List of contents

1 Abbreviations

2 Introduction and Objectives

3 Scope

4 Legal basis

5 Other valid documents

6 Definitions

6.1 Countries with comparable control of veterinary medicines

6.2 Reference authority

7 Documentation required (Art. 5a, VAM)

7.1 Documents submitted to the reference authority

7.2 Date of authorisation or last revision of the documentation

7.3 Results of the assessment and decisions by the reference authority

7.4 Other administrative data

7.5 Product information

7.6 Differences with regard to the product authorised by the reference authority

7.7 Other documents specific to the authorities

7.8 Information and documentation following authorisation by Swissmedic

8 Veterinary medicines with known active pharmaceutical ingredients (Art. 5b, VAM)

8.1 Known active pharmaceutical ingredient authorised by a foreign authority but not by the central European system or the FDA (Art. 5b, paragraph 1, VAM)

8.2 Known active pharmaceutical ingredients with central European or FDA authorisation (Art. 5b paragraph 2, VAM)

8.3 Transparency regarding major concerns

9 New active pharmaceutical ingredient or extended indication (Art. 5c, VAM)

9.1 Reduction of assessment (application required)

10 Parallel procedures in Switzerland and abroad (Art. 5d, VAM)

11 Process applied within Swissmedic

11.1 Processing of the application

11.2 Duration and costs of the procedure

12 Annex

12.1 Documents to be submitted

12.2 Flowcharts for the application processes
Change history

<table>
<thead>
<tr>
<th>Version</th>
<th>Valid and binding as of:</th>
<th>Modified without version change</th>
<th>Description, comments (by author)</th>
<th>Author's initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>03</td>
<td>11.11.15</td>
<td>07.07.17</td>
<td>In order to standardise document names, the published &quot;Information sheet&quot; (MB) ZL000_00_029e_MB Authorisation of veterinary medicines already authorised in foreign countries (Art. 13 HMG) is being replaced by &quot;Guidance documents&quot; (WL). The function and effects of the document are not changed as a result of the name change.</td>
<td>cis</td>
</tr>
<tr>
<td>02</td>
<td>29.09.14</td>
<td>03.10.14 / 05.01.15</td>
<td>More detailed instructions in Chapter 13 regarding submission of the LoQ and the Assessment Report of the DMF Restricted Part.</td>
<td>cis</td>
</tr>
<tr>
<td>01</td>
<td>01.01.14</td>
<td></td>
<td>Section 6: links revised</td>
<td>ps, apk</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Section 8: For the formal requirements in general and the requirements regarding Module 1 and the cover letter, reference is made to the Guidance Document Formal requirements and the associated list, Table of documents to be submitted.</td>
<td>ps, apk</td>
</tr>
</tbody>
</table>

1 Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMZV</td>
<td>Ordinance of the Swiss Agency for Therapeutic Products on the Requirements for the Authorisation of Medicinal Products (Medicinal Products Authorisation Ordinance) (SR 812.212.22)</td>
</tr>
<tr>
<td>AO</td>
<td>Administrative Ordinance</td>
</tr>
<tr>
<td>API</td>
<td>Medicinal product with active pharmaceutical ingredients</td>
</tr>
<tr>
<td>AR</td>
<td>Assessment Report</td>
</tr>
<tr>
<td>ASMF</td>
<td>Active Substance Master File</td>
</tr>
<tr>
<td>CVMP</td>
<td>Committee for Medicinal Products for Veterinary Use, EMA</td>
</tr>
<tr>
<td>CP</td>
<td>Centralised Procedure</td>
</tr>
<tr>
<td>DCP</td>
<td>EU Decentralised Procedure</td>
</tr>
<tr>
<td>DMF</td>
<td>Drug Master File</td>
</tr>
<tr>
<td>EFTA</td>
<td>European Free Trade Association</td>
</tr>
<tr>
<td>EMA</td>
<td>European Medicines Agency</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>EU-SmPC</td>
<td>Summary of Product Characteristics (EU)</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration (USA)</td>
</tr>
<tr>
<td>GCP</td>
<td>Good Clinical Practice</td>
</tr>
<tr>
<td>GxP</td>
<td>Good x Practices</td>
</tr>
<tr>
<td>HGebV</td>
<td>Ordinance on the fees levied by the Swiss Agency for Therapeutic Products (SR 812.214.5)</td>
</tr>
<tr>
<td>LoQ</td>
<td>List of Questions</td>
</tr>
<tr>
<td>LoOI</td>
<td>List of Outstanding Issues</td>
</tr>
<tr>
<td>MRP</td>
<td>EU Mutual Recognition Procedure</td>
</tr>
<tr>
<td>NtA</td>
<td>Notice to Applicant</td>
</tr>
<tr>
<td>Ph. Eur.</td>
<td>Pharmacopoea Europaea</td>
</tr>
<tr>
<td>Ph. Helv.</td>
<td>Pharmacopoea Helvetica</td>
</tr>
<tr>
<td>RMS</td>
<td>Reference Member State within the EU</td>
</tr>
<tr>
<td>SmPC</td>
<td>Summary of Product Characteristics (EU)</td>
</tr>
<tr>
<td>TPA</td>
<td>Therapeutic Products Act of 15 December 2000 (SR 812.21)</td>
</tr>
<tr>
<td>VAM</td>
<td>Ordinance on Medicinal Products of 17 October 2001 (SR 812.212.21)</td>
</tr>
</tbody>
</table>
2 Introduction and Objectives

When an application for authorisation is submitted for a veterinary medicine for which authorisation has already been granted in a country with comparable control of veterinary medicines, the Swiss Agency for Therapeutic Products (hereinafter Swissmedic or the Agency) takes the test results carried out by the foreign veterinary medicines authority into consideration provided that certain requirements are fulfilled.

This guidance document specifies the requirements and describes the internal process that are adopted by Swissmedic.

The guidance document serve primarily to assist Swissmedic in applying the provisions in a standardised manner and in accordance with the law. In addition, they are intended to provide transparency for applicants regarding the requirements in accordance with Swissmedic's practices.

Taking the test results from foreign authorisation procedures into consideration is intended to contribute towards ensuring that the authorisation of veterinary medicines in Switzerland is conducted in such a way that enables medicinal products already authorised in foreign countries to be made available in Switzerland as rapidly as possible, and ensures that the Agency's resources are deployed in a risk-based manner (Art. 1, para. 3, letter a, TPA).

3 Scope

The guidance document applies to Swissmedic's Veterinary Medicines division within the Authorisation sector for the following submissions:

- First authorisations including major variations of veterinary medicines
- Variations requiring approval to veterinary medicines that have already been authorised under Article 13, TPA provided that an assessment report is available for each variation in question
- Variations requiring approval to products that have been authorised outside of Art. 13, TPA, provided confirmation is given that the status of the dossiers (the one approved by Swissmedic and the one approved by the reference authority) is identical and in addition that the assessment report for each variation is provided

This guidance document is valid:

- For authorisation applications based on Arts. 5a - 5c, “Medicinal Products Ordinance” (VAM) and related to the following veterinary medicines authorised by foreign authorities (see Section 7.1 below):
  - Veterinary medicines with known active pharmaceutical ingredients (known APIs)
  - Medicinal products with new active pharmaceutical ingredients (new APIs) or new indications for them, provided they fulfil the criteria stated in Section 10
  - Veterinary medicines that are based on Art. 12, para. 4, “Ordinance on the Simplified Authorisation of Medicinal Products” (VAZV) - cannot be processed using the simplified authorisation procedure, but fulfil the criteria stated in Section 10
- For parallel processing of applications by Swissmedic and the EMA, in accordance with Art. 5d, VAM
- By analogy, for the authorisation of procedures in accordance with Art. 9, para. 3, TPA

The guidance document does not apply to:

- Variations requiring approval for which no assessment report on the variation in question is available
- Variations requiring notification
- Notification procedures in accordance with Art. 39, VAZV
4 Legal basis

The procedure for taking into account the results of evaluations carried out during the course of foreign authorisation procedures is derived in particular from the following legal bases (legal provisions and ordinances):

- Federal Act of 15 December on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA):
  - Art. 13 Medicinal products authorised in foreign countries

- Ordinance of 17 October 2001 concerning Medicinal Products (Medicinal Products Ordinance, VAM):
  - Art. 5a - 5d Medicinal products authorised in foreign countries (Art. 13, TPA)

5 Other valid documents

<table>
<thead>
<tr>
<th>Document identification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZL000_00_013e_CL</td>
<td>Formal control Application authorisation veterinary medicines Art.13, TPA</td>
</tr>
<tr>
<td>ZL000_00_024e FO</td>
<td>Application for authorisation / variation veterinary medicines</td>
</tr>
<tr>
<td>ZL000_00_0007e FO</td>
<td>Status of marketing authorisations abroad</td>
</tr>
<tr>
<td>ZL302_00_0001e FO</td>
<td>Quality variation requiring approval</td>
</tr>
<tr>
<td>ZL101_00_0003e FO</td>
<td>Information relating to quality for applications under Art. 13, TPA</td>
</tr>
<tr>
<td>ZL101_00_0004e WL</td>
<td>Guidance document Authorisation of veterinary medicine with known active pharmaceutical ingredient</td>
</tr>
<tr>
<td>ZL000_00_0001e WL</td>
<td>Guidance document Formal requirements</td>
</tr>
<tr>
<td>ZL000_00_0002e VZ</td>
<td>Overview documents to submitted</td>
</tr>
<tr>
<td>ZL000_00_0010e VV</td>
<td>Time limits for authorisation applications</td>
</tr>
<tr>
<td>ZA000_00_0001e VZ</td>
<td>List of all countries with comparable control of medicinal products</td>
</tr>
</tbody>
</table>

6 Definitions

6.1 Countries with comparable control of veterinary medicines

The following countries are recognised by Swissmedic as having comparable control of veterinary medicines based on Art. 5a, para. 4, VAM (status January 2013):

- Australia
- Canada
- EU and EFTA countries
- Japan
- New Zealand
- Singapore
- USA

In this guidance document, the veterinary medicines authorities of these countries are referred to as “foreign authorities”.

6.2 Reference authority

The term “reference authority” applies to the foreign authority that has already authorised the veterinary medicine concerned, and whose test results are used by the applicant as the basis for the authorisation application in Switzerland.

---

1 SR 812.21
2 SR 812.212.21
7 Documentation required (Art. 5a, VAM)

If a veterinary medicine has already been granted authorisation in a country with comparable control of veterinary medicines according to Section 7.1 above, the test results by the reference authority will be taken into account by the Agency during the authorisation procedure, provided that the applicant explicitly requests the Agency to do so in the form Application for authorisation / variation, veterinary medicines. In such cases, the Agency will also check that all necessary documents the procedure have been submitted in full.

7.1 Documents submitted to the reference authority

- **Comparability of foreign and Swiss documentation**

  The documentation submitted to Swissmedic must be identical to that provided to the reference authority as the basis for granting the authorisation of or approving a variation to the veterinary medicine. If the product has been authorised in more than one country with comparable control of veterinary medicines, the authorisation documentation need only be submitted once, in an identical form to that submitted to the reference authority. For subsequent applications for variations, the originally selected reference authority must remain the same.

- **Documentation for variation applications**

  For applications for variations to veterinary medicines according to Art. 13, TPA, an assessment report by the reference authority must be submitted. Applications for variations (including major variations) to veterinary medicines that were originally authorised by Swissmedic without taking Art. 13, TPA into account, a confirmation signed by a person entitled to act as a signatory or in charge of regulatory affairs must be submitted, stating that the documentation for the reference authority (prior to the approval of the variation) and that for Switzerland are identical.

- **Variations and / or additions since the decision by the foreign authority**

  In parallel with the application, all approved variations and / or additions made since the reference authority granted the authorisation must also be submitted to Swissmedic. The additional or replacement documents may either be within the application documentation or be submitted separately. The variations must be referred to in the cover letter, and a comparison showing the changes (present / proposed) must be appended to the corresponding final assessment report.

- **Information regarding safety signals**

  All relevant information and correspondence with the reference authority, such as communications regarding the initiation of a procedure, LoQ letters, experts' reports, interim results (milestones) and final reports, should also be submitted, but only in connection with current national and international safety signals. If applicable, relevant updates taking place during the authorisation process must be sent subsequently. For safety signals occurring after the authorisation abroad and the submission to Swissmedic, and that have been completed, only the final report and any modified product information texts must be submitted.

- **GLP / GMP / GCP**

  GLP / GMP / GCP compliance must be confirmed. Pending investigations (e.g. resolution of deficiencies, required follow-up inspections) must be stated in the cover letter.

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

  If a DMF / ASMF has been submitted to the reference authority for the application in question, the DMF / ASMF holder must submit an identical copy of the Restricted Part of it, including the Letter

---

3 For exceptions to this requirement, see Section 8.6 and 8.7
of Access. If the DMF / ASMF has been subsequently modified, the approved modifications, with the corresponding assessment report, must be submitted separately and noted in the cover letter together with a comparison showing the changes (present / proposed).

7.2 Date of authorisation or last revision of the documentation

The authorisation granted or the latest updated version of the entire documentation approved by the reference authority must not be over five years old⁴ at the time of submitting the application to Swissmedic (Art. 5a, para. 1, VAM). This ensures that the assessment by the reference authority has been carried out in line with the current status of science and technology. Differences with regard to currently valid guidelines that were not in force at the time of the authorisation abroad are acceptable if they are critically assessed and mentioned in the cover letter.

7.3 Results of the assessment and decisions by the reference authority

Results of the assessment that are provided to the Agency must enable an understanding of the decision process of the reference authority. The documents required are listed in the Annex. If a veterinary medicine has been authorised in more than one country with comparable control of veterinary medicines, only the official decision to grant the authorisation and the results of the assessment from the reference authority specified by the applicant need be submitted. If the applicant is submitting an application for either an authorisation or a variation concerning a veterinary medicine for which a decision from both the EMA and the FDA has been issued, Swissmedic must be provided with the assessment results of both authorities in the event that the decisions diverge and / or if an application is withdrawn. Any negative decisions concerning authorisation, a withdrawal by the applicant, a pending examination procedure or a suspension of the product for which the application is made, must be listed for all foreign authorities (in accordance with Section 7.1 above) on the form Status of authorisation applications abroad. The cover letter must refer clearly and openly to differing authorisation decisions of other authorities (refusal: communications leading to the withdrawal of the application divergences regarding indications, dosage, storage instructions, shelf life, other restrictions etc.).

7.4 Other administrative data

The applicant must state the request for the test results of foreign authorities to be taken into consideration in accordance with Art. 13, TPA / Arts. 5a – 5d, VAM on the form Application for authorisation / variation, veterinary medicines. All documents and forms to be submitted are listed in the checklist Formal control of authorisation application veterinary medicines Art. 13 TPA, which must also be submitted. Any other accompanying documents that are not listed in the check list must be mentioned in the cover letter. Proof of compliance with the current requirements of the Ph. Eur. / Ph. Helv. may be integrated within Part II or included separately, and confirmed in the checklist Formal control of authorisation application veterinary medicines Art. 13 TPA. If methods other than the relevant methods contained in the Ph. Eur. / Ph. Helv. are used, their equivalence to those in the Ph. Eur. / Ph. Helv. must be demonstrated.

7.5 Product information

Swissmedic must ensure that points specific to Switzerland are included in the product information, such as compliance with the requirements for the product information (e.g. storage instructions) or congruence with the wording of the product information for other veterinary medicines for which available data are comparable. The use of identical wording to that of the product information approved by the reference authority without review by Swissmedic is therefore not usually possible. If an authorisation has been granted by means of a centralised procedure (EMA Scientific Decision), or if authorisation has been granted by a Member State of the EU or EFTA, the valid product

⁴ Date of the official decision regarding authorisation or approval
information – the EU SmPC – may be approved (Art. 5a, para. 3, VAM). If the content of the
described product information differs with regard to Swiss requirements, Swissmedic must
consider these points. The Swiss requirements with regard to the details and texts on containers and
packaging materials must be respected (Art. 12 and Annexes, AMZV\textsuperscript{5}).

7.6 Differences with regard to the product authorised by the reference authority

In general the product that has been authorised in a foreign country must be identical to the product
that is the subject of the application in Switzerland. However, differences are possible in the following
cases:
- Differences relating to the place of manufacture of the finished product
- Differences relating to batch release
- Differences relating to quality control(s)
- Differences relating to the primary packaging or the manufacturer thereof
- Differences relating to the secondary packaging or the manufacturer thereof
- Differences relating to the package size, if this has no impact on the use of the product
- Difference relating to the product designation that has been authorised in a foreign country

The differences must be noted in the cover letter. Differences will be assessed by Switzerland in the
same way as variations, and lead to a longer processing time.

7.7 Other documents specific to the authorities

The documents from the reference authorities to be submitted are listed in the Annex (see section
15). In its examination, Swissmedic refers exclusively to documents submitted to it by the applicants.
Direct transfer of evaluation documents from foreign countries by the relevant authority to Swissmedic
is not possible.

7.8 Information and documentation following authorisation by Swissmedic

When the official decision is taken by Swissmedic to grant or reject the authorisation, the
authorisation procedure in accordance with Art. 5a – 5d of the VAM is completed.
Conditions that are imposed by the reference authorities and that have not been fulfilled at the time of
adoption of the official decision by the Agency are usually also imposed by Swissmedic.
Decisions taken by the reference authorities after the authorisation in Switzerland is granted and
concerning the fulfilment of the imposed conditions must be forwarded to the Agency within a
reasonable timeframe.

8 Veterinary medicines with known active pharmaceutical
ingredients (Art. 5b, VAM)

The following information is applicable to applications for the authorisation of a veterinary medicine
with a known API, i.e. veterinary medicines that contain an API that is, or has been, contained in
another veterinary medicine authorised by the agency\textsuperscript{6}.

8.1 Known active pharmaceutical ingredient authorised by a foreign authority but
not by the central European system or the FDA (Art. 5b, paragraph 1, VAM)

In the case of applications for the authorisation of a veterinary medicine with a known API (see flow
chart I in the Annex), the Agency will usually only review the outcome of the assessment by the
reference authority provided that the requirements stated in Art. 5a, VAM are met (see Section 8).

\textsuperscript{5} SR 812.212.22
\textsuperscript{6} See Art. 12, para. 1 of the Ordinance of the Swiss Agency for Therapeutic Products of 22 June 2006 on the simplified
authorisation of medicinal products and the authorisation of medicinal products by the notification procedure
(VAZV SR 812.212.23)
8.2 Known active pharmaceutical ingredients with central European or FDA authorisation (Art. 5b paragraph 2, VAM)

For applications for known APIs that have been approved by the EMA and / or the FDA, the Agency will not usually review the assessment reports provided that the requirements stated in Art. 5a, VAM are met (see Section 8).

For such applications, Swissmedic will review the background, the environment and the information for healthcare professionals to determine whether any safety signals are present which require particular attention. Should this analysis give rise to major concerns, the assessment report is examined and if any aspects remain unclear, the Agency will carry out a targeted review of the underlying documentation.

8.3 Transparency regarding major concerns

The reasons for concerns that may result in Swissmedic carrying out its own assessment are communicated to the applicant with the LoQ.

9 New active pharmaceutical ingredient or extended indication (Art. 5c, VAM)

Applications for the authorisation of a veterinary medicine with a active pharmaceutical ingredient or for new indications for them are usually the subject of a comprehensive assessment conducted by the Agency, using all documents submitted. Applications for the authorisation of products in accordance with Art. 12, para. 1, VAZV are also handled in this way.

However, in justified cases Swissmedic may limit such assessments, either on request or ex officio, based on the result of the corresponding assessment by the foreign agency (see flow chart II in the Annex).

9.1 Reduction of assessment (application required)

A reduced assessment for new APIs or for additional indications for them is possible for the following products in particular:

- Medicinal products classified or authorised as "MUMS" by the EMA or by the FDA.

or

- Medicinal products that fulfil all of the following requirements:
  - Treatment of a life-threatening disease
  - No treatment possibilities or only unsatisfactory ones available with authorised medicinal products
  - Considerable therapeutic benefit can be expected from the product
  - Central authorisation in the EU and / or authorisation in the USA, as long as the authorisation decisions and evaluation reports are not contradictory

The application to take the test results of the foreign authority / authorities into consideration must in all cases be scientifically justified.

For "MUMS" it is sufficient to provide the corresponding classification or authorisation by the EMA or the FDA.

In other cases, the scientific justification must address each of the conditions to be fulfilled and must include the key references in the annex.

If major concerns exist based on earlier assessments by Swissmedic, it is possible that the Agency will carry out its assessment even if the above criteria are fulfilled, and that further documents will be required.
10 Parallel procedures in Switzerland and abroad (Art. 5d, VAM)

When submitting an application under the normal authorisation process, it should be stated on the form *Status of marketing authorisations abroad* whether an authorisation application for the same medicinal product has already been submitted to the EMA.

As soon as the EMA issues a recommendation to the European Commission, the Agency will apply Art. 5a – 5c, VAM by analogy provided that the applicant submits the corresponding request, there are no major concerns based on the Agency's own evaluation and it appears likely that this procedure (procedure in accordance with Art. 13, TPA) will lead to an earlier decision being reached (see flow chart III in the Annex).

11 Process applied within Swissmedic

11.1 Processing of the application

During the administrative control, the Agency checks that the applicant has confirmed that the documentation submitted is the same as that authorised in a foreign country, and that all the documents required have been provided. The checklist *Formal control of authorisation application veterinary medicines Art. 13 TPA* constitutes an integral part of this stage of the assessment.

The Agency also checks whether the requirements regarding documentation as stipulated in Art. 5a – 5d, VAM have been fulfilled. The Submissions Division informs the applicant of the results of the administrative control.

All applications for products with known APIs and generics and all applications for variations in accordance with Section 9 that fulfil the relevant criteria will be assessed in accordance with Art. 13, TPA. Applications for products with new APIs or additional indications for them, and products under Art. 12, paragraph 4, VAZV will be checked to ensure that the criteria as stated in Section 10 are fulfilled and that the application is therefore eligible for processing in accordance with Arts. 5a – 5d, VAM.

If no questions are identified that require the issuance of an LoQ, the applicant will be sent a preliminary decision directly.

11.2 Duration and costs of the procedure

Where the authorisation holder submits an application for the evaluations by authorities in foreign countries to be taken into account in accordance with Art. 13, TPA / Arts. 5a – 5d, VAM, and the requirements described in the present instructions are met, the Agency's decision can be based on the results of the reference authority's evaluation, the overall fees applied for individual cases are reduced in accordance with the applicable Fee Regulation (part B, Section 8 of Annex 2, Ordinance on the Fees levied by the Swiss Agency for Therapeutic Products [HGebV SR 812.214.5]). The processing time is shortened if no LoQ arises.
12  Annex

12.1  Documents to be submitted

- Parts I to IV (NtA) identical to those submitted to the foreign authority
- If applicable, for DMF / ASMF an identical copy of the Restricted Part must be submitted, and must include the holder’s Letter of Access, the Assessment Report of the Restricted Part, the LoQ and the company’s answers to the Restricted Part.
- Cover letter including if applicable confirmations, explanations, critical assessments or additional documents which must be submitted in the following situations:
  - For divergent decisions regarding authorisation, e.g. different indications, dosage, storage instructions, shelf life, or additional restrictions, etc., and in the case of withdrawal, rejection or suspension of pending assessment procedures
  - For differences or additions with regard to the documentation and / or the DMF / ASMF (Applicant's Part and Restricted Part) that have taken place since the authorisation decision, a comparison (present / proposed), including a critical evaluation and assessment report, must be submitted
  - If methods other than the relevant methods contained in the Ph. Eur. / Ph. Helv. are used, their equivalence to those in the Ph. Eur. / Ph. Helv. must be demonstrated
  - For variations (including major variations) to veterinary medicines for which Art. 13, TPA was not previously taken into consideration, confirmation signed by a person authorised to do so or by the person in charge of regulatory affairs stating that the documentation submitted to the reference authority and that submitted in Switzerland are identical
  - For pending GxP investigations (e.g. to address shortcomings, if follow-up inspections are required)
  - For differences with regard to currently valid guidelines that were not yet in force at the time of the authorisation abroad
  - If documents have been translated, confirmation that the translation is an accurate representation of the originals
  - If information is required with regard to safety signals
  - Authorisation decision including additional documentation (test results) of the reference authority e.g. for authorisation based on the EU procedure:
    a) Centralised Procedure (CP)
       Based on foreign decision: CVMP Opinion
       As soon as the EU Commission’s decision is reached, this must be submitted.
    Additional documentation:
       Day 80 Assessment Report (AR)
       Day 120 LoQ
       Day 180 LoOI
       Answers to Day 120 LoQ
       Answers to Day 180 LoOI
       Day 210 AR
b) EU Mutual Recognition Procedure MRP and Decentralised Procedure DCP
   Based on foreign decision: Marketing Authorisation in RMS
   Additional documentation:
   - LoQ
   - Answers to LoQ
   - Day 90 RMS AR (for MRP)
   - Day 70 Preliminary AR (for DCP)
   - Final AR (MRP = Day 90 DCP ≥ Day 105)
   In the case of arbitration to CVMP (EMA), the EMA opinion must be submitted.

12.2 Flowcharts for the application processes

Flowchart I: Application known APIs and variations, with request to take Arts. 5a - 5d, VAM into consideration.
Flowchart II: Application for new APIs and / or related additional indication with request to take Arts. 5a – 5d, VAM into consideration.
Flowchart III: Application for authorisation / variation without foreign authorisation but with already pending application to EMA.
Flow chart I: Art. 5b VAM path

Abbreviations:
- MP: Medicinal product
- AR: Assessment report
- API: Known medicinal product
- LoQ: List of Questions
- SM: Swissmedic
- Doc: Document
- VAM: Medicinal products ordinance
- VV: Administrative ordinance, authorisation of medicinal products already authorised in foreign countries (Art. 13)

Application for known API and variations *) taking Art. 13, TPA into account

- Formal control incl. requirements in accordance with AO and Art. 5a-5d VAM
- Additional documents submitted
- Formal control OK. Doc requirements fulfilled?
- Yes: Communication that doc is OK. Processing in accordance with Art. 13
- No: Formal objection or decision not to process

Other authority in acc. with AO, Section 7.1

Additional documents submitted

Evaluation of application re. concerns identified
- Concerns remain?
- Yes: Directly to preliminary decision
- No: Official decision

If necessary LoQ -> Firm’s answers or directly to prelim. decision -> Official decision
- Concerns remain?
- Yes: Evaluation of application re. concerns
- No: Directly to preliminary decision

Evaluation of assessment report from reference authority
- Which reference authority?
- EMA and/or FDA
- Other authority in acc. with AO, Section 7.1

*) Already authorised by foreign authority or result of EMA recommendation to EU Commission (Art. 5d VAM)
Flow chart II: Art. 5c VAM path

**Application for new API and / or related AI**) with request for Art. 13, TPA to be applied

- Formal control, incl. requirements in accordance with AO
- Additional documents submitted
- Formal objection or decision not to process
- Communication that doc is OK
- Reduced assessment accepted?
  - Yes: Evaluation of the application
  - No: Preliminary decision: application of Art. 13, TPA refused

**Evaluation of EMA and / or FDA assessment report**

- Are there material differences between the decisions of EMA/FDA?
  - Yes: Evaluation of the application
  - No: Directly to preliminary decision

Abbreviations:
- MP Medicinal product
- LoQ List of Questions
- AI Additional indication
- New New active
- API pharmaceutical ingredient
- SM Swissmedic
- Doc Documents
- VAM Medicinal products ordinance
- AO Administrative Ordinance, Authorisation of medicinal products already authorised in foreign countries (Art. 13)

*) = Already authorised by EMA/FDA Or result of EMA recommendation to EU Commission (Art. 5d VAM)
Application for authorisation / variation without foreign authorisation but with already pending application to EMA

Procedure according to SM processes for corresponding type of application

Positive recommendation by EMA to EU Commission (Art. 5d VAM)

Firm asks SM if processing of application has started

Is SM's evaluation process already well advanced?

No

Request to change to Art. 5d VAM procedure and corresponding doc sent by firm

Procedure depending on type of application as in:

Application known API and variations*)
(taking Art. 13, PTA into account)

see Flow chart I

Application new API*and/or related AI*) with request for Art. 13, TPA to be applied

*) Already approved by foreign authorities or by EMA recommendation to the EU Commission (Art. 5d VAM)

Application continues using regular authorisation procedure

Abbreviations:

MP Medicinal product
Known Medicinal product with known active pharmaceutical ingredient
LoQ List of Questions
New Medicinal product with new active pharmaceutical ingredient
SM Swissmedic
Doc Documents
VAM Medicinal products ordinance
AO Administrative Ordinance, Authorisation of MP already authorised in foreign countries (Art. 13, TPA)