Guidance on applications according to ~~Paragraph~~Article 13 TPA for eCTD applications

Authors:	Lead: Ralph Maier, Swissmedic Review team Swissmedic Review team Interpharma
Responsible:	~~Submissions Division~~OSS, Swissmedic
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1 List of Abbreviations

CP	Centralised Procedure
CTD	Common Technical Document
DCP	Decentralised Procedure
DMF	Drug Master File
eCTD	electronic Common Technical Document
EMA	European Medicines Agency
FO	Form
GMO	Genetically Modified Organisms
GMP	Good Manufacturing Practice
KPA	Complementary and Herbal Medicines (Komplementär- und Phytoarzneimittel)
LCM	Life cycle management
LoQ	List of Questions
~~M1–M5~~	~~Module 1 – Module 5~~
MRP	Mutual Recognition Procedure
NeeS	Non-eCTD electronic submission
NTA	Notice to Applicants
PDF	Portable Document Format
PSUR	Periodic Safety Update Report
SmPC	Summary of Product Characteristics
STF	Study Tagging Files
TPA	Therapeutic Product Act (Federal Law on Medicinal Products and Medical Devices) of December 15, 2000 in the past known as LTP (Law on Therapeutic Products) / SR 812.21 Bundesgesetz vom 15. Dezember 2000 über Arzneimittel und Medizinprodukte (Heilmittelgesetz HMG) / SR 812.21 Loi fédérale sur les médicaments et les dispositifs médicaux du 15 décembre 2000 (Loi sur les produits thérapeutiques LPTh) TSE Transmissible Spongiform Encephalopathy
VAM	Ordinance on Medicinal Products of 17 October 2001 / SR 812.212.21(Verordnung über die Arzneimittel) SR 812.212.21(Ordonnance sur les médicaments)
VV	Administrative Ordinance Authorisation of medicinal products already authorised in foreign countries (~~Paragraph~~Article 13 TPA) of 27 November 2013 (Verwaltungsverordnung Anleitung Zulassung im Ausland bereits zugelassener Arzneimittel (Art. 13 HMG) / Ordonnance administrative Instructions Autorisation de médicaments à usage humain déjà autorisés à l'étranger (art. 13 LPTh))
XML	Extensible Markup Language

2 Definitions

Term	Definition
Reference country	The country in which the product, that is to be evaluated, has been approved. Swissmedic takes into account the evaluation of the health authority of this country.
Reference dossier	The dossier submitted in the reference country.
Reference authority	The health authority which has already approved the product that is to be evaluated by Swissmedic and to which the applicant refers in the Swiss submission.

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3 Legal Basis and Guidances

Federal Law on Medicinal Products and Medical Devices (Therapeutic Product Act TPA) of 15 December 2000 (Heilmittelgesetz HMG / Loi sur les produits thérapeutiques LPTh [1]), ~~Paragraph~~Article 13.
Medicinal products and procedures authorized in foreign countries:
"If a medicinal product or procedure is already authorized in a country having equivalent medicinal product control, the results of tests carried out for this purpose shall be taken into account."
Ordinance on Medicinal Products of October 17, 2001 with changes from 24 March 2010 (Arzneimittelverordnung VAM / Ordonnance sur les medicaments OMéd [2]), Paragraph 5a – 5d: see appendix 1 (available in German, French and Italian).

Administrative Ordinance Authorisation of medicinal products already authorised in foreign countries (~~Paragraph~~Article 13 TPA) of 27 November 2013 (Verwaltungsverordnung VV, Anleitung Zulassung im Ausland bereits zugelassener Arzneimittel, Art. 13 HMG / Ordonnance administrative Instructions Autorisation de médicaments à usage humain déjà autorisés à l'étranger (art. 13 LPTh))

Swiss Module 1 Specification for eCTD
Guidance for Industry on Providing Regulatory Information in eCTD Format
Questions & Answers of Swissmedic eCTD Implementation
Swiss eCTD Validation Criteria

Other guidances and documents: ~~see~~
https://www.swissmedic.ch/~~zulassungen/00153/index~~swissmedic/de/home/services/submissions.html

4 Possible scenarios

Possible scenarios of applications according to ~~Paragraph~~Article 13 TPA are described in Appendix 2.

5 Basic principles

This guidance deals only with the eCTD specific aspects of ~~Paragraph~~Article 13 ~~T~~TPA

PA submissions and should be read in conjunction with the VV.

1. The first submission of an application according to ~~Paragraph~~Article 13 TPA consists of two individual parts:
   a. A Swiss eCTD containing Module 1 only (no Modules 2-5)
   b. A reference dossier, i.e. the entire application (Modules 1-5) of the approved dossier of the reference country.

2. The initial Swiss eCTD sequence and the reference dossier have to be submitted simultaneously.

3. The Swiss eCTD must meet the current Swiss eCTD Validation Criteria.

4. Once Swissmedic approves the submission to undergo ~~Paragraph~~Article 13 TPA procedure, a consolidation sequence has to be submitted, containing Modules 2-5 of the original approved reference dossier and its already approved variations as well as the documents of the Swiss Module 1 which have not yet been provided (see also Table 1 and chapter 8).

[1] SR 812.21
[2] SR 812.212.21

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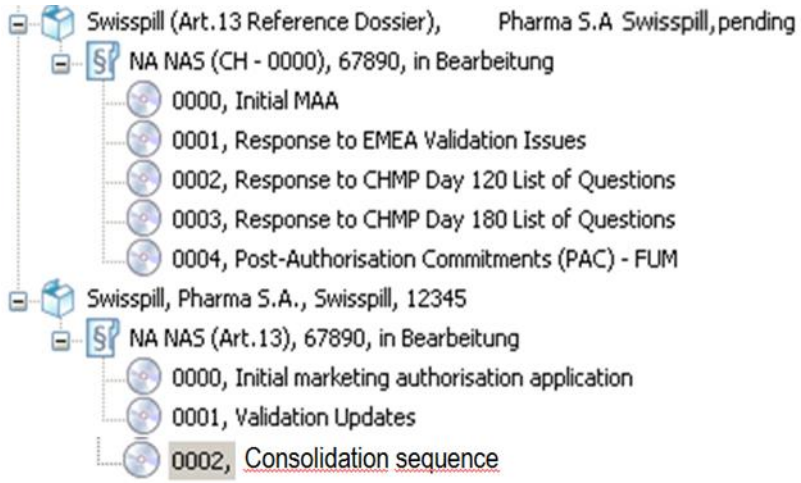
5. The product submitted in the reference country and in Switzerland must be identical.

Illustration 1: Designed example of an application according to ~~Paragraph~~Article 13 TPA



6 Reference dossier

The reference dossier consists of modules 1-5 as approved by the reference authority and should be in CTD format: either eCTD, NeeS or paper dossiers are accepted. Reference dossiers originally submitted in paper in the reference country must be submitted to Swissmedic as one paper copy and electronically on a device as described in the Guidance for Industry. Reference dossiers originally submitted in NTA format (e.g. Complementary and Herbal Medicinal Products / Komplementär- und Phytoarzneimittel KPA) should be converted into CTD format before being relayed to Swissmedic.

- If the reference dossier is in eCTD format, it must contain all sequences submitted to the reference authority.
- If the reference dossier is a NeeS or is in paper format, the approved version must be submitted including answers to questions and all changes as well as additional information added to the dossier. Swissmedic accepts NeeS that do not meet the current standards of NeeS (refer to TIGes Harmonised NeeS Guidance).
- If there have been updates to the product (e.g. a variation) after approval in the reference country the corresponding documentation must be submitted to Swissmedic, but separated from the one which led to initial approval in the reference country.
    - If the basis was an eCTD, all sequences regarding the variations must be submitted.
    - If the basis was a NeeS or a paper dossier, the variation(s) which led to approval of the updates must be submitted.
    - If the updates are not relevant to Switzerland (e.g. addition of a pack size in the reference country), the respective sequences do not have to be submitted.
    - If the updates are already included in the dossier, changes need to be specified as well as status (approved, pending). This information must be included in the tracking table as described in chapter 7.
- The reference dossier from the reference country will not undergo detailed technical validation at Swissmedic.
- The reference dossier can contain Study Tagging Files (STF), although in general STF are not accepted by Swissmedic.

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7 Swiss eCTD

7.1 General structure

The initial Swiss eCTD sequence (0000) of ~~a Paragraph~~an Article 13 TPA submission contains a Swiss Module 1 only, with the exception of documentation in Module 3 justifying any allowed difference. Module 1 contains all forms and documents required for the Swiss application according to the current valid version of the Swiss Module 1 Specification for eCTD. Although some documents are also included in the reference dossier, they must be submitted in the Swiss Module 1 as well.
For the documents mentioned below, the listed information has to be taken into account. If the field *comments* is empty, the documents must be provided in the initial sequence (0000). This table was created according to Swiss Module 1 Specification, version 1.3. For information about working documents please refer to the ~~current~~latest version of the Guidance for Industry on Providing Regulatory Information in eCTD Format.

Table 1

No	Title	comments
1.0	Cover Letter	Please explain the structure of the submission and if the product deviates from the one approved in the reference country. Please explain if any information of the reference country is not relevant for Switzerland (e.g. addition of a pack size in the reference country) or include this information in the tracking table (see Table 2).
1.2	Application for Marketing Authorisation and Variation	
1.2.1	Form - Application ~~for Authorisation / Variation Human Medicines~~	
1.2.2	~~Annexes -~~ Forms ~~-~~ Additional	
1.2.2.1.	Form Full Declaration	
1.2.2.2	Form Manufacturer Information	
1.2.2.3	Form Status Marketing Authorisations Abroad	
1.2.2.4++	~~Form Variation Requiring Notification~~	~~Notifications (*Meldepflichtige Änderungen/ Modifications soumises à l'obligation d'annoncer*) cannot be submitted via the Paragraph 13 TPA procedure.~~
1.2.2.5++	~~Form Quality Variation Requiring Approval~~	
1.2.2.6++	~~Form Application for Extension of Authorisation~~	~~Not applicable for Paragraph 13 TPA procedure.~~
1.2.2.7++		
1.2.2.8	Form Substances of Animal or Human Origin	
1.2.2.9++	~~Form Pharmaceutical Information for Parenteral Preparations~~	
1.2.2.10++	~~Form Co-Marketing Confirmation~~	~~Not applicable for Paragraph 13 TPA procedure.~~
1.2.2.11++	~~Form Import According to Paragraph 14 Section 2 TPA~~	~~Not applicable for Paragraph 13 TPA procedure.~~
1.2.2.12++		

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No	Title	comments
1.2.2.13	Form Change of Marketing Authorisation Holder	Not applicable for ~~Paragraph~~Article 13 TPA procedure.
1.2.2.14++	~~Checklist Formal Control Application Authorisation Human Medicines~~	~~Not applicable for Paragraph 13 TPA procedure.~~
1.2.2.15++	~~Checklist Formal Control Application Authorisation Human Medicines Art.13, TPA~~	~~For Paragraph 13 TPA applications~~
1.2.2.16	Form PSUR~~ /~~/PBRER for Human Medicines	Not applicable for ~~Paragraph~~Article 13 TPA procedure.
1.2.2.17	Form Declaration Radiopharmaceuticals	
1.2.2.18	Form Confirmation Regarding Substances from GMO	
1.2.2.19	Form DMF ~~for First Authorisation / Variations~~	
1.2.2.20	Form Information Relating to ~~Quality for~~ Applications under Art. 13~~,~~ TPA	Mandatory for ~~Paragraph~~Article 13 TPA procedure
1.2.2.21++	~~Form Notification Sample Packages~~	~~Not applicable for Paragraph 13 TPA procedure.~~
1.2.2.22++	~~Form Notification of No Marketing or Interruption to Distribution~~	~~Not applicable for Paragraph 13 TPA procedure.~~
1.2.2.23	Form Application for Recognition of Orphan Drug Status	
1.2.2.24++	~~Application for Recognition of Fast Track Status~~	~~Not applicable for Paragraph 13 TPA procedure.~~
1.2.2.25	Form PIP	
1.2.2.26	GCP Inspections	
1.2.2.99	Other Forms [extensional sections allowed]	
1.2.3	Annexes - Documents on Drug Product Quality	
1.2.3.1	DMF Letter of Access	
1.2.3.2	Ph. Eur. Certificate of Suitability for Active Substance	
1.2.3.3	Ph. Eur. Certificate of Suitability for TSE	
1.2.3.4	EMA Certificate for Plasma Master File (PMF)	
1.2.3.5	EMA Certificate for Vaccine Antigen Master File (VAMF)	
1.2.4	Annexes – Manufacturing	
1.2.4.1	GMP Certificate or Other GMP Documents	
1.2.4.2	Documentation Concerning Manufacturing Authorisation	
1.2.4.3	Complete Manufacturing Information with Flow Chart	
1.2.4.4	Confirmation on GMP Conformity	
1.2.5	Annexes – Others	
1.2.5.1	Comparison of Approved Information for Professionals with EU SmPC (for PSURs)	Not applicable for ~~Paragraph~~Article 13 TPA procedure.
1.2.5.2	Company Core Data Sheet (for PSURs)	
1.3	Product Information and Packaging Material	
1.3.1	Information for Professionals	Hyperlinking is not required.

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No	Title	comments
		A working document needs to be provided.
1.3.2	Patient Information	If applicable, a working document needs to be provided.
1.3.3	Packaging Information	
1.3.4	Information for Professionals from Other Countries	Information for professionals of reference country/countries
1.4.	Information about the Expert	Include latest version(s) when consolidation sequence is compiled
1.4.1	Quality	
1.4.2	Nonclinical	
1.4.3	Clinical	
1.5	Data of Bioavailability Studies (~~Generics~~Known Active Substance without Innovation)	
1.5.1	~~Swissmedic~~Information according to Appendix IV of the Guideline on the Investigation on Bioequivalence ~~Trial Information Form~~	The Swissmedic Bioequivalence Trial Information Form has to be cross referenced to the reference dossier. Since hyperlinking is not possible, references need to be provided in a way that allows an easy review. *(Example:* "Clinical study report ▪ Study no.: *50302* ▪ Study title: *XY* ▪ Location of the study protocol in the documentation: *Module 5.3.1.2, Section 16.1.1, page 1-24")* If applicable, working document needs to be provided.
1.5.2	Documents on the Reference Product	
1.5.3~~++~~	~~Confirmation of Identity of Submitted Product and Reference Product Used in the Bioequivalence Studies~~	
1.6	Environmental Risk Assessment	Include latest version when consolidation sequence is compiled
1.6.1	Non-GMO	
1.6.2	GMO	
1.7	~~Decision~~Decisions of Foreign Authorities	If the application ~~Paragraph~~Article 13 TPA is based on more than one reference country, the decisions of all countries concerned must be submitted (see VV)
1.7.1	Responses to LoQ	For ~~Paragraph~~Article 13 TPA applications: intended for LoQ from all European and non-European procedures
1.7.2	Assessment Report	For ~~Paragraph~~Article 13 TPA applications: intended for Assessment Reports from all European and non-European procedures
1.7.3	EU Decision	For ~~Paragraph~~Article 13 TPA applications: intended for decisions from all European procedures (CP, DCP and MRP) only

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No	Title	comments
1.7.4	FDA Decision	For ~~Paragraph~~Article 13 TPA applications
1.7.5	Decision of Other Foreign Authorities	For ~~Paragraph~~Article 13 TPA applications
1.7.6	~~Paragraph~~Article 13 Additional Documentation	See chapter 7.2
1.8	Information Relating to Pharmacovigilance	
1.8.1	Pharmacovigilance System	Include latest version when consolidation sequence is compiled
1.8.2	Risk Management System	Include latest version when consolidation sequence is compiled
1.9	Fast Track Status Decision	Not applicable for ~~Paragraph~~Article 13 TPA procedure.
1.10	Information ~~Related~~Relating to Paediatrics	Include latest version when consolidation sequence is compiled. If a waiver has been granted, include the information here. Data based on a PIP have to be submitted as part of the reference dossier or as separate submissions if submitted after initial approval in the reference country.
1.11	Orphan Drug Status Decision	
1.12	Art 14 Sec 1 Let abis-quater TPA Documents	
1.12.1	Proof of 10 Years EU/EFTA Authorisation	
1.12.2	10 Years EU/EFTA Authorisation - Documents on the Reference Product	
1.12.3	Proof of 30 Years Overall Medical Use - 15 Years Medical Use EU/EFTA	
1.12.4	Proof of 15 Years Cantonal Authorisation	
	Responses to Swissmedic LoQ	
	Additional Information	Recommendations/conclusions from scientific advisory boards in the reference country and any further information from the reference country, if considered necessary

++ This form is no longer applicable. The folder remains for life cycle maintenance.

7.2 Section 1.7.6 ~~Paragraph~~Article 13 TPA additional documentation

The requirements for additional documentation depend on the reference country as described in the VV, chapter 13.

The documents mentioned in the annex of the VV should only be placed in section 1.7.6 if there is no defined node for them in Swiss Module 1. They can be referenced to 1.7.6 by using hyperlinks (for example the risk management plan should be placed in section 1.8.2.).

A tracking table must be integrated in Module 1.7.6 ~~Paragraph~~Article 13 Additional Documentation. The table must include a chronological list of submissions in the reference country with a description of all changes made in the life cycle of the product since the initial Marketing Authorisation Application in the reference country and before submission to Swissmedic. This allows Swissmedic to follow the Marketing Authorisation process in the reference country.

→ Example (for a NeeS or paper without sequence numbers):

Table 2

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Date / Sequence	Module	Description
June 2008	1-5	Initial Application BfArM
June 2008	1.7.1	Response submission to the validation issues from the Belgian Health Authority
September 2008	1.7.2	Reference Member State Day 70 Preliminary Assessment Report Overview and LoQ Quality assessment Non-clinical and clinical assessment
September 2008	1.7.2	Concerned Member State Comments on Day 70 Preliminary Assessment Report from Belgium, France, Ireland, Italy, UK
April 2009/0000		Consolidation sequence switch from NeeS to eCTD
April 2009/0001	1.7.1	Day 106 Applicants response document in Decentralised Procedure Response document to Modules 1,3,4,5
May 2009	1.7.2	Reference Member State Day 106 Formal comments
May 2009	1.7.2	Reference Member State Day 120 Draft Assessment Report Overview and List of outstanding issues Assessment of the response to the questions raised by Reference Member State and Concerned Member State
	etc.	

7.3 How to maintain the lifecycle after approval?

The application types which can be submitted according to ~~Paragraph~~Article 13 TPA can be found in the VV.

8 Consolidation sequence

If Swissmedic agrees to the application according to ~~Paragraph~~Article 13 TPA, the applicant is required to submit a consolidation sequence.
For this purpose Modules 2-5 of the reference dossier are incorporated into the Swiss eCTD. This new eCTD sequence is a prerequisite for approval of the Swiss application. This can be done while the process is ongoing at Swissmedic, so there is no clock-stop.
Swissmedic requires the consolidation sequence to show the current approved status of the product in the reference country. The consolidation sequence contains data from Modules 2–5 of the original, approved reference dossier, and, in addition, all already approved variations. STFs in the consolidation sequence will be accepted.
Original reference country Module 1 data is not required (it exists in the reference dossier supplied at the time of initial application).

A signed declaration must also be submitted as an annex to the cover letter, e.g.: *We confirm that the content/data of the submitted consolidation sequence reflects the status of the reference dossier currently approved by the reference country and that there have been no changes to the dossier content as a result of the provision of this consolidation sequence.*
If answers to questions are required the consolidation sequence needs to be submitted with the answers to the questions. The consolidation sequence and the answers to questions must be sent as

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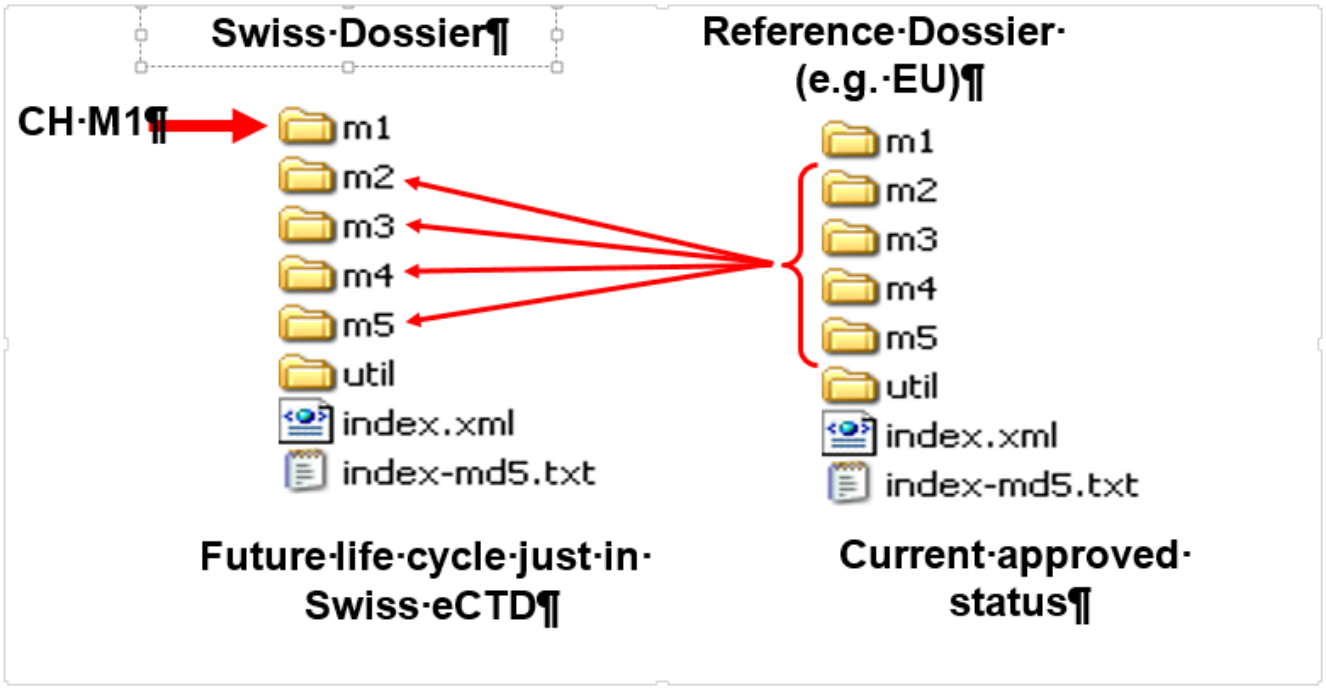
two separate sequences. For detailed requirements regarding hypertext linking from the response document to the documentation please refer to the Swiss Guidance for Industry.
If there is no list of questions the consolidation sequence must be sent with the answer to the preapproval letter as two separate sequences. Hypertext linking is only necessary if there are still open points to discuss.

Illustration 2: Incorporating the reference Modules 2-5 life cycle into the Swiss eCTD



Variations according ~~Paragraph~~Article 13 TPA should be submitted already consolidated (Module 1-5).

9 Timelines

The timelines for submission according to ~~Paragraph~~Article 13 TPA in eCTD format are the same as for paper submissions, please refer to the VV.

10 Switching to application according to ~~Paragraph~~Article 13 TPA after initial national application

If an applicant decides during an on-going national procedure with Swissmedic to apply for evaluation according to ~~Paragraph~~Article 13 TPA following a positive opinion in a reference country, the chapters 6 - 9 of this guidance must be followed. All specific additional documentation required for ~~Paragraph~~Article 13 TPA evaluation must be provided at the time the switch is made.

11 Deviations from the reference product

If the product submitted for evaluation according to ~~Paragraph~~Article 13 TPA differs from that in the reference country, the applicant has to provide supporting information in the appropriate sections of Modules 1, 2 and 3. Allowed differences are described in the VV, chapter 8.7 (e.g. different manufacturing site of the finished product).

Only those documents differing from to the reference dossier need to be included.

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For life cycle management reasons and ease of review it may, however, be appropriate to submit a full Module 2 and the corresponding information in Module 3, or at least parts of Module 2 and 3 where the differences occur. Justification of differences must be documented completely, including the appropriate forms as described in the VV, chapter 8.7.
The reference dossier reflects the situation of documents submitted in the reference country for approval. It does not contain information on differences. The initial Swiss eCTD sequence must contain any documentation which justifies any permitted differences (see VV, Chapter 8.7).
Differences need to be explained and justified in the cover letter: a tabular format is preferred.
Deviations which have occurred and their supporting documentation must be fully explained.
Be aware that differences which do not fall under chapter 8.7 of the VV and are therefore not permitted, will be treated as applications for variation; in this case the corresponding information in Module 1 must be submitted (e.g. form application/variation).

12 Appendix 1: Ordinance on Medicinal Products (Verordnung über die Arzneimittel VAM / Ordonnance sur les médicaments OMéd)

This document is available in German, French and Italian.

Verordnung über die Arzneimittel (Arzneimittelverordnung, VAM[2])

Änderung vom 24. März 2010

Der Schweizerische Bundesrat verordnet:

I
Die Arzneimittelverordnung vom 17. Oktober 20011 wird wie folgt geändert:

Art. 5a Im Ausland zugelassene Arzneimittel und Verfahren (Art. 13 HMG)

1 Beantragt eine Gesuchstellerin die Zulassung oder die Änderung einer Zulassung für ein Arzneimittel oder ein Verfahren, für welches die Zulassung in einem Land mit vergleichbarer Arzneimittelkontrolle bereits erteilt worden ist, so berücksichtigt das Institut die Ergebnisse der dafür durchgeführten Prüfungen, falls folgende Anforderungen erfüllt sind:

a. Die eingereichten Unterlagen aus dem ausländischen Verfahren, einschliesslich aller Änderungsanzeigen, sind nicht älter als fünf Jahre und entsprechen dem Stand der Zulassung im Ausland.
b. Es liegen alle Begutachtungsentscheide samt den dazu gehörigen Prüfungsergebnissen vor, welche im Rahmen von ausländischen Zulassungsverfahren ergangen sind.
c. Die Unterlagen enthalten alle für die Schweiz geforderten Angaben insbesondere zur Arzneimittelinformation und Kennzeichnung.
d. Die Unterlagen liegen in einer Amtssprache, in Englisch oder in einer Übersetzung in eine dieser Sprachen vor. Im Falle einer Übersetzung muss die Gesuchstellerin die Korrektheit der Übersetzung bestätigen.

2 Die Unterlagen nach Absatz 1 Buchstabe a können geringfügig von den im Ausland eingereichten Unterlagen abweichen, wenn dies hinreichend begründet wird. Eine geringfügige Abweichung ist namentlich eine andere Bezeichnung des Arzneimittels, eine andere Packungsgrösse oder eine andere Primär- oder Sekundärverpackung.
3 Liegt eine Zulassung in einem Mitgliedstaat der EU oder EFTA vor, so kann das Institut die jeweils gültige Form der Arzneimittelinformation auch für das Inverkehrbringen des Arzneimittels in der Schweiz genehmigen; vorbehalten bleiben Artikel 14 ff.
4 Das Institut veröffentlicht eine Liste der Länder mit vergleichbarer Arzneimittelkontrolle.

[2] SR **812.212.21**

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Art. 5b Anwendung auf Verfahren und Arzneimittel mit bekannten Wirkstoffen

1 Bei Gesuchen um Zulassung eines Verfahrens oder eines Arzneimittels mit bekannten Wirkstoffen beschränkt sich das Institut grundsätzlich auf eine Prüfung der eingereichten abschliessenden Prüfungsergebnisse (Evaluationsberichte) der ausländischen Behörde. Wecken diese Berichte oder eigene frühere Begutachtungen wesentliche Bedenken, so führt das Institut eine auf die bedenkenerweckenden Punkte beschränkte, eigene wissenschaftliche Begutachtung durch.

2 Bei Evaluationsberichten der zentralen Europäischen Arzneimittelbehörde (European Medicines Agency, EMA) und der Arzneimittelbehörde der Vereinigten Staaten von Amerika (United States Food and Drug Administration, US-FDA) verzichtet das Institut auf die Prüfung des Evaluationsberichts, es sei denn, die Entscheide dieser Behörden widersprechen sich oder das Institut hat aufgrund eigener früherer Begutachtungen wesentliche Bedenken gegenüber diesen Entscheiden.

Art. 5c Anwendung auf Arzneimittel mit neuen Wirkstoffen und die Erweiterung von deren Indikationen

Gesuche um Zulassung eines Arzneimittels mit neuem Wirkstoff oder dessen Indikationserweiterung unterzieht das Institut in der Regel einer umfassenden wissenschaftlichen Begutachtung. Es kann die Begutachtung in begründeten Fällen auf Gesuch hin oder von Amtes wegen, gestützt auf entsprechende ausländische Prüfungsergebnisse, angemessen reduzieren.

Art. 5d Parallele Verfahren in der Schweiz und im Ausland

Ergeht während eines laufenden Zulassungsverfahrens in der Schweiz eine Empfehlung der EMA an die EU-Kommission für das gleiche Arzneimittel oder Verfahren, so wendet das Institut auf Gesuch hin die Artikel 5*a*–5*c* analog an. Bestehen aufgrund der bis zu diesem Zeitpunkt erfolgten eigenen Begutachtung wesentliche Bedenken an den Prüfungsergebnissen der EMA, setzt das Institut seine wissenschaftliche Begutachtung fort.

Art. 25b Abs. 1 und 3 erster Satz

1 Kantone, in denen am 1. Januar 2002 eidgenössisch diplomierte Drogistinnen und Drogisten zur Abgabe von Arzneimitteln der Abgabekategorie C ermächtigt waren, dürfen Drogistinnen und Drogisten die Abgabe von Arzneimitteln der Abgabekategorie C gestatten, sofern die Voraussetzung nach Artikel 25 Absatz 4 HMG erfüllt ist.

3 Ist die Voraussetzung nach Artikel 25 Absatz 4 HMG nicht mehr erfüllt, so ist die Ermächtigung zu widerrufen. …

1 Diese Änderung tritt unter Vorbehalt von Absatz 2 am 15. April 2010 in Kraft. 2 Die Artikel 5*a*–5*d* treten am 1. Juli 2010 in Kraft.

24. März 2010 Im Namen des Schweizerischen Bundesrates

Die Bundespräsidentin: Doris Leuthard Die Bundeskanzlerin: Corina Casanova

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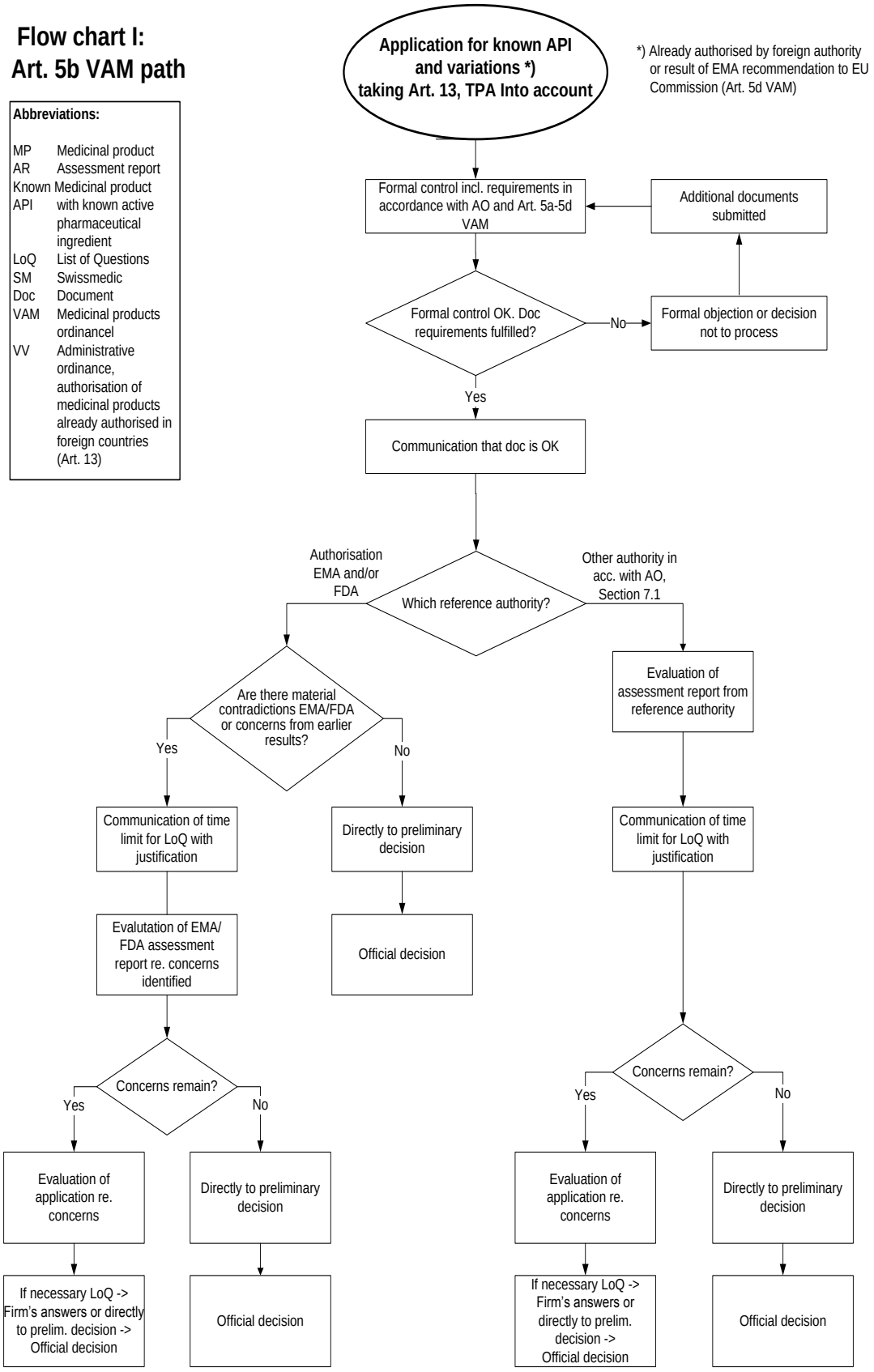
Appendix 2: Flow charts relating to the application process

Flow chart I: Application Known Active Substance, application in accordance with Arts. 5a - 5d VAM



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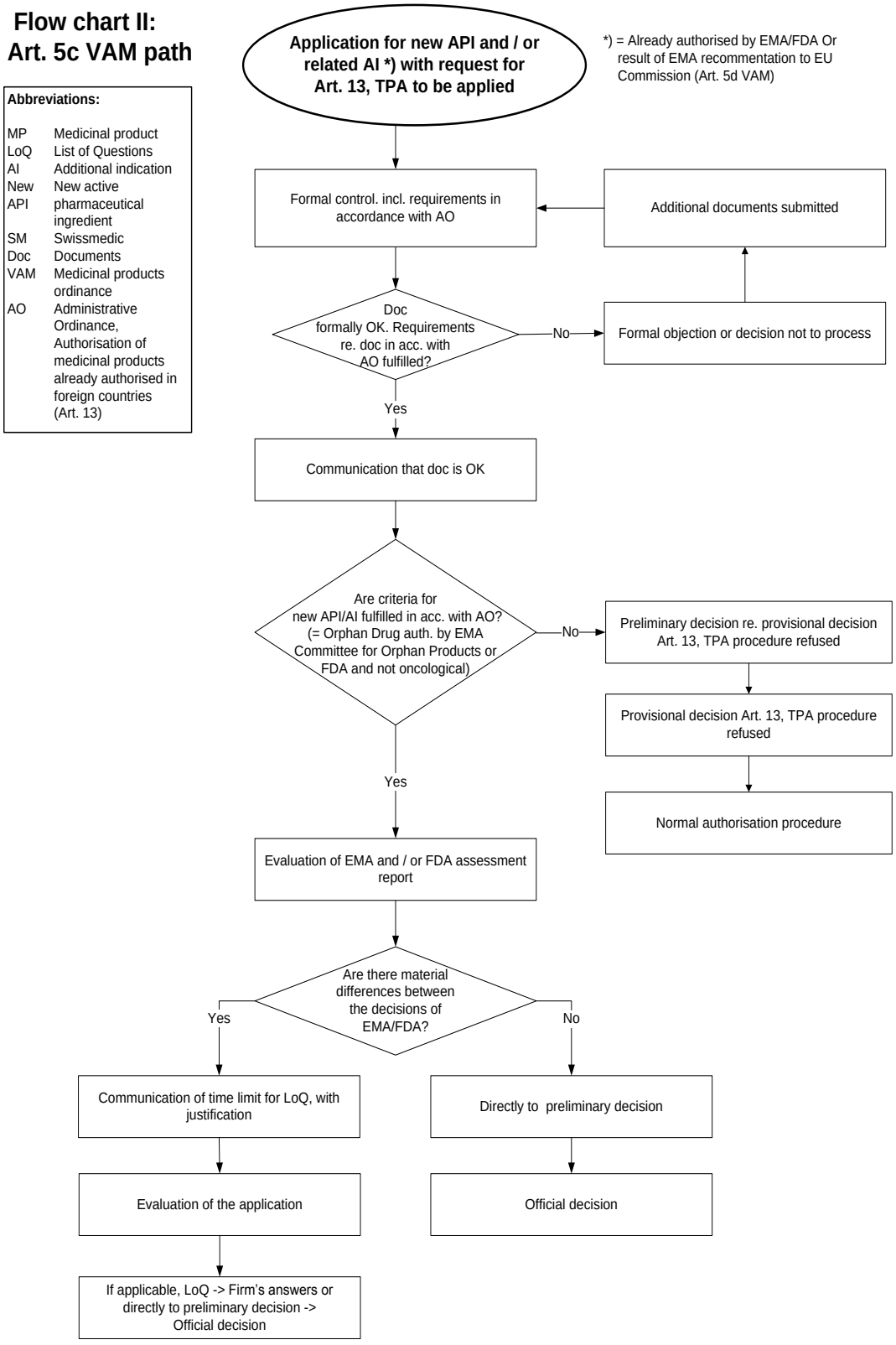
Flow chart II: Application New Active Substance and extended indication, application in accordance with Arts. 5a - 5d VAM



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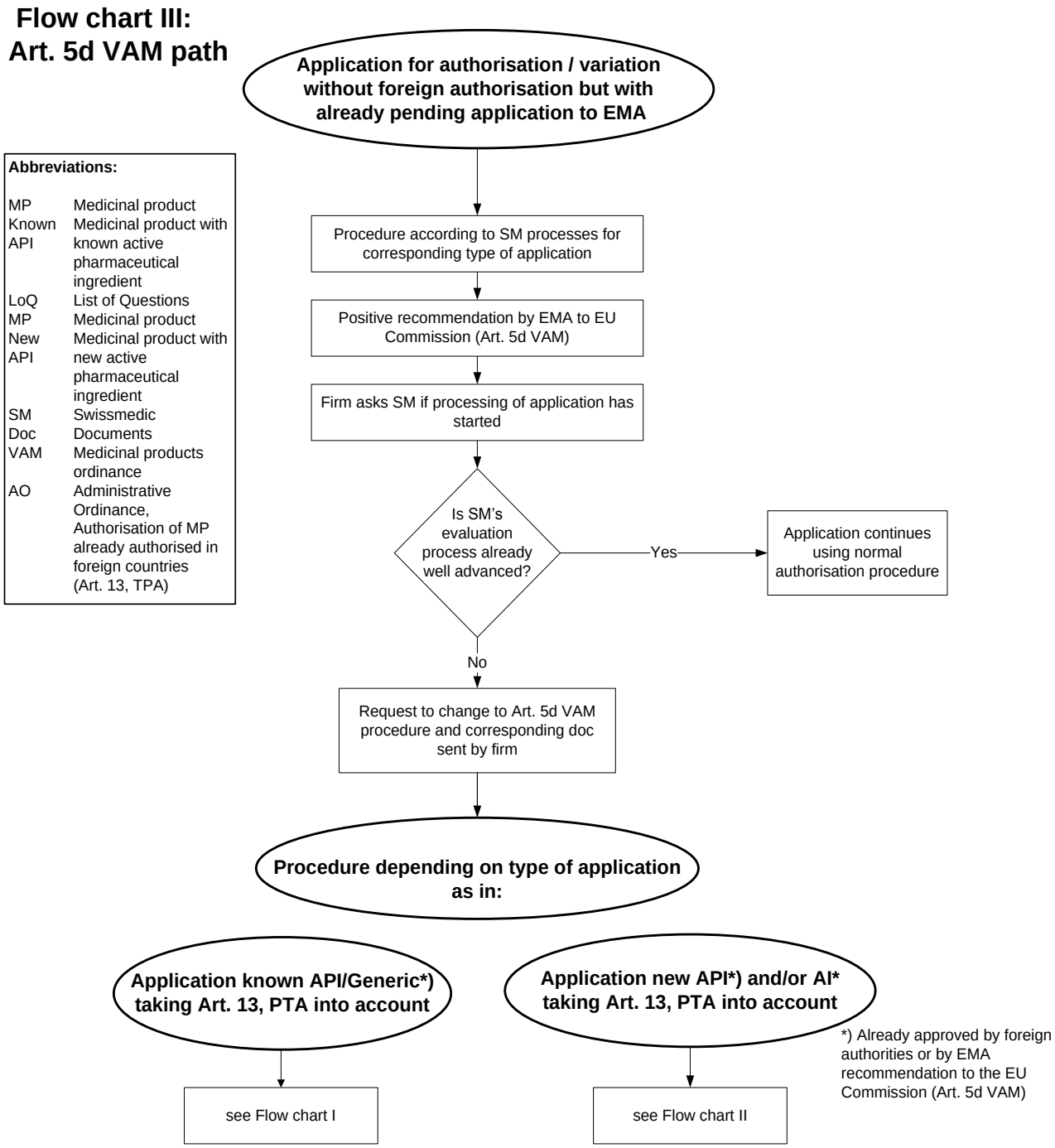
Flow chart III: Application for authorisation / Modification without authorisation in a foreign country, with pending application to the EMA



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