, the results of the review by the foreign authority will be taken into account in granting a temporary authorisation as per Art. 9 a TPA provided the documentation requirements and the criteria listed in Chapter 6 and Chapter 7 are fulfilled. Moreover, Swissmedic must have approved the preceding application for the granting of a temporary authorisation. The assessment is generally limited to an examination of the

benefit-risk relationship on the basis of the Assessment Report of the foreign reference authority. In line with Art. 9 a TPA in conjunction with Art. 18 ff TPLO, Swissmedic only grants temporary authorisation for a veterinary medicinal product with temporary authorisation in a foreign country. All data submitted post-application and all the results of the foreign authority's assessment of the fulfilment of the specific requirements attached to this authorisation must be submitted immediately to Swissmedic (see guidance document *Temporary authorisation of veterinary medicinal products HMV4* and flow chart I and II).

5.5 Application to parallel procedures in Switzerland and abroad (Art. 20 TPO)

When an application is submitted in the normal authorisation procedure, the applicant states in the form *Status of authorisation applications abroad HMV4* whether authorisation has already been requested for the same veterinary medicinal product in a country with comparable medicinal product control.

If the EMA issues a recommendation to the EU Commission while the authorisation procedure in Switzerland is ongoing, or if a positive authorisation decision is issued in a country with comparable veterinary medicinal product control, at the request of the applicant Swissmedic applies Art. 16 - 19 TPO analogously, provided the assessment that it has already performed has not given rise to any major concerns and it is foreseeable that this procedure (as per Art. 13 TPA) will result in a faster decision. If the assessment performed by Swissmedic up to this point has given rise to major concerns regarding the outcome of the review performed by the foreign reference authority, Swissmedic will continue with its own scientific assessment (see flow chart III in the Annex).

5.6 Process at Swissmedic

5.6.1 Processing of applications

During the formal check Swissmedic examines whether the applicant has confirmed the agreement of the documentation with the documentation authorised abroad and whether the required documentation is complete. Swissmedic also checks compliance with the documentation requirements in Art. 16 TPO. The applicant is informed in writing of the result of the formal check if deficiencies are observed.

All new authorisation applications requesting application of Art. 13 TPA for KAS and variations as described in Chapter 6 that fulfil the formal requirements of this guidance document are always assessed in accordance with Art. 13 TPA.

The process for variations not requiring assessment is based on the requirements in the guidance document *Variations veterinary medicinal products HMV4*.

For applications for authorisation of a veterinary medicinal product with a new active substance or additional indications, and for veterinary medicinal products which are not eligible for simplified authorisation based on Art. 12 para. 5 TPLO, Swissmedic checks whether the justification for reduced assessment can be accepted and the application accordingly qualifies for the process described in Art. 16 - 20 TPO.

If no questions are identified that necessitate a LoQ, the preliminary decision is sent to the applicant directly.

5.6.2 Cost of the process

If the applicant applies for reviews by foreign authorities as per Art.13 HMG in conjunction with Art.16 - 20 TPO to be taken into account, if it fulfils the conditions described in this guidance document, and if the authorisation decision by Swissmedic can consequently be based on the outcome of the reviews performed by the reference authority, the flat-rate fees applicable to the individual case are reduced by 60% as per Art. 10 FeeO-Swissmedic.

6 Annex

6.1 Documentation to be supplied

- Part I to IV (NTA) as submitted to the foreign authority.
- Where applicable: for the DMF / ASMF a copy of the Restricted Part identical to that submitted to the foreign authority, including the Letter of Access, Assessment Report on the Restricted Part, LoQ and the company's responses to the Restricted Part, must be submitted by the holder.
- Swiss Part I (as per the guidance document *Formal requirements HMV4* and the related Directory *Overview of documents to be submitted HMV4*).
- Cover letter. If applicable, confirmations, explanations, critical assessments or additional documentation must be submitted in the following situations:
 - In case of deviating authorisation decisions, e.g. deviations with respect to indications, dosage, storage instruction, shelf life or other restrictions or similar, withdrawal, rejection, suspension or an ongoing review procedure
 - In case of deviations in or additions to the documentation and / or the DMF / ASMF (Applicant's Part and Restricted Part) since the authorisation decision was issued: a comparison (old / new) incl. a critical assessment and an Assessment Report
 - If methods other than the respective methods in Ph. Eur. / Ph. Helv. are used, their equivalence with the methods in Ph. Eur. / Ph. Helv. must be stated in the form *Information for application Art.13 TPA HMV4* and corresponding evidence must be provided.
 - For variations without prior reference to Art. 13 TPA: confirmation by an authorised signatory that the Swiss documentation is identical to the documentation of the reference authority
 - If GxP investigations are ongoing (e.g. elimination of deficiencies, necessary follow-up inspections)
 - If there are differences compared with the currently valid guidelines that were not yet in force when the authorisation was granted in the foreign country
 - For translations: confirmation that the translation is correct
 - If information concerning safety signals is required
- For minor variations, the full Assessment Report and the decision by the reference authority.
- For authorisation applications the decision incl. additional documentation (review outcome) from the reference authority.

If not all the documents listed below were produced during the foreign approval procedure in the EU, this must be mentioned in the cover letter. In general, documents used in the foreign procedure must be submitted/marked/dated in such a way that the chronology of the assessment and the decision issued by the foreign authority is clear and transparent:

a) Centralised Procedure (CP)

Basis of the foreign decision: CVMP Opinion
The Decision of the EU Commission must be submitted as soon as it becomes available.

Additional documentation: Day 70 Assessment Report (AR)
Day 120 LoQ
Day 180 LoOI
Answers to Day 120 LoQ
Answers to Day 180 LoQ I
Day 210 AR

b) EU Mutual Recognition Procedure MRP

Basis of the foreign decision: Marketing Authorisation in RMS

Additional documentation: LoQ Day 57
Answers to LoQ Day 65
Assessment of the applicant's responses to LoQ (Day 70)
Day 90 AR
If the request is sent to the CVMP (EMA) for arbitration, the EMA's Opinion must be submitted

c) EU Decentralised Procedure DCP

Basis of the foreign decision: Marketing Authorisation in RMS

Additional documentation: LoQ I (Day 105), LOQ II Day (150 [30])
Answers to LoQ I, LOQ II
AR including assessment of the applicant's responses to LoQ I (Draft Day 120 [0])
Assessment of the applicant's responses to LOQ II (Day 190 [70])
Day 70 Preliminary AR
Final AR (≥ Day 105)
If the request is sent to the CVMP (EMA) for arbitration, the EMA's Opinion must be submitted

For applications relating to non-EU countries, the equivalent documents from the applicable reference authorities must be provided.

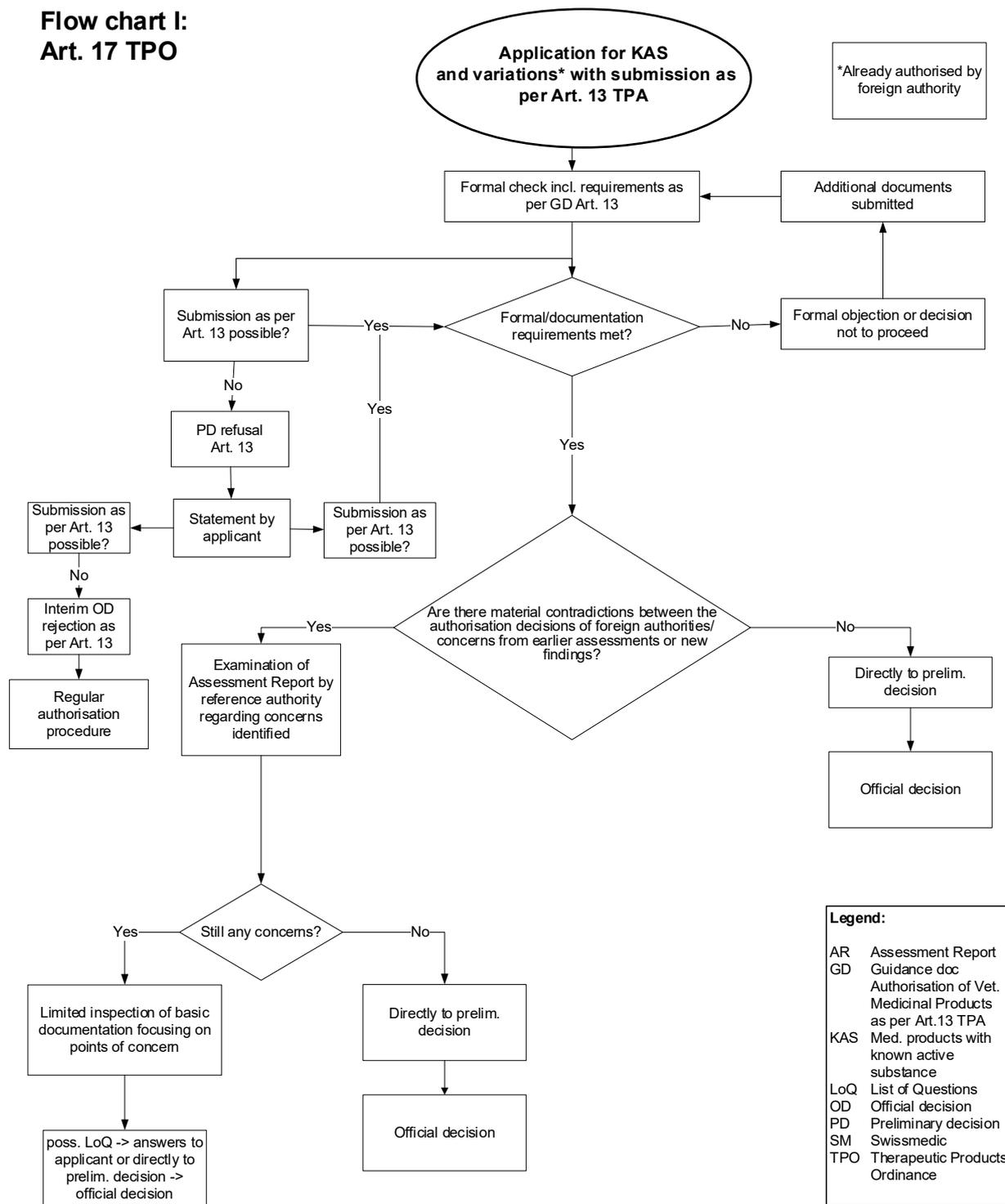
6.2 Flow charts of the application process

Flow chart I: Known active substance application and / or application requesting Art. 13 (Art. 17 TPO)

Flow chart II: NAS application and / or AI requesting Art. 13 TPA (Art. 18 TPO)

Flow chart III: Application for authorisation / variation without authorisation abroad but with an application ongoing in a foreign country (parallel procedures; Art. 20 TPO)

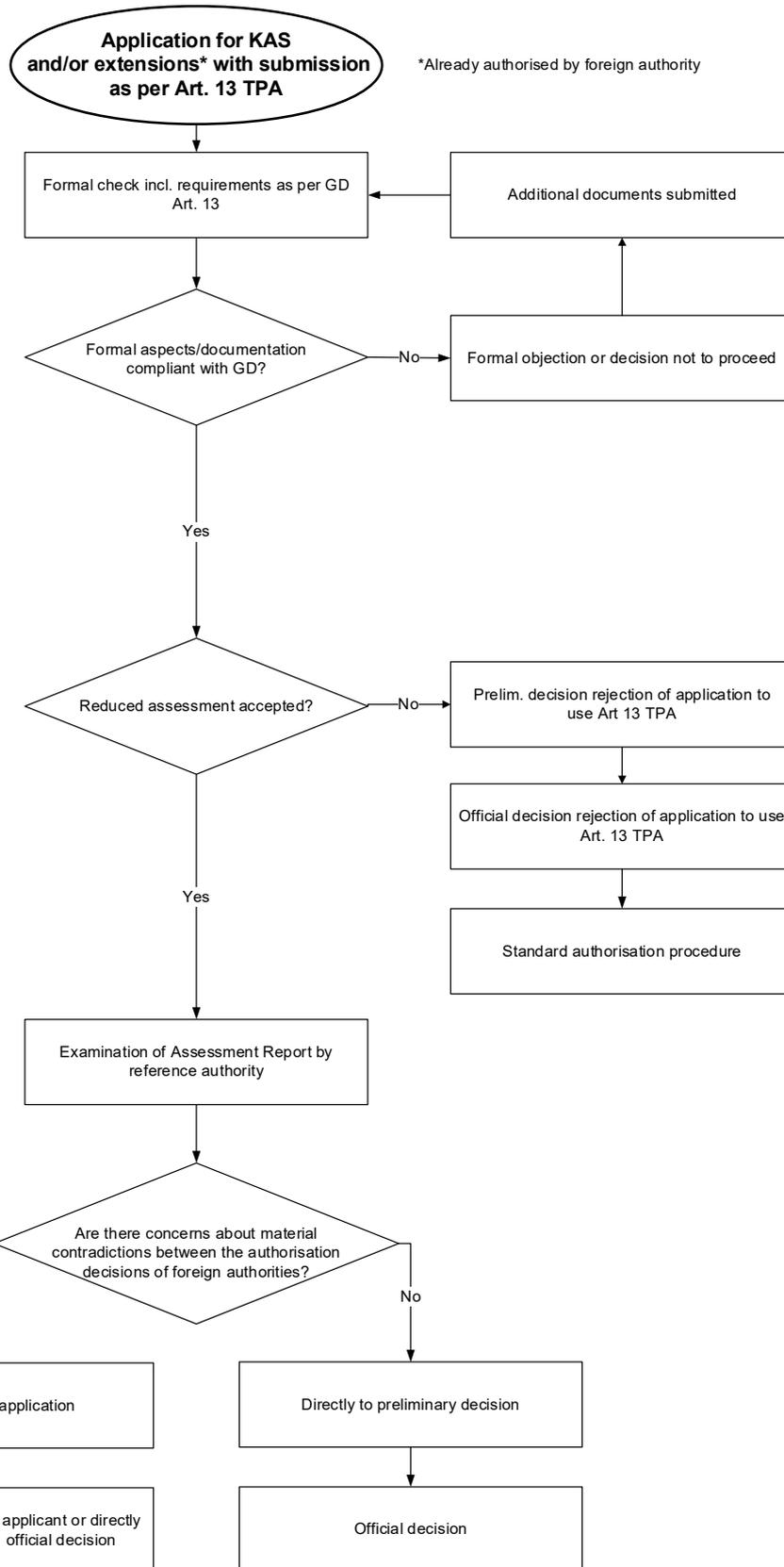
**Flow chart I:
Art. 17 TPO**



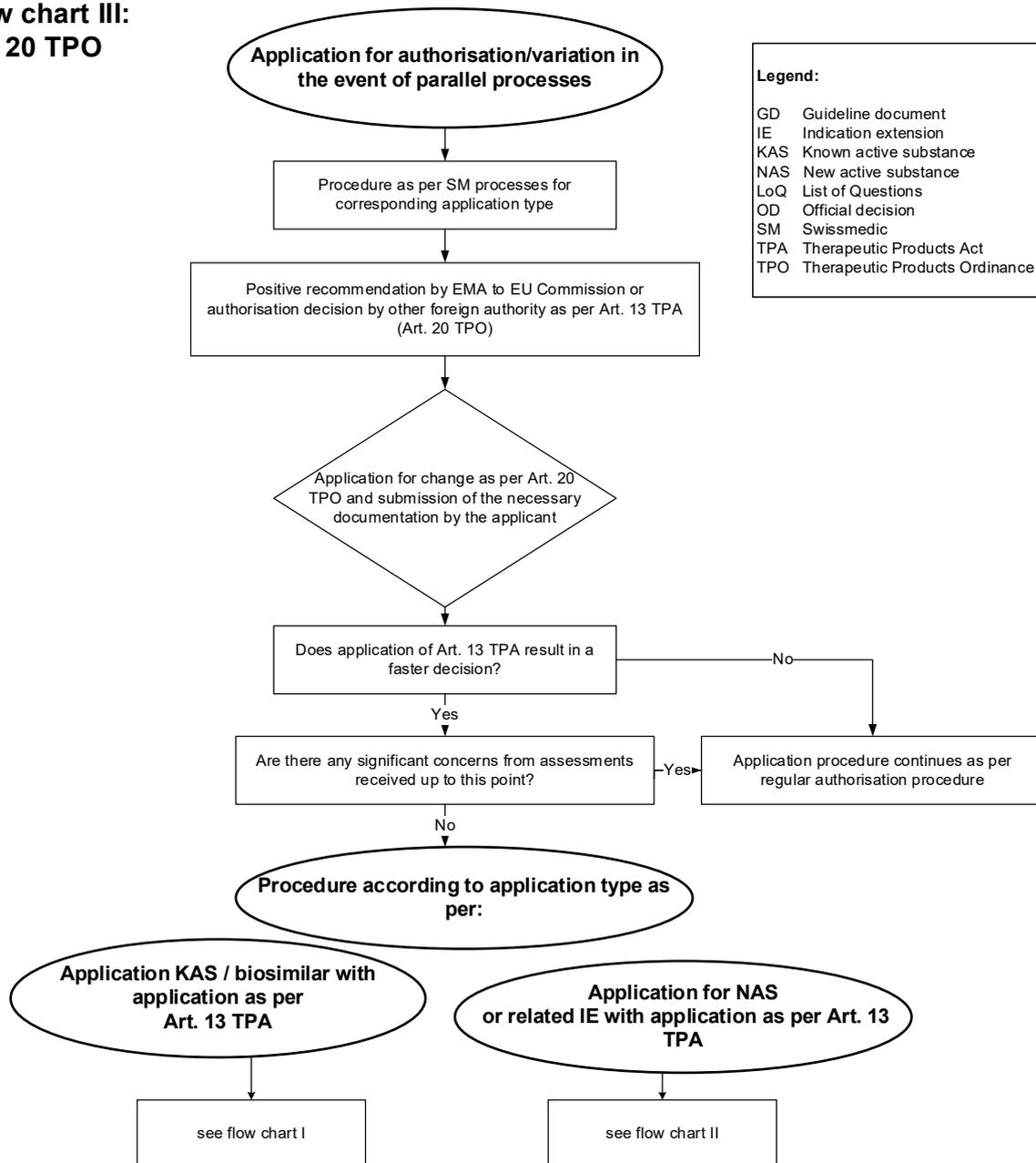
**Flow chart II:
Art. 18 TPO**

Legend:

AR	Assessment Report
GD	Guidance doc Authorisation of Vet. Medicinal Products as per Art.13 TPA
IE	Indication extensions
KAS	Med. products with known active substance
LoQ	List of Questions
OD	Official decision
PD	Preliminary decision
SM	Swissmedic
TPO	Therapeutic Products Ordinance



**Flow chart III:
Art. 20 TPO**



Change history

Version	Change	sig
3.1	New layout, no content adjustments to the previous version.	dei
3.0	Adaptation of guidance document due to new structure of changes for VMP (early revision of VMP regulations)	ps/fg
2.1	Formal adjustments to the header and footer No content adjustments to the previous version.	dei
2.0	Updating of the list of countries with comparable veterinary medicinal product control Clarifications in sections 3 and 5: Art. 13 TPA can be applied for minor variations of types IA / IA _{IN} / IB as long as these are processed in an Assessment Report	ps/fg
1.0	Implementation of TPO4	ps/fg