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Change history

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01	**30.05.17**		**Formal adaptation to Swissmedic's requirements management: Administrative ordinance converted into Guidance document; content unchanged**	**fua**

1 Definitions, terms, abbreviations

1.1 Definitions and terms

1.1.1 Countries with comparable control systems for medicinal products

The following countries are recognised by Swissmedic as having comparable control systems for medicinal products based on Art. 5a, para. 4, VAM (Status January 2013):

- Australia
- Canada
- EU and EFTA Member States
- Japan
- New Zealand
- Singapore
- USA

The regulatory authorities for medicinal products in these countries are referred to in the present Guidance Document as *foreign authorities*.

1.1.2 Reference authorities

The term *reference authority* refers to the foreign authority which has already authorised the medicinal product in question, and whose evaluation is used by the applicant as the basis for the authorisation of the product in Switzerland.

1.2 Abbreviations

API	Active pharmaceutical ingredient
AMZV	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)
ASMF	Active substance master file
CHMP	Committee for Medicinal Products for Human Use (EMA)

CxMP	Committee for Medicinal Products, EMA
DCP	Decentralised Procedure (EU)
DMF	Drug Master File
eCTD	Electronic submission as Common Technical Document
EFTA	European Free Trade Association
EMA	European Medicines Agency
ERA	Environmental Risk Assessment
EU	European Union
FDA	Food and Drug Administration (USA)
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
ICH E2E	International Conference of Harmonisation Guideline Pharmacovigilance Planning
LoQ	List of Questions
LoOI	List of Outstanding Issues
MRP	Mutual Recognition Procedure (EU)
NtA	Notice to Applicant
Ph. Eur.	Pharmacopoeia Europaea
Ph. Helv.	Pharmacopoeia Helvetica
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
RMP	Risk Management Plan
RMS	Reference Member State of the EU
TPA	Therapeutic Products Act
SmPC	Summary of Product Characteristics
VAM	Medicinal Products Ordinance
VAZV	Ordinance of the Swiss Agency for Therapeutic Products of 22 June 2006 on the Simplified authorisation of medicinal products and the notification procedure for the authorisation of medicinal products (VAZV; SR 812.212.23)

2 Introduction and Objective

When an application for the authorisation of a medicinal product, already authorised in a country with a comparable control system for medicinal products, is submitted the Swiss Agency for Therapeutic Products (hereafter referred to as Swissmedic or the Agency) will take into consideration the results of the investigations carried out by the foreign regulatory agency on the medicinal product, provided that certain requirements are fulfilled.
This guidance species the requirements of, and describes the internal process that are adopted by Swissmedic to ensure that the conditions for such authorisations are met.
The instructions constitute a guidance document intended for administrative bodies and thus do not directly specify the rights and duties of individuals. The instructions 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 to ensure that the corresponding applications can be processed with the greatest possible efficiency.

The Swiss Agency aims to accelerate the authorising of medicinal products which have already been approved in foreign countries by implementation of the conditions described below.
Consideration of the results of foreign authorisation procedures is intended to contribute towards: Processing the authorisation of medicinal products in Switzerland in such a way that medicinal products already authorised in foreign countries are made available to patients in Switzerland as rapidly as possible and also to ensure the targeted, risk-assessed use of the Agency's resources (Art. 1, para. 3, section A of *The Therapeutic Products Act*, TPA).

3 Scope

These instructions are intended for Swissmedic's Authorisation sector and apply to:

- First authorisations, including major variations, for new human medicines

- Variations, requiring approval, to medicinal products that have already been authorised in accordance with Art. 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) are identical and in addition that the assessment report for each variation is provided.

This guidance document is valid:
- For authorisation applications based on Art. 5 a-c of the Medicinal Products Ordinance (VAM) and related to the following medicinal products authorised by foreign authorities (see Section 1.1.1 below):
  - Medicinal products with known active pharmaceutical ingredients (APIs)
  - Medicinal products with new APIs and extensions of indications, provided that the criteria specified in Section 8 are fulfilled
  - Medicinal products that are not eligible for simplified authorisation based on Art. 12, para. 4, VAZV, provided that the criteria specified in Section 8 are met.
- 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 is not valid for:
- Variations requiring approval for which no assessment report on the variation in question is available
- Variations requiring notification
- Recognition of batch releases

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[1]):
- Art. 13 Medicinal products authorised in foreign countries

Ordinance of 17 October 2001 concerning Medicinal Products (Medicinal Products Ordinance, VAM[2])
- Art. 5a - 5d Medicinal products authorised in foreign countries (Art. 13, TPA)

5 Other valid documents

Document ID
ZL000_00_012e_CL Formal control application authorisation human medicines Art.13, TPA
ZL000_00_003e_FO Application for Authorisation / Variation human medicines
ZL000_00_007e_FO Status of marketing authorisations abroad
ZL302_00_001e_FO Quality variation requiring approval
ZL101_00_003e_FO Information relating to quality for applications under Art. 13, TPA
ZL000_00_005e_WL Guidance document Authorisation of human medicine with known active pharmaceutical ingredient
ZL101_00_003e_WL Guidance document Authorisation Biosimilar
ZL000_00_009d_WL Zulassung Allergenpräparate (only in German and French)
ZL000_00_003e_WL Guidance document Authorisation radiopharmaceutical

1 SR 812.21
2 SR 812.212.21

Anleitung zum Einreichen von Zulassungsgesuchen für pflanzliche Arzneimittel der Humanmedizin (Phytoanleitung) (only in German and French)
ZL000_00_008d_WL Zulassung Antidot (only in German and French)
ZL000_00_007d_WL Zulassung Medizinalgas (only in German and French)
ZL000_00_006e_WL Guidance document Time limits for authorisation applications
ZA000_00_001e_VZ List of all countries with comparable control of medicinal products
ZL000_00_001e_WL Guidance document Formal requirements
ZL000_00_002e_VZ Overview of documents to submitted
Guidance Paragraph 13 TPA v1.3.

6 Requirements relating to documentation (Art. 5a, VAM)

For a medicinal product which has already been granted an authorisation in a country with a comparable control system for medicinal products (as specified in Section 1.1.1 above) the assessment 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". In such cases, the Agency will also check that all necessary documents the procedure have been submitted in full.

6.1 Documentation submitted to the reference authority

- *Comparability of foreign and Swiss documentation*

In principle, the documentation submitted to Swissmedic must be identical with that on which the reference authority has based its authorisation of the medicinal product or a variation thereof3 (final version).
If the product has been authorised in more than one country with comparable regulatory authorities, 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.
The full documentation must be submitted to Swissmedic in CTD format[4] together with the country-specific Module 1 assessed by the reference authority. If the documentation was authorised in NtA format (Parts I – IV) by the reference authority, it may also be submitted in the same format to Swissmedic.

- *Documentation for variation applications*

In order for Art. 13, TPA to be applied to applications for variations, an assessment report by the reference authority must be submitted. For applications for products 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.
For applications for major variations with no prior reference to Art. 13, TPA in accordance with Section 7 , the documentation and the corresponding documents for the first approval must also be submitted where the majority of the information relates to the first approval. If an application for a major variation is submitted subsequently in eCTD format, it is not necessary to create an electronic baseline file for the previously submitted paper documentation.

- *Variations and / or additions after 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. This additional or replacement documentation can either be integrated within the application documentation or the module in question, or be submitted separately. The variations must be referred to in the cover letter,

3 For exceptions, see Section 6.7

4 Common Technical Document gemäss Leitlinie M2 (eCTD) und M4 (CTD) der ICH (International Conference on Harmonization). Besteht aus den folgenden Modulen: 1 (Country specific), 2 (Summary), 3 (Quality), 4 (Preclinical), 5 (Clinical).

and a comparison showing the changes (old / new text) 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.

- *Risk Management Plan in accordance with ICH E2E*

A Risk Management Plan, in accordance with ICH E2E requirements, must be submitted for new active pharmaceutical ingredients and / or additional indications for them.

- *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 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 (old / new text).

6.2 Date of the authorisation or the last revision of the documentation

The authorisation, or the last updated version of the entire documentation that was approved by the reference authority, and in particular modules 2.3, 2.4 and 2.5 (Quality, Non-Clinical Overview, Clinical Overview) or parts IC2, IC3 and IC4, must not be older than 5 years[5], taken from the date on which the application is submitted to Swissmedic. This ensures that the evaluation by the reference authority took place based on current levels of know ledge of science and technology.
Deviations from the dossier with respect to currently valid guidelines that were not yet in force at the time of the authorisation in a foreign country are possible if they are critically assessed and mentioned in the cover letter.

6.3 Results of the examinations and decisions on the part of 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 (see section 11).
If a medicinal product has been authorised in more than one country with a comparable control system for medicinal products, 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 medicinal product 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 1.1.1 above) on the form "*Status of authorisation applications abroad*". The cover letter must refer clearly and openly to differing

[5] Date of the formal decision or approval

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.).

6.4 Points that are specific to Swiss module 1

In addition to the documentation submitted to the reference authority, the Agency requires the administrative data of the Swiss Module 1 in accordance with the Guidance Document *Formal requirements* and *the associated list, Table of documents to be submitted*.
The applicant must request on the form *Application for authorisation / Variation*, that the assessments carried out by foreign authorities are taken into account, in accordance with Art. 13 of the TPA / Art. 5a – 5d VAM.
All of the required annexes and forms for Module 1 (for complementary and herbal medicine, Parts 1A and 1B NtA) are listed in the checklist *Formal control application authorisation human medicines Art. 13 TPA*, the latter which must also be submitted. Additional documents that are not stated in the checklist must be referred to in the cover letter.
Proof that the current requirements of the Ph. Eur. / Ph. Helv. are met can be integrated within Module 3 CTD (for NtA: Part II) or attached separately and must be confirmed in the checklist *Formal control application authorisation human medicines Art. 13 TPA* Compliance with the requirements of the Ph. Eur. / Ph. Helv. must be confirmed in the checklist for administrative control relating to Art. 13, TPA. If instead of the appropriate methods of the Ph. Eur. / Ph. Helv., other methods are used, the equivalence of the chosen methods to the Ph. Eur. / Ph. Helv. methods should be demonstrated.
The Environmental Risk Assessment (ERA) (Module 1) need only be submitted for medicinal products that have been authorised by a country with a control system for medicinal products comparable to that of Switzerland but that is not a member of the EU.
Specific requirements anticipated for the spontaneous reporting of suspected adverse drug reactions in Switzerland (e.g. special questionnaires with regard to enhanced pharmacovigilance), should be specifically mentioned in the cover letter when submitting the application.

6.5 Product information

Swissmedic must ensure that points that are specific to Switzerland are respected, such as compliance with the requirements for product information (e.g. information regarding pregnancy or instructions for storage) or consistency of terminology used in the patient information with that used for comparable medicinal products. Consequently, adoption of the exact wording of the product information approved by the reference authority without re-examination by Swissmedic is normally not possible.
However if an authorisation has been granted by means of a centralised procedure (EMA Scientific Decision) or by an EU or EFTA Member State, the valid product information (EU-SmPC) can be approved as the Swiss product information (Art. 5a, paragraph 3, VAM). If there are differences in content to Swiss regulations, Swissmedic must check that the above-mentioned points specific to Switzerland are included. In all cases, the language requirements and the mandatory declarations regarding genetically modified organisms must be respected.
The Swiss requirements regarding the information and texts on containers and packaging must also be complied with (Art. 12 and annexes, AMZV[6]).

6.6 Requirements regarding languages and the translation of the documentation

The documentation for Modules 2 to 5 and country-specific Module 1 or Parts I – IV, and the documentation required as stated in the Annex (see section 11) must be submitted to the Agency in either one of Switzerland's official languages or in English. Translations into one of these languages are also accepted, as long as the authorisation holder provides written confirmation that the translation is accurate. The Switzerland-specific module 1 (or, for complementary and herbal medicines, Parts 1A and 1B), plus the product information and the packaging elements, must be submitted in one of Switzerland's official languages (information for health professionals / product information in German or French).

[6] SR 812.212.22

6.7 Differences in comparison with the medicinal 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

Where differences exist between the authorisation in a foreign country and the application submitted to Swissmedic, it is essential to provide Swissmedic with the documentation that was submitted to the reference authority for authorisation. The differences must be stated in the cover letter. Differences are assessed by Swissmedic in the same way as a variation, but do not require lengthy processing times.

6.8 Compliance with Swiss-specific requirements

It is essential to fulfil the specific requirements stated in the following instructions issued by the Swiss Agency for Therapeutic Products (some of which are available in French and German only), which are specific to the various types of application. The corresponding documentation must be submitted together with the application for authorisation:

- *Guidance document for Authorisation of human medicine with known active pharmaceutical ingredient*
- *Guidance document for the authorisation of biosimilar*
- *Guidance document for the authorisation of allergen product*
- *Instructions for the submission of authorisation applications for herbal medicines for human use;*
- *Guidance document for the authorisation of antidote*
- *Guidance document for the authorisation of medicinal gas*
- *Guidance document for the authorisation of radiopharmaceutical*

6.9 Other documentation specific to certain authorities

The documents from the reference authorities to be submitted are listed in the Annex (see section 11). 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.

6.10 Information and documentation to be provided following the 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.

7 Medicinal products with known active pharmaceutical ingredients (Art. 5b VAM)

The following explanations apply to applications for the authorisation of a known active pharmaceutical ingredient, i.e. medicinal products that contain an active pharmaceutical ingredient that is, or was, already contained in another medicinal product authorised by the Agency[7].
The consideration of results of investigations by foreign authorities within the framework of an application for the authorisation of a new pharmaceutical form, new dosage strength, a new route of administration and / or a new recommended dose for an original product pursuant to Art. 12, TPA, is also subject to the provisions stipulated in Section 7 resp. 7.2 of the current instructions.
The consideration of the test results of foreign authorities within the framework of an application for the authorisation of an additional pharmaceutical form, dosage strength, an additional route of administration, an additional indication and / or recommended dose for a medicinal product with a known pharmaceutical ingredient is also subject to the provisions stipulated in Section 7 resp. 7.2.
If there is a considerable difference between the Swiss regulations and those of the reference authority for examining a product (e.g. complementary and herbal medicines, establishment of the dispensing categories), Swissmedic reserves the right to carry out its own evaluation. The result obtained by the foreign authority will, as far as possible, also be taken into account.

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

For applications for the authorisation of a medicinal product with known active pharmaceutical ingredients (see flow chart I in the Annex), the Agency usually only examines the results of the reference authority's evaluation, as long as the requirements in accordance with Art. 5a, VAM (see Section 6) are respected.
The quality, efficacy and safety of the medicinal product are evaluated and assessed regarding whether the reference authority's examination results can be used by Swissmedic to reach a decision regarding authorisation, based on the reference authority's assessment reports. Reasonable evidence for a potential unfavourable risk-benefit ratio may arise from this approach, which will be further assessed on the basis of a targeted, in-depth review of the underlying documentation.
Swissmedic also reviews the background and the context of such applications to ascertain whether reasons exist for carrying out its own scientific evaluation. Such reasons may include: an earlier rejection or withdrawal of an application for this medicinal product or one from the same class of substances in Switzerland or in another country with comparable control systems for medicinal products as stated in Section 1.1.1, or if new scientific findings have emerged since the authorisation abroad was granted.

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

In the case of applications for known APIs that have been authorised by EMA and / or the FDA, the Agency usually refrains from examining the assessment report provided that the requirements of Art. 5a, VAM are respected (see Section 6 above).
For such applications, Swissmedic evaluates whether safety signals exist which require consideration, based on the background, the context and the information for healthcare professionals. Should this analysis give rise to major concerns concerning quality, safety and / or efficacy based on an earlier assessment of a product with the same active pharmaceutical ingredient or in the same class of substances, or as a result of material differences between the authorisation decisions on the part of the EMA and the FDA (approval by one and rejection or partial rejection by the other, differing indications and / or therapeutic regimen or other similar differences), the assessment reports will be examined and in the case of any doubt, a specific review of the underlying documentation will be carried out. If it is not possible to overcome such concerns relating to an authorisation decision by the

[7] See Art.12 paragraph 1 of the Ordinance by the Swiss Agency for Therapeutic Products of 22 June 2006 on the simplified authorisation of medicinal products (notification process) (VAZV; SR **812.212.23**)

reference authority following examination of the assessment reports, the Agency will conduct a scientific evaluation of the points in question, taking into account additional documentation.

7.3 Transparency regarding major concerns

The reasons for concerns leading to Swissmedic carrying out an independent assessment will be provided in writing to the applicant in a communication "Time limit LoQ".

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

Applications for the authorisation of a medicinal product with a new active pharmaceutical ingredient or an additional indication are usually assessed independently and comprehensively by the Agency, based on all documentation submitted. This also applies to applications for the authorisation of products in accordance with Art. 12, paragraph 4, VAZV.
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).

8.1 Reduced assessment on application

A reduced assessment of an application under Art. 13, TPA for a medicinal product with new API or for an additional indication for it, or for products authorised in accordance with Art. 12, paragraph 4, VAZV, is possible only for medicinal products that are classified and authorised as Orphan Drugs by the EMA Committee for Orphan Medicinal Products (COMP) or the FDA Orphan Drug Act as orphan drugs. This classification excludes oncological medicinal products, for which Swissmedic always carries out its own assessment.
For an application requesting the consideration of the examination results of the foreign authority (or authorities) for orphan drugs, the corresponding recognition of orphan status, and authorisation by the EMA or the FDA, must be submitted.
The simplified evaluation is normally restricted to an examination of the submitted authorisation decisions and the EMA and / or FDA assessment reports. The Agency carries out this process as described in Section 7.1.
If the above criteria (orphan drug which is not oncological) are not fulfilled, an intermediate decision (Refusal to take Art. 13, TPA into consideration) is issued and the application is then subject to the normal authorisation process.

8.2 Ex-officio reduced evaluation

The Agency may also decide to carry out an *ex officio* reduced assessment of its own in justified cases, particularly when it is in the interests of public health to expedite the procedure (e.g. authorisation of a vaccine in the case of a pandemic). The Agency will agree upon the procedure to be followed with the applicant on a case-by-case basis.

9 Parallel procedure 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 application for authorisations in foreign countries* 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).

10 Process applied within Swissmedic

10.1 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 application authorisation human medicines Art. 13 TPA* is integral to 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 all applications for variations in accordance with Section 7 that fulfil the relevant criteria will be assessed in application of 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 8 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.

10.2 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.

10.3 Availability to the public and transparency

Swissmedic maintains an internal list, with details of the medicinal products concerned, of authorisation applications requesting that a foreign authorisation be taken into account. This information may be used for statistical purposes and published as a summarised form.

11 Annex

The following documents (decisions and additional documentation) must be submitted as additional information:

11.1 Documents to be submitted for applications to all reference authorities

- Modules 1 to 5, or Parts 1 to IV (NtA) as submitted to the foreign authority (for applications for major variations with previous reference to Art. 13, TPA in accordance with Section 7, the documents for the first authorisation must also be submitted if they are the main source of reference)
- 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.
- Swiss Module 1 (in accordance with the Guidance Document *Formal requirements* and the associated list, *Overview of* documents to be submitted*)* including the checklist *Formal control application authorisation human medicines Art. 13, TPA.*
- Cover letter (in accordance with the Guidance Document *Formal requirements* and the associated list, *Overview of* documents to be submitted*).* If applicable, confirmations, explanations, critical assessments or additional documentation must be submitted in the following situations:
  - In the case of differing authorisation decisions, e.g. concerning indications, dosage, storage instructions, shelf life, or other restrictions and similar issues, and in the case of withdrawal, rejection, suspension or ongoing investigation 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, instead of the appropriate methods of the Ph. Eur. / Ph. Helv., other methods are used, the equivalence of the chosen methods to the Ph. Eur. / Ph. Helv. methods should be demonstrated.
  - In the case of applications for variations without prior reference to Art. 13, TPA, confirmation signed by a person entitled to act as a signatory or in charge of regulatory affairs stating that the documentation for the reference authority and Switzerland are identical
  - In the case of ongoing GxP investigations (e.g. resolution of deficiencies, follow-up inspections required)
  - In the case of specific requirements for implementing the spontaneous recording of suspected adverse drug reactions in Switzerland (e.g. special questionnaire in the context of enhanced pharmacovigilance)
  - In the case of deviations from the currently valid guidelines that were not in force at the time of authorisation in a foreign country
  - For translations, confirmation that the translation is accurate
  - In the case of information required regarding safety signals
- Authorisation decision including additional documentation (results of assessment) by the reference authority in accordance with Sections 11.2 to 11.10. (In the case of a differing decision between FDA and EMA, see Section 6.3).

11.2 Authorisation based on the EU Centralised Procedure (CP)

Basis for foreign decision:	CxMP / CHMP Opinion As soon as the EU Commission decision is available, it must be submitted.
Additional documentation:	Day 80 Assessment Report Day 120 LoQ Day 180 LoOI Answers to Day 120 LoQ Answers to Day 180 LoOI Day 210 Assessment Report Risk Management Plan RMP for new APIs and additional indications Paediatric Investigation Plan and amendments (if available)

11.3 Authorisation based on the EU Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP)

Basis for foreign decision:	Marketing Authorisation in RMS (Letter of approval or Letter end of procedure)
Additional documentation:	LoQ Answers to LoQ Day 90 RMS Assessment Report (for MRP) Day 70 Preliminary Assessment Report (for DCP) Final Assessment Report (MRP = Day 90; DCP ≥ Day 105) In case of arbitration to CHMP (EMA), *if applicable*, the EMA opinion should be submitted.

11.4 Authorisation based on authorisation in EU und EFTA States: National authorisations

Basis for foreign decision:	Marketing Authorisation (Letter of approval or Letter end of procedure)
Additional documentation	LoQ Answers to LoQ Assessment report or evaluation report

11.5 Authorisation based on authorisation in USA / FDA

Basis for foreign decision:	Approval Letter (no rolling submission)
Additional documentation:	LoQ Answers to LoQ Assessment Report: Standard or Priority Review *If available:* Summary Basis of Approval (SBA) *If requested:* Risk Minimization Action Plan (RiskMAP) ERA

11.6 Authorisation based on authorisation in Japan

Basis for foreign decision:	Marketing Authorisation
Additional documentation:	LoQ (translated into German, French or English) Answers to LoQ (translated into German, French or English) Review Reports of New Drug Applications PMDA (translated into German, French or English) Review Summaries and Overall Summary Basis of Decision (translated into German, French or English) ERA

11.7 Authorisation based on authorisation in Canada

Basis for foreign decision:	Notice of Compliance (NOC)
Additional documentation:	LoQ Answers to LoQ Assessment Report *If available*: Summary Basis of Decision ERA

11.8 Authorisation based on authorisation in Australia

Basis for foreign decision:	Marketing Authorisation
Additional documentation:	LoQ Answers to LoQ Assessment Report ERA

11.9 Authorisation based on authorisation in Singapore

Basis for foreign decision:	Marketing Authorisation
Additional documentation:	LoQ (translated into German, French or English) Answers to LoQ (translated into German, French or English) Assessment Report (translated into German, French or English) ERA

11.10 Authorisation based on authorisation in New Zealand

Basis for foreign decision:	Marketing Authorisation
Additional documentation:	LoQ Answers to LoQ Assessment Report ERA

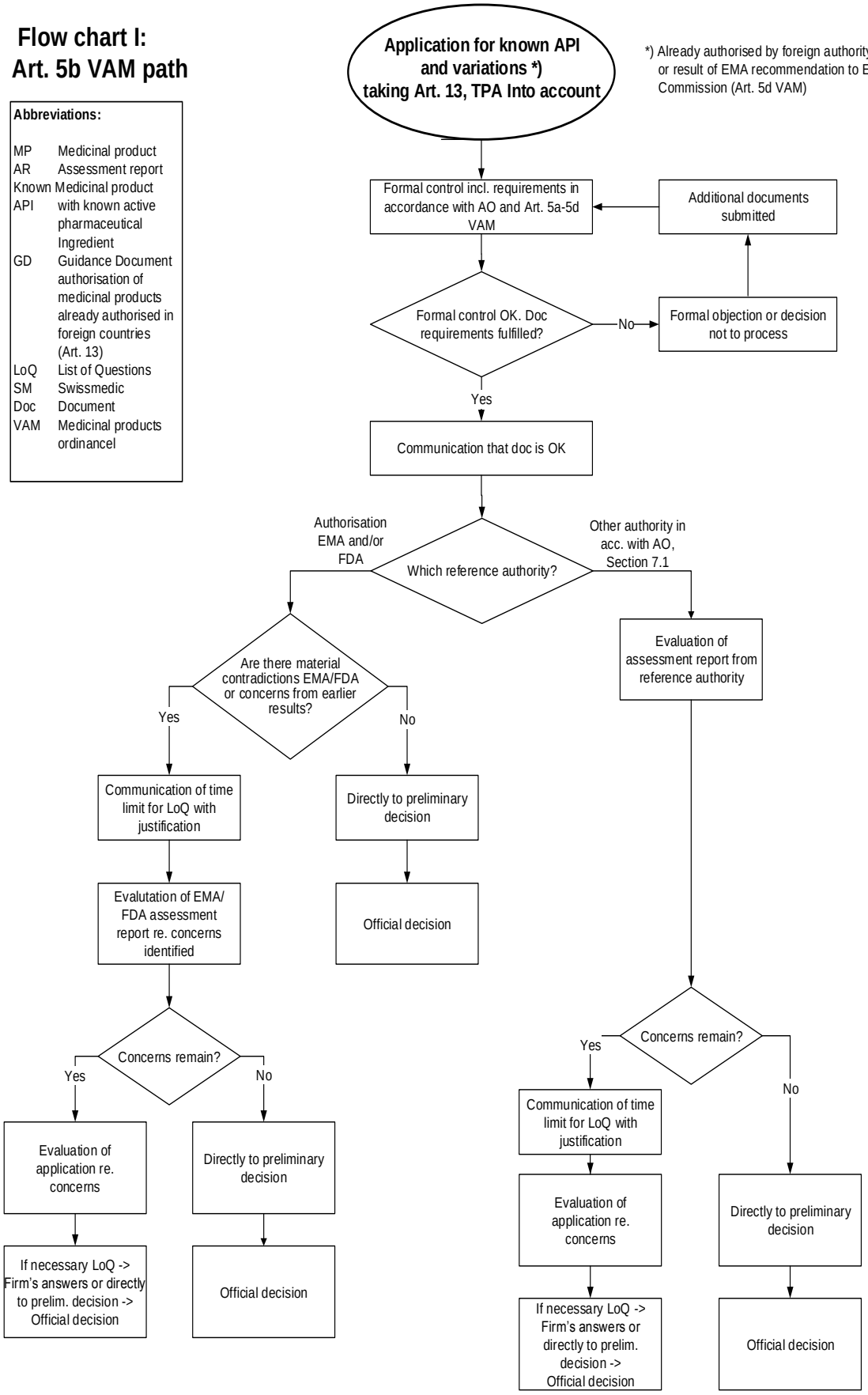
11.11 Flow charts relating to the application process

Flow chart I:	Application for known API and variations, application in accordance with Arts. 5a - 5d VAM
Flow chart II:	Application for new API and / or related AI, application in accordance with Arts. 5a - 5d VAM
Flow chart III:	Application for authorisation / variation without foreign authorisation but with already pending application to the EMA

Flow chart I: Art. 5b VAM path

Abbreviations:

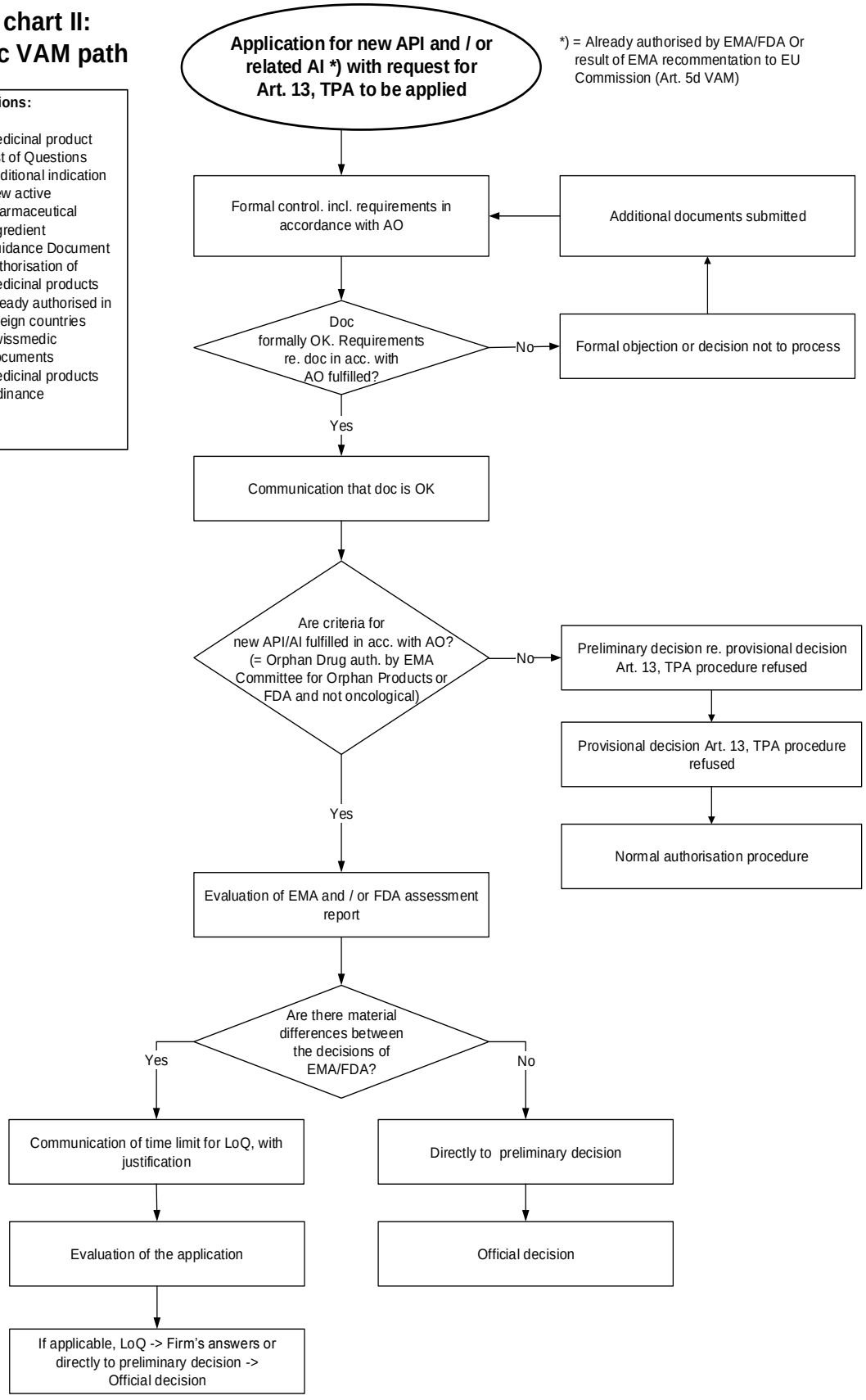
MP	Medicinal product
AR	Assessment report
Known API	Medicinal product with known active pharmaceutical Ingredient
GD	Guidance Document authorisation of medicinal products already authorised in foreign countries (Art. 13)
LoQ	List of Questions
SM	Swissmedic
Doc	Document
VAM	Medicinal products ordinancel



Flow chart II: Art. 5c VAM path

Abbreviations:

MP	Medicinal product
LoQ	List of Questions
AI	Additional indication
New	New active
API	pharmaceutical Ingredient
GD	Guidance Document authorisation of medicinal products already authorised in foreign countries
SM	Swissmedic
Doc	Documents
VAM	Medicinal products ordinance



Flow chart III: Art. 5d VAM path