Guidance document
Formal requirements

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List of contents

1 Introduction

1.1 Terms, definitions, abbreviations

1.1.1 Abbreviations

AAA	Accelerated Application Hearing
ASMF	Active Substance Master File
CCDS	Company Core Data Sheet
CDS	Core Data Sheet
CEP	Certificate of Product
CHM	Complementary and Herbal Medicines
Common Technical Document:	format for authorisation applications, divided into Modules 1-5
DMF	Drug Master File
DMF/ASMF Holder	Holder of the Drug Master File / Active Substance Master File
Doc	Documents
eCTD	electronic Common Technical Document
eDok	Swissmedic application submission format, paper version + electronic version (see Swissmedic website)
FTP	Fast-Track authorisation Procedure
GMO	Genetically Modified Organisms
HMP	Human medicinal products
HPC	Healthcare Professional Communication
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IHP	Information for Healthcare Professionals

KAS	Known Active Substance
LoA	Letter of Access
LoQ	List of Questions
MAH	Marketing Authorisation Holder
MDR	Regulation (EU) 2017/745 on medical devices (EU-MDR)
MedD	Medical device
MUMS	Minor Use and Minor Species
NAS	New Active Substance
NTA	Notice to Applicants, format for authorisation applications, divided into Parts I-IV
ODS	Orphan Drug Status
PBRER	Periodic Benefit-Risk Evaluation Report
PDP	Pediatric Development Plan, FDA
PI	Patient Information
PIP	Paediatric Investigation Plan
PL	Package Leaflet (of veterinary medicinal products)
PMF	Plasma Master File
PPN	Procedure with Prior Notification
PSUR/PBRER	Periodic Safety Update Report/Periodic Benefit Risk Evaluation Report
PVP	Pharmacovigilance Plan
RMP	Risk Management Plan
SAP number	Identification number in the Swissmedic's SAP business case application, e.g. for medicinal products, applications, products
SmPC	Summary of Product Characteristics
temp.	Temporary new authorisation
tempAI	Temporarily authorised additional indication
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, SR 812.21)
TV	Technical Validation (of applications in eCTD format)
VMP	Veterinary Medicinal Products
VMPI	Veterinary Medicinal Product Information = Information for healthcare professionals + package leaflet
WL	Guidance Document

1.1.2 Definitions

Data carrier	CD, DVD, blu-ray disc
Binder	A4 rigid ring binder with two sets of holes, 50mm or 80mm spine
Loose-leaf binder	Plastic folder for hole-punched documents, A4, two sets of holes
Dividers	Set of dividers with light cardboard or plastic tabs
Cover sheets	The cover sheets made available online by Swissmedic, with the titles and the bar codes for separating the individual sections within the authorisation documentation, Modules 1-5 (CTD) and Parts I-IV (NTA) respectively.

1.1.3 Description of the requirements

The requirements are described in tabular form, and are numbered.

No.	Subject	Requirement	C / O	Exceptions
1.1.3.1	Description of the subject	Explanation of the requirement	C=compulsory O=optional (C=subject to objections)	Descriptions of special cases and requirements
…	…	…	…	…

1.1.4 Symbols used and their meaning

This symbol means: “Please note!”
Information marked with this symbol is explanatory and provides additional information.

This symbol means: "Example / Summary".
Examples and summaries are intended to help clarify the requirements, and serve as additional information.
Purpose of this guidance document

1.2 Objective of this guidance document

Since this guidance document is an Administrative Ordinance document aimed at the administrative bodies, it does not directly specify the rights and obligations of private individuals. Swissmedic uses this guidance document first and foremost as a resource for applying the legal provisions in a uniform and equitable manner. The publication of this document provides transparency concerning how applications should be structured so that they can be processed efficiently and completed in accordance with Swissmedic's practices and systems.
This document also takes into account all publications on this subject in the Swissmedic Journal in recent years.
In the case of divergences between the formal requirements specified in previous documents and those specified in the guidance document *Formal requirements*, the present document takes precedence.

1.3 Scope

This guidance document applies to all submissions to Swissmedic. It specifically does not apply to:

- Requirements related to the content of applications
- Medical devices
- Market monitoring cases other than those explicitly mentioned
- Legal cases
- Inspections
- Certificates
- Clinical trials
- Notifications for narcotics
- Submission of laboratory orders

The requirements of the directory *Overview of documents to be submitted* must be taken into account in addition to the requirements described in this guidance document. Requirements specific to certain types of application that cannot be found here are described in the relevant guidance documents.

2 General requirements

2.1 Submission formats

No.	Subject	Requirement	C / O	Exceptions
2.1.1	Paper submission in CTD format	There are two options: ***Entirely paper-based submission:*** Module 1-5: One original as hard copy The individual sections of Modules 2-5 of the paper original must be marked by dividers/tabs. In addition, the paper original must be subdivided using the cover sheets provided electronically by Swissmedic. Furthermore, the IHP / PI / VMPI / packaging must be submitted electronically on a data carrier. ***Paper submission with eDok copy:*** One paper original for Modules 1-5 plus an identical electronic copy on a data carrier The individual sections must be submitted as an eDok copy on the data carrier in accordance with the instructions (see WL Guidance eDok) The paper original (with the modules submitted separately) must not contain dividers or cover sheets. In addition, the IHP / PI / VMPI / packaging must be submitted on a data carrier.	C	
2.1.2	Paper submission in NTA format (veterinary medicinal products only)	There are two options: ***Entirely paper-based submission:*** One original as hard copy The individual sections of the paper original (Parts Ic-IV) must be marked by dividers/tabs. In addition, the paper original must be subdivided using the cover sheets provided electronically by Swissmedic. In addition, the veterinary medicinal product information / packaging must be submitted electronically on a data carrier. ***Paper submission with eDok copy:*** One paper original for Parts I-IV plus an identical electronic copy on a data carrier. The individual sections must be submitted as an eDok copy on the data carrier in accordance with the instructions (see WL Guidance eDok). The paper original (with the parts submitted separately) must not contain dividers or cover sheets. In addition, the veterinary medicinal product information / packaging must be submitted electronically on a data carrier.	C	
2.1.3	Binding of the paper documents	Paper documents for Modules 1-5 (or Parts I-IV respectively) must be submitted in binders or folders, divided by module	C	
2.1.4	Cover sheets	Swissmedic provides cover sheets with the section titles and barcodes for separating the individual sections of paper submissions in the CTD or NTA structure (these cover sheets are available for download on the Swissmedic website). These cover sheets must be printed out by the applicant and placed in the authorisation documents in front of the corresponding section. All sections must also be separated by dividers. If a section exceeds the volume of a (standard Swiss) ring binder, a cover sheet for the relevant section must be inserted as the first sheet of each new binder.	C	The cover sheets are not required for the submission of an eDok copy.

No.	Subject	Requirement	C / O	Exceptions
2.1.5	Numbering system CTD / NTA	The official structure (CTD, NTA) for the numbering of the individual sections must remain unchanged.	C	
2.1.6	eCTD	The special requirements for an eCTD submission are published on the Swissmedic website. The following documents should be taken into consideration: ▪ Guidance for Industry on Providing Regulatory Information in eCTD Format ▪ Questions and answers by Swissmedic on eCTD implementation ▪ Swiss Module 1 Specification for eCTD ▪ Swiss eCTD Validation Criteria ▪ Guidance on applications according to paragraph 13, TPA for eCTD applications	C	
2.1.7	Additional Word or PDF documents	Companies that do not work with Swissmedic's eGov Portal must submit Word versions of the information for healthcare professionals and patients / veterinary medicinal product information and PDF versions of packaging (or manuscripts in Word format) on an electronic data carrier.	C	

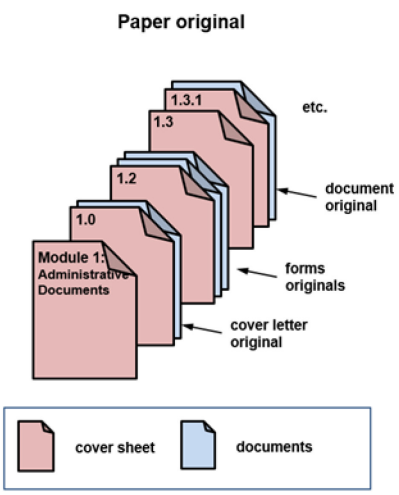
Other requirements applicable to documents to be submitted can be found in the "Overview of documents to be submitted". Details of the requirements relating to content can be found in the guidance documents published on the Swissmedic website.

Entirely paper-based submissions: Staples must not be used for entirely paper-based submissions. Staples may still be used for paper documents submitted with eCTD or eDok.

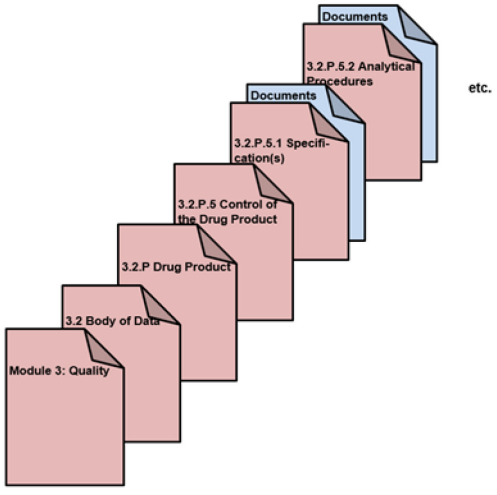
No transparent folders may be used.

When using the cover sheets, please note:

Example for cover sheets: Module 1



Example for cover sheets: Module 3



Paper applications, submission of publications:
In connection with the submission of documentation, the reference documents do not need to be submitted in paper form if they are publicly available, free of charge, at all times. In this case electronic submission of the published data alone is sufficient. The applicant should clearly state what references can be found on the CD and specify the corresponding versions and dates.

Life cycle following the transfer of authorisation:
After the authorisation of a medicinal product has been transferred, it is preferable to continue using the existing submission format (particularly in the case of eCTD).
Option 1:
The existing MAH transfers the eCTD life cycle to the new MAH. The new MAH continues using the existing eCTD life cycle.
Option 2:
The existing MAH does not transfer the eCTD life cycle to the new MAH. The new MAH submits the authorisation transfer on paper and continues using the life cycle as eCTD after the transfer. The transfer is consolidated in the new life cycle. However, a baseline will be required for certain sections of the dossier (e.g. module 3).

Option 3:
The existing MAH does not transfer the eCTD life cycle to the new MAH. The new MAH submits the transfer on paper and continues using the life cycle on paper after the transfer of the medicinal product.

Summary of submission formats

		eGov Portal	eCTD	Paper	
				Paper original with eDok copy	**Entirely paper-based submission**
Module 1 / Parts Ia/Ib in paper form	**Cover letter, forms, etc. of each**	---	1 copy	1 copy	1 copy
	Draft healthcare professional / patient information / veterinary product information	---	---	1 copy	1 copy
	Packaging	---	---	1 copy	1 copy
	Staples	---	Permitted	Permitted	**Not permitted**
Paper documentation (Modules 2-5 / Parts 1c to IV)		---	-	1 copy	1 copy
Electronic documentation on CD/DVD (Modules 1-5 / Parts I to IV)		---	1 copy	1 copy	-
Electronic documentation by eGov Portal (Modules 1-5 / Parts I to IV)		1 copy			
Cover sheets (Modules 1-5 / Parts I to IV)		---	-	-	1 cover sheet per section
Dividers (Modules 2-5 / Parts 1c to IV)		---	-	-	1 set of dividers per section
Additional Word documents Packaging (also accepted as PDF) and or IHP/PI/VMPI		Contained in the electronic submission.	On eCTD data carrier	On data carrier with electronic documentation	On data carrier

2.2 Time limits

No.	Subject	Requirement	C / O	Exceptions
2.2.1	General	The time limits are those stipulated in the guidance document *Time limits for authorisation applications*.	C	
2.2.2	Time limits for resolving shortcomings regarding formal requirements	In the event of formal objections, applicants will be given a maximum of 60 days to rectify the shortcoming. Extensions cannot be granted.	C	

2.3 Signatures / Signatory authority

No.	Subject	Requirement	C / O	Exceptions
2.3.1	Signatory authorised to commit the firm	Applicants may delegate third parties to submit applications and notifications on their behalf. In such cases, the corresponding power of attorney must be submitted with the application.	C	
2.3.2	Signatures	Cover letters, forms and other documents requiring an original signature must be submitted in paper form and bear the original signature of an authorised signatory. The signature does not have to be that of a person recorded in the Commercial Register as having signatory authority. It may also be that of a person duly authorised by the applicant to sign documents for the corresponding operation.	C	Users of the Swissmedic eGov portal are subject to the applicable contractual conditions.
2.3.3	Signatures for DMF/ASMF applications	The documentation required for a DMF/ASMF (Form Part B and Letter of Access) must bear the original signature of the DMF/ASMF holder for each new application.	C	

Swissmedic does not accept scanned, electronic or printed out signatures on paper submissions.

2.4 Confirmation of receipt

No.	Subject	Requirement	C / O	Exceptions
2.4.1	Confirmation of receipt	Swissmedic does not send confirmations of receipt by post.	C	Swissmedic confirms receipt of type IA, IA_{IN} and IB (HMP) variations, and variations that do not require assessment (VMP; if the applicant is **not** a portal user), applications for advertising permits and licence applications. Confirmation of receipt always sent for fast-track requests.

Authorisation holders may consult the status of their application online on the Swissmedic eGov Portal. For details, see the Swissmedic website and the Guidance for the Swissmedic eGov Portal.

2.5 Module 1

2.5.1 Cover letter

Requirements applicable to the cover letters of certain types of application can be found in the section on the application in question.

No.	Subject	Requirement	C / O	Exceptions
2.5.1.1	General	▪ Medicinal product name plus appropriate details if other designations have been used for the medicinal product in the documentation (e.g. other product names, chemical name, development code no.) ▪ Name of the active substance ▪ If known: Authorisation number ▪ If known: Application ID ▪ Application type (for applications for variation, including the type of variation) and short scientific justification ▪ List of all administrative documents and other documentation submitted (for each Module/Part, with number of binders) ▪ For eCTD submissions: number of data carriers.	C	Variation types IA, IA_{IN} and IB (HMP), as well as variations without assessment and variations with assessment with a time limit “Reduced” (VMP) can be submitted without cover letters provided no further information or reasons need to be stated.
2.5.1.2	Dispatch of authorisation documents	Authorisation documents will only be sent if specifically requested by the applicant applicant and is subject to a fee. If an authorisation document is required, this must be expressly stated in the cover letter for all submission types.	O	Users of the Swissmedic eGov portal can download an up-to-date authorisation document themselves by logging into the Portal.
2.5.1.3	Documents not submitted	If documents required by Swissmedic are not submitted, the reasons for omitting them must be explained in the cover letter.	C	
2.5.1.4	Additional information for out of stock situations	▪ Pharmaceutical form, authorisation holder in Switzerland ▪ Details of the medicinal product to be imported (foreign authorisation no., medicinal product designation, pharmaceutical form, authorisation holder) ▪ Name and address of the firm in the country of export from which the medicinal product to be imported will be obtained ▪ Name and address of the repackaging company ▪ Contact details of the Responsible Person for the authorisation holder ▪ 24-hour emergency number	C	

2.5.2 Forms

No.	Subject	Requirement	C / O	Exceptions
2.5.2.1	Forms *New authorisation of human medicinal products / New authorisation of veterinary medicinal products*	An original of the form must be submitted for each authorisation number and for each application type. Dosage strength number: state the various dosage strengths.	C	
2.5.2.2	Form *Variations and extensions HMP* / Form *Variations VMP*	The forms consist of an administrative part with sections 1 (Basic information) to 7 (Signature) and section 8 with the list of variations. In the form for HMP, a template starting on a new page exists for every variation. In the form *Variations VMP*, all	C	

No.	Subject	Requirement	C / O	Exceptions
		changes are separated into individual templates by variations without assessment and variations with assessment. Each template begins on a new page. A form can also be used for a variation application, a multiple application, a collective application or a collective-multiple application. Further information can be found in Chapter 3.12 of this guidance document: "Variations and extensions".		
2.5.2.3	*Full declaration* form	The complete qualitative and quantitative composition of the medicinal products must be stated.	C	
2.5.2.4	Form *Manufacturer information*	For medicinal products with herbal active substances, the requirements set out in the Guidance document *Details required regarding manufacturers of herbal active substances* must be met. The requirements set out in the Guidance document *Authorisation of homeopathics, anthroposophics and other complementary medicinal products* must be observed on the form *Manufacturer information* when authorising homeopathic and anthroposophic medicinal products without an indication and with a reduced dossier. Furthermore, the requirements of the guidance document *Simplified information requirements on the form manufacturer information* for the reduced dossier must be applied to applications for authorisation with a reduced dossier.	C	
2.5.2.5	Form *Status of authorisation applications abroad*	If the status changes while an application is in progress, the form containing the response to the List of Questions or the response to the preliminary decision must be resubmitted.	C	If no submission / authorisation for the relevant medicinal product exists in other countries, there is no need to submit the form *Status of authorisation applications abroad*. The reasons for omitting the form should be set out in the cover letter.
2.5.2.6	Form *Confirmation regarding substances from GMO*	This form must always be submitted if it is possible that the medicinal product may contain substances derived from GMO. This applies irrespective of whether substances have to be declared in accordance with the Guidance document *Product information for human medicinal products*. If the medicinal product contains GMO, the declaration is to be made according to Art. 27 para. 3 TPO and the form does not need to be submitted.	C	

Form *Manufacturer information* should only be submitted if it is required for the application type in question. If the form is submitted for other application types, Swissmedic will neither check it nor approve it.

The currently valid versions of the forms are available on the Swissmedic website. The use of forms that are no longer valid after the transitional period stipulated by Swissmedic (usually three months) has expired will result in Swissmedic issuing a formal objection. Unless otherwise explicitly stated by Swissmedic, the default transitional period for forms is 3 months. If additional application requirements are associated with a new version of a form, a default transitional period of 3 months likewise applies to these new requirements.

Incomplete forms may also result in a formal objection.

2.5.3 Medicinal product information

2.5.3.1 Mandatory submission

No.	Subject	Requirement	C / O	Exceptions
2.5.3.1.1	Submission is mandatory for human medicinal products in dispensing categories A and B	Information for healthcare professionals and patients must both be submitted.	C	Dosage forms in accordance with *Art. 14, para. 2, TPLRO* that are only administered by doctors or dentists (e.g. products for injection or infusion) do not require patient information. For these medicinal products, the information for healthcare professionals should be inserted in the packaging. **Complementary medicinal products:** Information for healthcare professionals is not required for homeopathic and anthroposophic medicinal products according to *Art. 24, Art. 25 para. 2 KPTPO*, medicinal products for gemmotherapy according to *Art. 35 para. 2 KPTPO* and Asian medicinal products without an indication according to *Art. 30 et seq. KPTPO*. Medicinal product information is not required for homeopathic and anthroposophic medicinal products without an indication according to *Art. 25 para. 1 KPTPO*, homeopathic and anthroposophic medicines without an indication and medicinal products for gemmotherapy without an indication according to *Art. 27 KPTPO* and Schüssler salts without an indication according to *Art. 28 KPTPO*.
2.5.3.1.2	Submission is mandatory for human medicinal products in dispensing category D	Information for healthcare professionals and patients must both be submitted.	O	**Medicinal products according to Art. 14 para. 1 let. a$^{ter\text{-}quater}$ TPA** Information for healthcare professionals is not required. **Herbal medicinal products** Information for healthcare professionals is mandatory for certain active substance groups (e.g. anthraquinone laxatives, medicinal products containing St. John's wort, ginkgo and echinacea). If a product contains other active substances, Swissmedic can waive the requirement for information for healthcare professionals in response to an application to this effect. **Complementary medicinal products:** For Asian medicinal products according to Art. 29 KPTPO, the Agency can waive the requirement for information for healthcare professionals in response to an application to this effect. Information for healthcare professionals is not required for homeopathic and anthroposophic medicinal products according to *Art. 24, Art. 25 para. 2 KPTPO*, medicinal products for gemmotherapy according to *Art. 35 para. 2 KPTPO* and Asian medicinal products without an indication according to *Art. 30 et seq. KPTPO*. Medicinal product information is not required for homeopathic and anthroposophic medicinal products without an indication according to *Art. 25 para. 1 KPTPO*, homeopathic and anthroposophic medicines without an indication and medicinal products for gemmotherapy without an indication

No.	Subject	Requirement	C / O	Exceptions
				according to *Art. 27 KPTPO* and Schüssler salts without an indication according to *Art. 28 KPTPO*. **The requirement to provide information for healthcare professionals is waived for the following categories of medicinal products, provided that appropriate reasons are given:** Baby foods, bath additives and compresses (healing clay, poultices), disinfectants, dietary supplements, intimate hygiene products, products for sensitive skin, Tear substitutes, nasal products (with secretolytic and moistening effect), laxatives (only bulking and filling agents), vitamin products (only those with water-soluble vitamins), dental products (products for the gingiva and the other oral mucosa, products with fluoride, products to prevent tooth decay, tooth surface and to desensitise the dentine).
2.5.3.1.3	Submission is mandatory for human medicinal products in dispensing category E	Information for healthcare professionals or patients is not required	C	
2.5.3.1.4	Submission is mandatory for veterinary product information	Information for healthcare professionals and package leaflet are compulsory.	C	Information for healthcare professionals does not have to be prepared for veterinary medicinal products in dispensing category E, veterinary medicinal products that can be dispensed in pet and bee-keeping shops, or homeopathic preparations without an indication. Product information is not required (Art. 14, paras. 1 and 3, TPLRO) if Swissmedic has given its consent and if all the required information is placed on the container used for dispensing. The requirements for the information and texts on containers and packaging material must comply with Art. 13 and 14, in conjunction with Annex 6, TPLRO)

2.5.3.2 Requirements

No.	Subject	Requirement	C / O	Exceptions
2.5.3.2.1	Cover letter (in addition to the requirements in section 2.5.1 “Cover letter”)	State version on which the text submitted is based (i.e. the latest version approved by Swissmedic) For safety-relevant changes: ▪ In the subject line: "Safety-relevant change to the product information" ▪ Discussion regarding enhanced measures (e.g. HPC) ▪ State reasons for the safety relevance in the text ▪ If the safety-relevant changes are in connection with a national or international safety signal, mention this in the cover letter		
2.5.3.2.2	Templates for medicinal product information	The templates for information for healthcare professionals and patient information available on the Swissmedic website must be used to submit manuscripts of medicinal product information for human medicinal products.	C	
2.5.3.2.3	Templates for veterinary medicinal product information	Applicants are recommended to use the templates for information for healthcare professionals and package leaflets for veterinary medicinal products available on the Swissmedic website to submit	O	

No.	Subject	Requirement	C / O	Exceptions
		manuscripts of veterinary medicinal product information.		
2.5.3.2.4	References in the medicinal product information	Statements made in the medicinal product information must be scientifically justified and proved. Suitable references are study reports, publications, or other scientific documentation. References to study reports, publications, other scientific documentation, a summary or an overview must always cite the corresponding page number. Example: *Study xyz, binder 3, page 736.* Or *Binder 2, Reference 38: Müller et al, title etc., page 13* A simple reference to the firm's internal Core Data Sheet (CDS) or the Company CDS (CCDS) or the Summary of Product Characteristics (SmPC) is not permitted, since this is not a scientific reference. References must not be removed while the application is in progress.	C	Veterinary medicinal products: Reference to EU-SmPC is possible in exceptional cases
2.5.3.2.5	Marking of changes	All changes compared to the last approved version must be clearly marked as such. The marking must be shown in the manuscripts throughout the entire application process. Changes must be marked/highlighted using Word's "Track Changes" function. No other forms of marking/highlighting will be accepted. If a manuscript contains changes affecting several pending applications, it must be apparent which changes were requested with which application, e.g.by using different editor IDs. If an application for a variation contains changes to texts inserted during several rounds of text corrections, and if the text has not yet been approved, confirmation must be given that the corrections suggested by Swissmedic in the previous version have been made. Corrections by Swissmedic that have not yet been agreed upon must be clearly marked as corrections made to the text by Swissmedic, e.g. by inserting a comment.	C	Veterinary medicinal products: As of the answer to the preliminary decision, only those changes that do not correspond to the proposed corrections by Swissmedic must be marked.
2.5.3.2.6	Safety-relevant changes to the medicinal product information	The application requires either a Direct Healthcare Professional Communication (DHPC) or a justification for not submitting a DHPC. Within the framework of an application concerning safety-relevant changes, no further changes to the last approved text may be made in addition to the justified, safety-related changes. Other changes must be applied for separately. The content of safety-relevant changes concerns new, more restrictive statements in the sections "Dosage / use", "Contraindications", "Warnings and precautionary measures", "Interactions", "Pregnancy / breast feeding" and "adverse reactions". If the patient information is also concerned, the corresponding changes must be submitted at the same time as those concerning the information for healthcare professionals.	C	Veterinary medicinal products: Only changes concerning serious and life-threatening reactions or irreversible damage are considered to be safety-relevant
2.5.3.2.7	Information for healthcare professionals from other countries, EU-SmPCs	For EU-SmPCs: the last version approved in the EU, stating the date on which the approval was granted, should be submitted. For medicinal products or changes that have not yet been approved: the applicant's proposal for the EU-SmPC must be clearly marked as the applicant's draft.	O	

No.	Subject	Requirement	C / O	Exceptions
2.5.3.2.8	Resubmission: of rejected changes	Changes to the text that were rejected by Swissmedic for a first authorisation or earlier applications can be requested again only if they are documented by new data.	C	

For medicinal products that are authorised exclusively for export, a manuscript for the basic information is checked and approved. Depending on the requirements (according to dispensing category), this basic information can be for healthcare professionals or patients, or can be information on the outer packaging.

The information for healthcare professionals and patients for human medicinal products and the basic information and package leaflet for veterinary medicinal products must be submitted in an official Swiss language for approval.

2.5.4 Packaging

No.	Subject	Requirement	C / O	Exceptions
2.5.4.1	Submission methods for packaging (folding cartons, labels, sachets, etc.)	The format and number of copies to be submitted are as specified in the "Submission formats" table in section 2.1. Colour laser print-outs in original format ('mock-ups') can be submitted instead of original prints of packaging (folding cartons, labels, sachets, etc.) In addition, packaging should be submitted on a data carrier as a single file with searchable text (OCR).	C	Paper copies are not required when making a submission in eCTD format. Users of the Swissmedic eGov portal do not need to submit an additional electronic data carrier for the packaging. Packaging does not have to be submitted for homeopathic and anthroposophic medicinal products without an indication according to *Art. 25 para. 1 KPTPO*, homeopathic and anthroposophic medicines without an indication and medicinal products for gemmotherapy without an indication according to Art. 27 KPTPO, Schüssler salts without an indication according to Art. 28 KPTPO and Asian medicinal products without an indication according to *Art. 30 et seq. KPTPO*.

2.5.5 Curriculum vitae of the experts

No.	Subject	Requirement	C / O	Exceptions
2.5.5.1	Dated and signed curriculum vitae of the experts	Required for: ▪ The overview (CTD: Module 2.3, 2.4, 2.5) ▪ Statement by an expert The original of the document is not required	C	

2.5.6 Documentation of Environmental Risk Assessment

No.	Subject	Requirement	C / O	Exceptions
2.5.6.1	Environmental risk assessment (incl. the related reports)	***Human medicinal products*** ▪ Applications for new active substances ▪ Biosimilar applications ▪ KAS and extensions only if an elevated environmental impact is anticipated. ▪ Applications for additional indications (type II variations) that are likely to have a substantial environmental impact. ▪ For Art. 13 TPA applications, an ERA is only required if the authorisation was granted in a non-EU country. ▪ Non-submissions must be substantiated. ***Veterinary medicinal products*** ▪ An ERA (at least a Phase I assessment) is part of every new authorisation.	C	

No.	Subject	Requirement	C / O	Exceptions
		▪ Non-submissions must be substantiated.		

2.5.7 Decisions by foreign authorities

No.	Subject	Requirement	C / O	Exceptions
2.5.7.1	Cover letter (in addition to the requirements in section 2.5.1 "Cover letter")	If final Assessment Reports by foreign authorities with comparable medicinal product control systems exist (in accordance with the list published on the Swissmedic website), but are not enclosed with the application, the reasons for omitting them must be stated in the cover letter.	C	
2.5.7.2	Final Assessment Reports by foreign authorities	Final Assessment Reports by foreign authorities with comparable medicinal product control systems exist (in accordance with the list published on the Swissmedic website).	O	

2.5.8 PVP / RMP / Pharmacovigilance planning documents (human medicinal products only)

No.	Subject	Requirement	C / O	Exceptions
2.5.8.1	General	Documentation on pharmacovigilance planning should be submitted in accordance with Annex 3 TPO (ICH Guideline E2E and EU Guideline on good pharmacovigilance practices (GVP) – Modules V.A and V.B). Swissmedic prefers that if an EU RMP is available, it should be submitted. To be submitted: ▪ for all new authorisation applications for medicinal products with at least one new active substance (incl. orphan drugs) and their indication extensions ▪ for applications for the authorisation of medicinal products that are not eligible for a simplified authorisation procedure (Art. 12, para. 5 let a-e TPLO), namely vaccines, sera and toxins, blood products, biotechnological medicinal products and advanced therapy medicinal products (ATMP)	C	

The US REMS format (Risk Evaluation and Mitigation Strategy) is not accepted as implementation of the ICH Guideline.

- *The following do not require an RMP:*
  - *Applications for authorisation of a biosimilar.*
  - *Applications for authorisation of a KAS.*
  - *Applications for authorisation of medicinal products under Art. 14 para. 1 let. a$^{bis\text{-}quarter}$ TPA.*

If an RMP is submitted for an application that does not require one, this will usually not be assessed or approved by Swissmedic.

2.5.9 Paediatric Investigation Plan

No.	Subject	Requirement	C / O	Exceptions
2.5.9.1	PIP	The requirements are based on the guidance document *Paediatric Investigation Plan*.	C	

2.5.10 Information on the bioequivalence trial / reference product

No.	Subject	Requirement	C / O	Exceptions
2.5.10.1	Information on the bioequivalence trial	If the proof of the transferability of the test results for the reference product is based on pharmacokinetic bioequivalence trials, information	C	

No.	Subject	Requirement	C / O	Exceptions
	(human medicinal products only)	according to EMA/CHMP/600958/2010/Corr* "Appendix IV of the Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev.1)" should be submitted.		
2.5.10.2	Veterinary medicinal products: Information on the bioequivalence trial and reference product	If the proof of the transferability of the test results for the reference medicinal product is based on pharmacokinetic bioequivalence trials, confirmation must be provided that the test medicinal product used in the bioavailability trial is identical to the product submitted to Swissmedic for authorisation.	C	

2.5.11 Information on GCP inspections

No.	Subject	Requirement	C / O	Exceptions
2.5.11.1	Information on GCP inspections	A completed EMA GCP inspections template must be submitted for all application types whose documentation includes clinical trials (including bioequivalence trials).	C	

2.5.12 GMP/Certificates/Establishment licences

No.	Subject	Requirement	C / O	Exceptions
2.5.12.1	Proof of GMP compliance, certificates and establishment licences	For foreign manufacturers, to be submitted in accordance with: Guidance document *GMP compliance by foreign manufacturers*	C	

For veterinary medicinal products: The documents cited must be submitted under Part 1a6 manuf.

2.5.13 Manufacturing information: flow chart for vaccines and blood products

No.	Subject	Requirement	C / O	Exceptions
2.5.13.1	Presentation of the manufacturing steps for vaccines and blood products	Clear, summarised presentation of the manufacturing steps and sites as a flow chart	C	

2.5.14 Evidence that the obligation to notify pursuant to the Nagoya Ordinance is satisfied

No.	Subject	Requirement	C / O	Exceptions
2.5.14.1	Evidence that the obligation to notify pursuant to the Nagoya Ordinance is satisfied	According to Art. 3 para. 2 TPO, a new application for authorisation of a medicinal product whose development is based on the utilisation of genetic resources or related traditional knowledge must include the registration number pursuant to Art. 4 para. 3 or Art. 8 para. 5 NagO. The registration number is issued by the Federal Office for the Environment (FOEN) and provides the applicant with proof of compliance with the obligation to notify according to Articles 4, 5 or 8 NagO, and is a prerequisite for authorisation under Art. 9 paragraph 2 TPO. The requirements of NagO as well as Arts. 2 and 9 TPO must be satisfied for all new authorisation applications that involve substances (active substances or excipients) whose development is based on a genetic resource, if access to the	C	Access to the genetic resource or related traditional knowledge took place prior to 12 October 2014.

No.	Subject	Requirement	C / O	Exceptions
		genetic resource was gained after 12 October 2014 (see Art. 25*d* NCHA). If the utilisation of traditional knowledge relating to genetic resources pursuant to Article 23*p* NCHA is involved, the obligation to notify according to Article 4 is similarly applicable. If the use of a genetic resource from Switzerland pursuant to Art. 8 NagO is involved, evidence that the obligation to notify has been met is to be provided once Art. 8 NagO has taken effect from 1 January 2017. Further information on the Nagoya Protocol and its implementation in Switzerland can be found on the website of the responsible authority and the National Focal Point for the Nagoya protocol at the FOEN.		

2.5.15 Information on combination products (medicinal products with a medical device component)

No.	Subject	Requirement	C / O	Exceptions
2.5.15.1	Requirements pertaining to the documentation on the medical device (MedD) component of a combination product	In general, a distinction is made between combination products with **non-separable** MedD components according to Art. 2 para. 1 let. f MedDo (SR 812.213) and those with a **separate** MedD component. Here the **non-separable** combination is understood to be a physically inseparable unit (described in the EMA Guideline *Quality documentation for medicinal products when used with a medical device*, EMA/CHMP/QWP/BWP/259165/2019 as ***integral***) or as having use-specific non-separability (described in the EMA Guideline as ***co-packaged***). In the case of **separable** combinations (described in the EMA Guideline as ***referenced***), the MedD component is not co-packaged with the human medicinal product. However, the medicinal product refers to a specific MedD for combined use. It must be indicated using check boxes in section 6.7 of the form *New authorisation of human medicinal products* and section 5.6 of the form *Variations and Extensions HMP* whether the product is a combination product, and if so, what type of combination it is. Depending on the type of combination, the following requirements apply: a) **Non-separable**, physical unit, ***integral***: MedD **with CE marking**: If the MedD component has a CE mark showing it meets the conformity requirements, the corresponding declaration of conformity from the medical device manufacturer must be provided in module 3.2.R. For MedD components with a CE mark in the **higher risk classes** Im, Is, Irsi, IIa, IIb and III, a certification from one of the designated conformity assessment bodies (EC certificate, CE mark with 4-digit identification number from the conformity assessment body) must also be provided in module 3.2.R. MedD **without CE marking**: If the MedD component does not have a CE mark, it must be demonstrated in module 3.2.R that it satisfies the applicable basic safety and performance requirements in Annex I of the	C	Does not apply to veterinary medicinal products

No.	Subject	Requirement	C / O	Exceptions
		new MDR. For MedD components without a CE mark in the higher risk classes Im, Is, IIa, IIb and III, in keeping with Art. 117 MDR a Notified Body Opinion must also be provided in module 3.2.R. b) **Non-separable combination**, use-specific non-separability, ***co-packaged*** In line with the EMA requirements, additional proof of meeting the MedD requirements, its proposed purpose, use and the associated risks are required to assess combinations with use-specific non-separability (*co-packaged*). Combinations with use-specific non-separability (*co-packaged*) must therefore be **CE marked**. However, the details of the manufacturer, authorised representative and importer of the MedD do not need to be included on the labelling as the authorisation holder bears full responsibility for the combination product approved under medicinal product legislation. The suitability of the MedD components with the specific human medicinal product must also subsequently be demonstrated for both types of non-separable combination (*integral* and *co-packaged*). The requirements in this regard (data and dossier file storage) can be found in the EMA guideline on combination products (*Quality documentation for medicinal products when use with a medical device*, EMA/CHMP/QWP/BWP/259165/2019). c) **Separable combination, *referenced:*** MedD components of separable combinations must meet the conformity requirements according to Art. 1 para. 3 let. b MedDO ("CE labelling"). In addition, the corresponding declaration of conformity from the medical device manufacturer must be provided in module 3.2.R. For medical device components in the **higher risk classes** Im, Is, Irsi, IIa, IIb and III, a certification from one of the designated conformity assessment bodies (EC certificate, CE mark with 4-digit identification number from the conformity assessment body) must also be provided in module 3.2.R. The suitability of the medical device component in this combination with the specific medicinal product must also be demonstrated. The requirements in this regard (data and dossier file storage) can be found in the EMA guideline on combination products (*Quality documentation for medicinal products when used with a medical device*, EMA/CHMP/QWP/BWP/259165/2019).		
		*Please note: All documents required for the MedD components of a non-separable combination product (with a MedD component Im, Is, Ir; IIa, IIb or III; NBOp or certificate of conformity to be issued by the notified body) should always be present when submitting the application. Due to expected bottlenecks at the certification bodies, the applicant can agree a later submission date with Swissmedic, but this should not delay the approval process for a new authorisation or variation (with the exception of type IB or type IA/IAIN variation applications to be approved in advance or after the fact). This later submission date must be set out in the cover letter, stating the binding timescale, and substantiated with corresponding documentation from the certification body. Since products submitted to Swissmedic for approval that have received the official decision which concludes the approval process are directly marketable, all documents relevant to the approval must be present and can be checked before this official decision is issued.*		

2.6 Modules 2-5

2.6.1 List of contents and labelling of binders for paper submissions

No.	Subject	Requirement	C / O	Exceptions
2.6.1.1	Contents	To be submitted for all paper submissions, for the documentation supplied (Modules 2-5) The *Overall CTD Table of Contents* (Section 2.1) is the table of contents for the entire CTD (Modules 2–5) Each module has its own list of contents The level of detail of the list of contents is defined in the *Granularity Document* (Annex to the ICH document *Organisation of The Common Technical Document for the Registration of Pharmaceuticals for Human Use M4*)	C	
2.6.1.2	Labelling of the binders	Labelling on the binder spines: ▪ Name of the medicinal product ▪ If available: Authorisation no. ▪ Module concerned by the documentation ▪ Separate numbering of all volumes per module or for all volumes within the entire documentation (always stating the total number of binders) ▪ If appropriate, reference numbers and / or page numbers ▪ Applicant	C	
2.6.1.3	List of contents of the binders	The individual studies must be separated using the cover sheets provided by Swissmedic. If there are several binders for a single study, the cover sheet for the first binder must be placed at the top of every subsequent binder. Every binder must contain a list of contents. An overall list of contents of the studies must be submitted. It must show exactly which pages are contained in each binder, e.g. *Study xyz, binder 3, pages 632 to 895.* Voluminous annexes should be given their own list of contents. Cover sheets must be included in every binder, as described above.	C	

Documentation sent to Swissmedic spontaneously that does not fall within the framework of an application will be returned to the authorisation holder, at the expense of the latter (e.g. update to Module 3).

2.6.2 References

No.	Subject	Requirement	C / O	Exceptions
2.6.2.1	Extent of cross-referencing	A fundamental concept regarding the CTD is to avoid repeating information that is presented in Modules 3, 4 and 5 in the summaries and overviews of Module 2. For that reason, comprehensive cross-referencing of the documents in Module 2 to the other parts of the CTD, in accordance with the ICH guidelines, is mandatory	C	
2.6.2.2	Type of cross-referencing	The use of the CTD/NTA chapter numbers ("cross strings" according to the ICH) serves as the basis for the cross referencing Chapter numbers should be expanded in line with the ICH guidelines by the insertion of a short additional text, e.g. stating the volume, the page numbers or "see study xyz"	O	

No.	Subject	Requirement	C / O	Exceptions
2.6.2.3	Referencing in Modules 3.3; 4.3; 5.4 (references to literature)	▪ The references must be numbered consecutively ▪ A list of contents must be submitted, and must state the exact binder for each reference and its number, e.g. Binder 2, references 38 to 89 Reference 38: Müller et al, title, etc. (pages within this reference 1 to 13) reference 39: Wang et al, title, etc. (pages within this reference 1 to 45). ▪ If several binders are used for the references, the cover sheet for the first binder must also be inserted at the top of each binder. ▪ Every binder must also contain a list of contents for the references that are contained in it. ▪ In the information for healthcare professionals / patients, reference must be made to the corresponding module, the reference number, the page number and the binder number (e.g. Module 5.4, reference 22, page 5, binder 2)		
2.6.2.4	References to literature in the overviews for Module 2	The references contained in the overviews (Modules 2.3–2.5) constitute an integral part of the submission and must be submitted in the corresponding modules. For eCTD applications, the references must be linked either from the body text or from the list of references in the overviews.		

A formal objection will be issued for referencing that cannot be found, that is incorrect or that is not sufficiently comprehensive. Furthermore, referencing must not be based on a complex cascade structure with various lists of contents (more than two intermediate steps).

2.7 Answers to communications from Swissmedic during the ongoing application process

No.	Subject	Requirement	C / O	Exceptions
2.7.1	Cover letter	Must always be included.	C	
2.7.2	Complete submission	Missing documents will be requested by Swissmedic. The processing of the application will only continue once Swissmedic has received all the documents it has requested, plus any test samples it may have requested. Replies to the List of Questions: If no complete answer or no justified written application for the time limit to be extended is received by the date stated in the List of Questions, the corresponding questions are considered to be unanswered. Under certain circumstances, this may lead to a negative preliminary decision or a negative official decision, and costs will be applied.	C	
2.7.3	Statement / Answer to the preliminary decision	The conditions imposed in the preliminary decision must be fulfilled within the time limit specified and submitted collectively.	C	

3 Special requirements

3.1 Company meetings

The requirements set out in the form *Company meetings* and the guidance document *Meetings for applicants held with the Authorisation sector* must be observed.

3.2 Recognition of important medicinal product status

3.2.1 Recognition of orphan drug status (ODS) for human medicinal products

No.	Subject	Requirement	C / O	Exceptions
3.2.1.1	General	The applicant must at least have a delivery and an invoice address in Switzerland. A separate application for ODS recognition must be submitted for each individual orphan indication.	C	

3.2.2 Recognition of MUMS status for veterinary medicines

No.	Subject	Requirement	C / O	Exceptions
3.2.2.1	General	The applicant must at least have a delivery and an invoice address in Switzerland. Minor use: a separate application for recognition must be submitted for each individual indication. Minor species: for the treatment of animal species or categories other than cattle, pigs, horses, dogs, cats, sheep (not including milk ewes) and poultry (not including laying hens)	C	

3.3 Application for temporary authorisation (tempA/tempAI HAM)

No.	Subject	Requirement	C / O	Exceptions
3.3.1	Cover letter (in addition to the requirements in section 2.5.1 “Cover letter”)	Mandatory as of 1 Apr. 2021: “Application for an AAA for an authorisation procedure in connection with a temporary authorisation (tempA/tempAI)”.Mention authorisation applications or any questions or decisions on the part of other authorities, if applicable. see also: VZ *Overview of documents to be submitted* and guidance document *Temporary authorisation of human medicinal products.* The decision minutes on the AAA should be submitted as a Word file.	C	

3.4 Request for fast-track procedure for human medicinal products

No.	Subject	Requirement	C / O	Exceptions
3.4.1	Cover letter (in addition to the requirements in section 2.5.1 “Cover letter”)	“Application for an AAA for a fast-track procedure (FTP)” Mention authorisation applications or any questions or decisions on the part of other authorities, if applicable see also: VZ *Overview of documents to be submitted* and guidance document *Fast-track authorisation procedure.*	C	

No.	Subject	Requirement	C / O	Exceptions
		The decision minutes on the AAA should be submitted as a Word file.		

3.5 Request for procedure with prior notification for human medicinal products

No.	Subject	Requirement	C / O	Exceptions
3.5.1	Cover letter (in addition to the requirements in section 2.5.1 "Cover letter")	Possible date for the Pre-submission Meeting or reason why this is not considered necessary. Planned submission date for the test eCTD sequence (if applicable) Planned date of the actual submission of the application (state within a time frame of +/- 2 calendar weeks)	C	
3.5.2	Timing of request	To be submitted in writing, at the earliest 6 months and at the latest 3 months prior to the planned submission of the application.	C	

A procedure with prior notification can only be carried out if the authorisation application is subsequently submitted in the CTD format, via Portal, as an eCTD application or as a paper version with an eDok copy.

If a submission in eCTD format is planned, it is strongly recommended that applicants with no or limited experience of eCTD submit a test sequence at least 3 weeks prior to submitting their application. In that way, it is possible to avoid the risk of exceeding time limits as a result of technical shortcomings.

3.6 Authorisation of new active substances

No.	Subject	Requirement	C / O	Exceptions
3.6.1	Cover letter (in addition to the requirements in section 2.5.1 "Cover letter")	Short presentation of the clinical trials conducted and, if applicable, of the pharmaceutical characteristics and the manufacturing processes.		
3.6.2	Modules 2-5/ Parts Ic to IV	See the Guidance document *Authorisation of human medicinal product with new active substance* and Guidance document *Authorisation of veterinary medicinal products*	C	

3.7 New authorisation KAS

No.	Subject	Requirement	C / O	Exceptions
3.7.1	Cover letter (in addition to the requirements in section 2.5.1 "Cover letter")	Short presentation of the clinical trials conducted and, if applicable, of the pharmaceutical characteristics and the manufacturing processes.	C	
3.7.2	Timing of submission	The application may not be submitted more than two years before document protection expires.	C	
3.7.3	Modules 2-5/ Parts Ic-IV	See the Guidance document *Authorisation of human medicinal product with known active pharmaceutical substance* and Guidance document *Authorisation of veterinary medicinal product with known API*	C	

3.8 Similar biological medicinal products (biosimilars) – human medicinal products only

No.	Subject	Requirement	C / O	Exceptions
3.8.1	Cover letter (in addition to the requirements in section 2.5.1 "Cover letter")	▪ Justification for requesting an authorisation process in accordance with Guidance document *Authorisation biosimilar.* ▪ Short presentation of the clinical trials conducted and, if applicable, of the pharmaceutical characteristics and the manufacturing processes. ▪ State where the comparability studies between the biosimilar and the comparator product can be found in the documentation ▪ Justification of the divergence if the dosage form, dosage strength and / or the excipients of the biosimilar are different from those for the reference product ▪ Demonstrate the suitability of foreign comparator products according to section 5.4 of the Guidance document *Authorisation Biosimilar.*	C	
3.8.2	Modules 2-5	▪ See the Guidance document *Authorisation Biosimilar*	C	

3.9 Applications under Article 13 TPA

No.	Subject	Requirement	C / O	Exceptions
3.9.1	Cover letter (in addition to the requirements in section 2.5.1 "Cover letter")	Note if specific requirements are foreseen for implementing the spontaneous recording of suspected adverse drug reactions in Switzerland (e.g. special questionnaires within the framework of enhanced pharmacovigilance)	C	
3.9.2	Documentation to be submitted for human medicinal products	The complete documentation in CTD format (Modules 2-5 plus the country-specific Module 1) or NTA format (Parts I-IV), as it was submitted to the reference authority. Results of the assessment by the reference authority, including additional documentation (final assessment report and additional test results). RMP: In the Switzerland-specific module 1.8.2, the current RMP must be submitted for first applications for authorisation of medicinal products with at least one new active substance (NAS) and applications for authorisation of a new indication for such medicinal products. This also applies to medicinal products that cannot be authorised under the simplified procedure according to Art. 12 para. 5 let. a-e TPLO. Biosimilars are not required to include an RMP.	C	
3.9.3	Documentation to be submitted for veterinary medicinal products	The complete documentation (Parts I-IV), as it was submitted to the reference authority. All documents and assessment results issued while the procedure abroad was in progress (List of Questions plus responses, assessment reports, decisions etc.) must be submitted under Part 1a3. Documents relating to post-approval variations (if any) should also be submitted under Part 1a3.	C	

3.10 Submissions according to Art. 14 para. 1 let. a$^{bis-quater}$ TPA

No.	Subject	Requirement	C / O	Exceptions
3.10.1	Documents to be submitted	See guidance document *Authorisation in accordance with Art. 14 para. 1 let. a$^{bis-quater}$ TPA* and the *Overview of documents to be submitted*	C	

3.11 Co-marketing medicinal products

No.	Subject	Requirement	C / O	Exceptions
3.11.1	Cover letter (in addition to the requirements in section 2.5.1 "Cover letter")	Name and authorisation of the basic preparation and any admissible differences compared to the basic preparation	C	
3.11.2	Conversion of a co-marketing authorisation into a stand-alone authorisation – Variation A.106 (HMP) or E.103 (VMP)	▪ Submission of a complete and identical set of documentation, i.e. the entire life cycle of the basic product must be submitted in chronological order including labelling/designation of the previous submission date and module. Alternatively, if there is a relevant declaration of consent from the authorisation holder of the basic product, only the actually approved documentation (Module 2-5) and any forms to be amended from Module 1 can be submitted. Confirmation from the authorisation holder for the co-marketing medicinal product that no changes have been made to the previous version – except the forms to be updated – should then also be submitted for Module 1. If the authorisation holder for the existing basic medicinal product dispenses with authorisation, its documentation can also be transferred to the existing co-marketing medicinal product. ▪ If the authorisation documentation exists in eCTD format, the affected modules must always be submitted as a new eCTD sequence. ▪ Confirmation that the documentation submitted is identical to that for the basic product (including any additional material that was approved in the meantime). Alternatively: Submission of a declaration of consent from the authorisation holder of the basic product to Swissmedic, stating that the latter will include the scientific documentation for the files in the procedure concerning conversion of the co-marketing medicinal product to a separate authorisation. ▪ Confirmation that the authorisation holder has at its disposal all the documents it requires to fulfil its healthcare-related responsibilities, and accepts all the obligations associated with the authorisation of a stand-alone medicinal product.	C	
3.11.3	Conversion of a stand-alone authorisation into a co-marketing authorisation and vice versa (status change) – Variation A.107 (HMP) or E.104 (VMP)	Declaration of consent to the status change from both the holder of authorisation for the co-marketing medicinal product and the holder of authorisation for the basic product (see form *Authorisation for co-marketing of medicinal product*). Concerning the new basic product: ▪ The holder of authorisation for the current basic product can give its written consent to the documentation in Swissmedic's possession being formally transferred to the current co-marketing medicinal product. ▪ If the authorisation documentation exists in eCTD format, the affected modules must always be submitted as a new eCTD sequence.		

No.	Subject	Requirement	C / O	Exceptions
		Concerning the new co-marketing medicinal product: ▪ Module 1, as for new submission for a co-marketing medicinal product.		

An application for the conversion of a stand-alone authorisation into a co-marketing authorisation (A.107 or E.104) may only be submitted if a simultaneous application for the conversion of the existing co-marketing MP into a stand-alone authorisation is also submitted (A.106 or E.103). The basic medicinal product thus switches its status with that of the co-marketing MP ("role reversal").

*Concerns section 3.11.2 where a complete and identical document set is submitted as an **eDOK**. All the documentation should be submitted in a single eDOK. The marketing authorisation holder should create the folders for the "historic" documents at the lowest level of the eDOK structure..*
The folder names should include the year, month and type of submission as follows::

- *Definition of date format: YYYY_MM_DD*
- *Definition of type of submission: Free text, the marketing authorisation holder decides how the variation is described*
- *Example: 2021_03_01_var-type1b*

The documents can then be filed in this folder.

- *Note: Paths should not be too long (maximum 180 characters)*

Concerns section 3.11.2 where an identical document set is submitted as an eCTD. The current eCTD of the basic medicinal product should be submitted as a separate eCTD to act as a "reference dossier". Please also see the relevant information sheets.

- *When submitting via the Portal, option "Art. 13" is selected. A "reference dossier" can then be submitted in accordance with the requirements for Portal use. Please also see the relevant information sheets.*

3.12 Variations and extensions

No.	Subject	Requirement	C / O	Exceptions
3.12.1	Submission of the form *Variations and extensions HMP* / Submission of the form *Variations VMP*	**Submission of a variation application:** A form consisting of the administrative part (sections 1-7) plus the corresponding variation template. e.g. HMP: B.II.b.1 with the requested variation (B.II.b.1.a "Secondary packaging site"). e.g. VMP: B.21 (Variation of secondary packaging site without assessment) or F.II.b.1 a-z (Variation of manufacturing site with assessment). **Submission of a multiple application:** A form consisting of the administrative part (sections 1-7) plus the corresponding variation templates. e.g. HMP:. twice B.II.b.1 with the requested variations (B.II.b.1.a "Secondary packaging site" and B.II.b.1.b "Primary packaging site"). VMP: as for HMP. **Submission of a collective application:** A form consisting of the administrative part (sections 1-7) plus the corresponding variation template. e.g. HMP: B.II.b.1 with the requested variation (e.g. B.II.b.1.a "Secondary packaging site"). In the administrative part, the table under section 1 (Basic information) must be reproduced and completed according to the number of authorisation numbers/medicinal products concerned. If additional forms have to be submitted (e.g. form *Manufacturer information*), the forms listed in section 4 (Additional forms to be submitted) should be submitted for each medicinal product concerned. Extensions cannot be submitted as a collective application. VMP: as for HMP.	C	

No.	Subject	Requirement	C / O	Exceptions
		Submission of a collective-multiple application: A form consisting of the administrative part (sections 1-7), where the table under section 1 (Basic information) was reproduced and completed according to the number of authorisation numbers/medicinal products concerned, plus the corresponding variation templates. (e.g. HMP: B.I.b.1 and B.I.b.2 with the requested variations (e.g. B.I.b.1.b "Tightening of specification limits" and B.I.b.2.a "Minor change to an approved test procedure"). If additional forms have to be submitted, the forms listed in section 4 (Additional forms to be submitted) should be submitted for each medicinal product concerned. VMP: as for HMP		
3.12.2	Completion of the form *Variations and extensions* / Submission of the form *Variations VMP*	The conditions to be fulfilled and documentation to be submitted for the requested variation must be confirmed by ticking the checkbox. An implementation date must always be given for type IA and IA_{IN} variations (HMP) and variations without assessment (VMP). This date must be in the past and must be provided in the format “DD.MM.YYYY”. The text fields "Scope / justification for the change" and "Present / Proposed" must be completed. It is not sufficient simply to refer to the documentation or the company's internal codes. If needed, a table can also be copied into the text fields. Variation templates that are not required should be omitted. Further information can be found in the guidance document *Variations and extensions HMP* or guidance document *Variations VMP*	C	If type IA/IA_{IN} variations (HMP) are part of a multiple application that includes type IB or II variations and/or extensions (HMP) or variations without assessment (VMP) are part of a multiple application that includes variations with assessment (VMP), there is no need to provide an implementation date and the variations do not have to be already implemented.
3.12.3	"Other variation"	The templates for "Other variation" can be found in the *Variations and extensions HMP* form under the individual variations (e.g. B.I.a.1.z) and at the end of section A Regulatory changes (A.z Other regulatory change), at the end of section B. Quality changes (B.z. Other quality change) or at the end of section C. Safety, efficacy and pharmacovigilance changes (C.I.z Other change relating to safety, efficacy and pharmacovigilance). The form *Variations VMP* includes, where relevant, the template “Other variation time limit’ “Reduced” in the individual variation templates and at the end of the individual sections E, F and G. Templates with time limit “Standard” are also included at the end of each section. The templates for "Other variation" may be used only if the requested variation is not included in the list of variations.	C	
3.12.4	Updating the documentation	Updates to the documentation (e.g. Module 3/Part II) may be submitted only in connection with one or more variation applications. Every variation should be identified and submitted as a type IA/IA_{IN}, type IB and/or type II variation (HMP) or as a variation with or without assessment (VMP). Documents submitted spontaneously or updates without an application for a variation will be returned to the applicant at the latter's expense.	C	
3.12.5	Editorial changes	Editorial changes to Module 3/Part II (incl. additions such as adding validation documents without changes to the test method, updated stability results or change to the shelf life or retest period) are not variations. Therefore, proceed as follows: If an updated Module 3/Part II comprises a type II (HMP) variation or a variation with assessment (VMP) and several independent editorial changes, for example, the variation must be submitted with the form *Variations and extensions HMP* or form *Variations VMP*, and the editorial changes must be indicated under "Present / Proposed".	C	

No.	Subject	Requirement	C / O	Exceptions
		If an updated Module 3/Part II consists purely of editorial changes, these changes can be submitted as “Other changes” B.z, type IA (HMP) or variation without assessment (VMP).		
3.12.6	Documentation for Collective applications	▪ The documentation for collective applications in paper format does not need to be submitted separately for each authorisation, but only once (1 original/1 copy). For collective applications in eCTD format, the documentation should be submitted individually for each medicinal product. ▪ Hybrid collective applications comprising both human and veterinary medicinal products are not admissible. If both human and veterinary medicinal products are affected, two separate (collective) applications must be submitted	C	
3.12.7	Number of variations per variation no.:	Attention must be paid to the precise wording (i.e. singular or plural) of a variation in the forms *Variations and extensions HMP* and *Variation VMP*. For example: the variation B.I.b.2.a ("Minor changes to an approved test procedure" (for an HMP)) or B.12.a) (Minor change to an approved test procedure (for a VMP) applies to the variations to one test procedure only. If, for example, the test procedures for (1) identification using mass spectrometry, (2) impurities using HPLC and (3) bacterial endotoxins using the kinetic-turbidimetric method undergo minor changes, variation B.I.b.2.a) (HMP) or V.12 a) (VMP) must be submitted three times.	C	
3.12.8	Multiple variations relating to the same quality variation template (HMP: section B; VMP: section F, Quality changes requiring assessment)	Multiple variations relating to the same quality variation template may be submitted as a single type II variation (HMP: z – change in the respective variation template, VMP: z – change, time limit “Standard”). The precondition is that all changed parameters be set out in detail in the “Present” / "Proposed” list. For VMP variations, the number of the variation template to which all variations relate should also be listed under Description of/justification for the variation. Example HMP: Several specifications for the finished product have to be changed (variation template B.II.d.1): three specification limits are to be tightened up (3x type IA variations B.II.d.1.a), one new specification parameter is to be added (1x type IA variation B.II.d.1.c) and one specification parameter is to be deleted (1x type IB variation B.II.d.1.d) while two variations are outside the authorised range of specification limit values (2x type II variations B.II.d.1.e). In this case it is permissible to submit a single type II variation B.II.d.1.z, though all changed parameters and specification limit values must be set out in detail in the “Present” / "Proposed” list. VMP: Submission as described for HMP, but under template “F.z Other quality variation”, with reference to the variation template (see above) to which the variations relate (e.g. “F.II.d.1 Variation of specification parameters and/or limits of the finished product”).	O	Excepted from this rule is a change of active substance manufacturer (template B.I.a.1).

Pages with variation templates that are not the subject of the application must be deleted prior to submission to Swissmedic. If this is not done, Swissmedic will raise a formal objection to the application.

If several variations involving the same variation template are requested in a multiple application, the template should be reproduced by the applicant on the Variations and extensions form according to the number of variations.

Example: a secondary packaging site (B.II.b.1.a), a primary packaging site (B.II.b.1.b), and a new manufacturing site for non-sterile medicinal products (B.II.b.1.e) are requested. A separate template B.II.b.1 must be completed for each variation (3 copies of template B.II.b.1). The form therefore includes the same variation template three times, with one of the requested variations checked on each separate template. The three variations may not be checked on a single template.

In the case of type IA variations, there must be a gap of no more than 12 months between the implementation date and date of notification to Swissmedic.

In the case of type IA_{IN} variations (HMP), there must be a gap of no more than one month, and in the case of variations without assessment (VMP), there must be a gap of no more than 60 calendar days between the implementation date and date of notification to Swissmedic.

3.13 Conditions imposed by Quality Assessment, Nonclinical Assessment and Clinical Assessment

No.	Subject	Requirement	C / O	Exceptions
3.13.1	Cover letter	Indication of which type of condition is required (condition imposed by Quality Assessment, Nonclinical Assessment or Clinical Assessment). Wording of the condition imposed by the official decision. ID of the application for which the condition was imposed.	-	

The fulfilment of a condition imposed in respect of a collective application can be requested as a collective application.

The fulfilment of conditions should always be submitted separately and not together with other applications, e.g. variations in quality.

Swissmedic will assess whether conditions have been fulfilled in accordance with the decision letter separately and invoice them separately.

3.14 Renewal, non-renewal, no marketing and interruption to distribution

3.14.1 Renewal and non-renewal

No.	Subject	Requirement	C / O	Exceptions
3.14.1.1	Regular renewal	In accordance with the regulatory time limit specified in *Art. 12 para. 1 TPO*, the application must be received by Swissmedic at the latest 6 months before the authorisation expires. Renewal applications submitted too late will not be admitted. Furthermore, the application must not be submitted sooner than one year before the authorisation expires.	C	Does not apply to the renewal of a temporary authorisation.
3.14.1.2	Application for renewed authorisation	Submission of the administrative documents for Module 1 in accordance with the Directory *Overview Documents to be submitted* with the	C	

No.	Subject	Requirement	C / O	Exceptions
		confirmation that all the information is in line with that for the product concerned		

If no application for renewal is submitted to Swissmedic before six months prior to the expiry of the authorisation, an official decision is issued to cancel the authorisation for the medicinal product once the current authorisation period expires. The deletion will be published automatically in the Swissmedic Journal.

If the authorisation holder has missed the deadline for submitting the application for renewal, it may apply for renewed authorisation of the medicinal product provided the authorisation has not yet expired.

The renewed authorisation will be published in the Swissmedic Journal the month after the authorisation decision has been issued, accompanied by the comment "Renewed authorisation following expiry of the authorisation".

Even application for renewed authorisation will not always prevent an interruption in the marketable status of the medicinal product concerned. This will only be possible if Swissmedic has sufficient time to review the above-mentioned documents.

Renewals cannot be submitted as a collective application.

3.14.2 Discontinuation of authorised medicinal products

No.	Subject	Requirement	C / O	Exceptions
3.14.2.1	Discontinuation of medicinal product (notification)	If eCTD: new eCTD sequence	C	
3.14.2.2	Discontinuation of medicinal product with deferred withdrawal (application)	Only for medicinal products distributed in Switzerland, i.e. not possible for "export authorisations". Maximum deferral period that can be applied for: 1 year (not beyond the expiry date of the authorisation certificate). If eCTD: new eCTD sequence	C	
3.14.2.3	Cover letter for discontinuation of medicinal product with deferred withdrawal (in addition to the requirements in section 2.5.1 “Cover letter”)	Justification for discontinuation with deferred withdrawal	C	

In the case of collective medicinal product information texts, a type IB C.1.7.a) (HMP) minor variation requiring notification in advance or a variation without assessment B.3 v) (VMP) must be submitted for the medicinal product not concerned by the discontinuation at the same time.

3.14.3 Discontinuation of dosage strength number

No.	Subject	Requirement	C / O	Exceptions
	(None)	-	-	

If the entire dosage strength number is being deleted as part of the discontinuation of the pack size, this is not a nAE IA discontinuation of pack size A.103 application type, but must be submitted as an AE IB deletion of dosage strength C.I.7 b) (HMP).

If the cover letter concerns the discontinuation of several dosage strength numbers at once, this must be considered as an application

3.14.4 Notification in accordance with Art. 11 TPO: No marketing / interruption to marketing and Placing on the market / Renewed placing on the market

	Subject	Requirement	C / O	Exceptions
	(None)			

3.15 Complementary medicinal products: Reduced dossiers

No.	Subject	Requirement	C / O	Exceptions
3.15.1	Renewal of the authorisation	▪ See the Guidance document *Renewal and discontinuation of authorisation on change of status(main authorisation/export licence)* ▪ Additional documents: Form *Full declaration.*	C	

See the Guidance document *Simplified information requirements on the Manufacturer Information form for the reduced dossier*

See the Guidance document *Authorisation of Homeopathics, anthroposophics and other complementary medicinal products*

3.16 Complementary medicinal products: notification procedure HOMANT

No.	Subject	Requirement	C / O	Exceptions
3.16.1	Criteria for application of the notification procedure	See the Guidance document *Authorisation for homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy without indication in the notification procedure*	C	
3.16.2	Entering of data and labelling the CD-ROM	See the HOMANT user manual Offline	C	
3.16.3	Modification of basic company dossiers and master dossiers	See the Guidance document *Variations and extensions* and Guidance document *Authorisation for homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy without indication in the notification procedure*.		
3.16.4	Extension and no extension	▪ See the Guidance document *Renewal and discontinuation of authorisation on change of status (main authorisation/export licence)* ▪ Applications must be submitted at the earliest 1 year and at the latest 6 months prior to the expiry of the authorisation ▪ Completed form *Renewal of authorisation by notification procedure homeopathic and anthroposophic medicinal products* incl. number of the products to be extended and the number of products to be discontinued. ▪ Additional documents: A copy of the official authorisation decision with a list of the authorised medicinal products (as an annex) must be submitted with each application. The applicant should delete from this list those medicinal products for which authorisation renewal is **not** required (discontinuation of the renewal). The deletions should additionally be highlighted using coloured markings to make them easier to find. All documents should be stamped by the marketing authorisation holder.	C	

No.	Subject	Requirement	C / O	Exceptions
3.16.5	Discontinuation of medicinal product (notification)	▪ See the Guidance document *Renewal and discontinuation of authorisation on change of status (main authorisation/export licence)* ▪ Additional documents: A copy of the official authorisation decision with a list of the authorised medicinal products (as an annex) must be submitted with each application. The applicant should delete from this list those medicinal products for which authorisation renewal is **not** required (discontinuation of the renewal). The deletions should additionally be highlighted using coloured markings to make them easier to find. All documents should be stamped by the marketing authorisation holder.	C	
3.16.6	Discontinuation of medicinal product with deferred withdrawal (application)	▪ See the Guidance document *Renewal and discontinuation of authorisation on change of status (main authorisation/export licence)* ▪ Cover letter with justification ▪ Additional documents: A copy of the official authorisation decision with a list of the authorised medicinal products (as an annex) must be submitted with each application. The applicant should delete from this list those medicinal products for which authorisation renewal is **not** required (discontinuation of the renewal). The deletions should additionally be highlighted using coloured markings to make them easier to find. All documents should be stamped by the marketing authorisation holder. ▪ Maximum deferral period that can be applied for: 1 year (not beyond the expiry date of the product). The delay must be the same for all medicinal products in the application.	C	

Authorisation holders are responsible for submitting applications for renewal within the time limit. Swissmedic does not issue reminders.

Renewals cannot be submitted as a collective application.

If no application for renewal is submitted to Swissmedic before six months prior to the expiry of the authorisation, an official decision is issued to cancel the authorisation for the medicinal product once the current authorisation period expires. Deletion appears in the list "Homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy without an indication for which authorisation has been discontinued by the notification procedure in accordance with the KPTPO".

If the authorisation holder has missed the deadline for submitting the application for renewal, it may apply for renewed authorisation of the medicinal product provided the authorisation has not yet expired.

Once the official decision has been issued, the renewed authorisation is published in the list ***"Homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy without an indication authorised by the notification procedure in accordance with the KPTPO"****.*

Even application for renewed authorisation will not always prevent an interruption in the marketable status of the medicinal product concerned. This will only be possible if Swissmedic has sufficient time to review the above-mentioned documents.

3.17 Complementary medicinal products: Asian medicinal products

No.	Subject	Requirement	C / O	Exceptions
	(None)	-	-	

See the Guidance document *Authorisation of Asian medicinal products*

3.18 Authorisation of individual teas, cough and throat lozenges and pastilles in dispensing category E by the notification procedure (human medicinal products only)

No.	Subject	Requirement	C / O	Exceptions
3.18.1	Cover letter for notifications (in addition to the requirements in section 2.5.1 "Cover letter")	The shelf life must be stated in the cover letter as well as the storage instruction, including reasons. Where applicable, for cough and throat lozenges and pastilles the maximum content of essential oils specified per unit must be justified in each case (see Annex 5 KPTPO, section 1.3).	C	
3.18.2	Module 1 for teas	Administrative documents must be submitted, see *Overview of documents to be submitted*	C	
3.18.3	Module 1 for sweets	Administrative documents must be submitted, see *Overview of documents to be submitted* In addition, the flavour manufacturer must submit a detailed, qualitative list of ingredients for the flavours used. Alternatively, the applicant may confirm the absence of substances subject to declaration according to Annex 3 TPLRO. If the medicinal product is promoted as "kind to teeth / tooth-friendly" an expert report by a recognised dental institute must be submitted.	C	
3.18.4	Basic company dossier	An approved basic company dossier is required for a new authorisation in the notification procedure. The documents to be submitted are listed in the *Overview of documents to be submitted*. For changes that affect the basic company dossier, a cover letter listing the requested change must be submitted together with the documents specified in the *Overview of documents to be submitted*.		
3.18.5	Cover letter for basic company dossier	For changes that affect the basic company dossier, the reason for the requested change must be given in the cover letter.		

3.19 Authorisation / variations, veterinary medicinal products by the notification procedure in accordance with Art. 39, TPLO / Art. 22, TPO

No.	Subject	Requirement	C / O	Exceptions
	(None)	▪ -	-	

The time limits are those stipulated in the guidance document *Notification procedure for veterinary medicinal products*.

Note the form New authorisation by notification procedure veterinary medicinal products

3.20 Market surveillance

3.20.1 PSUR/PBRER:

No.	Subject	Requirement	C / O	Exceptions
	(None)	-	-	

In connection with PSUR/PBRER submissions, RMP updates may be submitted. An RMP update is called for if new findings require changes to the safety concerns, to pharmacovigilance activities or to risk-mitigation measures (see Guidance document "RMP ICH E2E Information submission" HMP).

If an RMP update is submitted, the appropriate box must be checked in the PSUR/PBRE form.

For veterinary medicinal products, no PSUR/PBRER form is required.

3.20.2 Advertising permit

No.	Subject	Requirement	C / O	Exceptions
	(None)	-	-	

One copy in paper form must be submitted with the advertising (e.g. advertisements or storyboards, etc.).

The definitive version of electronic media should always be submitted on a CD/DVD.

3.21 DMF/ASMF and Plasma Master Files

3.21.1 DMF/ASMF

No.	Subject	Requirement	C / O	Exceptions
3.21.1.1	General	The Applicant's Part of the DMF/ASMF must be submitted in Module 3 of the CTD format for human medicinal products and Part II of the NTA format for veterinary medicinal products. The entire DMF (Applicant's and Restricted Part) must also be submitted separately. The authorisation holder is responsible for ensuring that the manufacturer of the active substance submits the currently valid version of the DMF / ASMF (Applicant's Part and Restricted Part) synchronously with the authorisation application (see instructions). The formal control of authorisation documentation can only be completed if the full DMF/ASMF (Applicant's Part and Restricted Part) and the Letter of Access and the fully completed form *DMF* are submitted	C	
3.21.1.2	Form *DMF*	Swissmedic will not confirm receipt of the DMF. The form consists of parts A and B. The authorisation holder completes part A and sends a copy of the entire form (parts A and B) to the DMF / ASMF holder. The original, signed by the authorisation holder, is submitted together with each application for first authorisation or variation. The DMF / ASMF holder completes part B. The fully completed, signed form (copy of part A and the part B signed by the DMF/ASMF holder) is submitted	C	

No.	Subject	Requirement	C / O	Exceptions
		directly together with the cover letter, Letter of Access, and the Applicant's Part and Restricted Part of the DMF holder. For applications according to Art. 13 TPA, the final Assessment Report of the Restricted Part, the LoQ and the answers of the DMF holder relating to the Restricted Part should also be submitted.		
3.21.1.3	Letter of Access	The DMF/ASMF must always be accompanied by a Letter of Access from the manufacturer in accordance with Annex 2 of the EU Guideline on Active Substance Master File Procedure. The Letter of Access must contain the name of the medicinal products and the name of the authorisation holder. The Letter of Access must be submitted by both the DMF/ASFM holder (original) and the applicant (copy).	C	
3.21.1.4	CTD	The Applicant's Part should be integrated into part 3.2.S of the authorisation documentation. The authorisation holder's specifications should be inserted in part 3.2.S.4.1. If the active substance is sourced from several manufacturers, the instructions in section 6 of the EU "Guideline on Active Substance Master File Procedure" must be observed. If additional specifications (e.g. particle size) are added to the active substance specification, the test procedure in question must be documented under 3.2.S.4.2. Part 3.2.S.4.4 must document three batch analyses containing the results of any additional testing.	C	

DMF/ASMF may only be submitted in connection with an application for authorisation or variation, an extension or as part of a periodic review procedure.

Swissmedic must receive the DMF/ASMF – including the form DMF (parts A and B), Letter of Access and cover letter –before and no later than three calendar days after it has received the application for first authorisation or application for a variation. If there is no application for a DMF/ASMF, a reminder will be sent to the authorisation holder.

If no application is received within 60 calendar days of the reminder being sent to the authorisation holder, Swissmedic will return the DMF/ASMF at the sender's cost if the DMF/ASMF was sent from Switzerland. If the DMF/ASMF was sent from abroad, it will be disposed of in a controlled manner at the end of the 120 days.

It is only possible to omit the paper copy of the DMF/ASMF documentation if the DMF/ASMF is submitted in eCTD format.

For veterinary medicinal products: Applicants should submit the cover letter and Letter of Access for the DMF under Part 1a4 doc prod quality. The same applies to flow charts on manufacturing (and also to the storage of CEP). The form DMF must be stored in Part 1a5 forms /footer, as must the form *Declaration by the Responsible Person for foreign manufacturers*

3.21.2 Plasma Master Files (PMF; human medicinal products only)

No.	Subject	Requirement	C / O	Exceptions
3.21.2.1	Annual updates and variations	Annual updates to PMF (for the purpose of satisfying conditions of authorisation) should be submitted with an appropriate cover letter for each PMF. Variations to the Plasma Master File (e.g. additional donation centres, change in plasma country of origin, changes in test kits, etc.) must be submitted as the appropriate variation type using the form *Variations and extensions*. For each PMF, the variation application is submitted for one or more PMF variations according to the highest category (type II, IB, IA/IA$_{IN}$) according to the classification in the European Guideline under point "B.V.a.1 PMF / VAMF" or "D. PMF / VAMF" *(Guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation (EC) No. 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products and on the documentation to be submitted pursuant to those procedures*).	C	

The submission of a PMF annual update is considered to represent compliance with the conditions imposed on an authorisation.

3.22 Special medicinal product types and the corresponding submission

3.22.1 Radiopharmaceuticals

No.	Subject	Requirement	C / O	Exceptions
3.22.1.1	Cover letter (in addition to the requirements in section 2.5.1 "Cover letter")	Name of the active substance or the radionuclide (if possible, use the INN) Area(s) of use in diagnostics and / or treatment. For kits, the marker nuclide must also be stated. Dosage form(s)		
3.22.1.2	Establishment licences	Permit from the Federal Office of Public Health to handle radioactive substances: Copy of the original or the application (see Radiological Protection Ordinance, RPO)	C	
3.22.1.3	Other requirements	Guidance document *Authorisation radiopharmaceutical*		

3.22.2 Allergen products (human medicinal products only)

No.	Subject	Requirement	C / O	Exceptions
3.22.2.1	Cover letter and forms if more than five allergen products are concerned.	If an application concerns more than five allergen products, a list of the allergens – grouped into allergen groups if expedient – must be included. All the necessary forms and the cover letter must be submitted in one copy in this case. The cover letter must mention the list that has additionally been submitted.	C	
3.22.2.2	Modules 2-5	See the Guidance document Authorisation of allergen product		

3.22.3 Antidotes

No.	Subject	Requirement	C / O	Exceptions
3.22.3.1	Module 1	Draft of the information for healthcare professionals and, if appropriate, of the patient information (e.g. for use outside the hospital) Medicinal products manufactured in Switzerland: Drafts texts in accordance with Swiss requirements Medicinal products manufactured abroad: the texts approved abroad (in a national language of Switzerland or in English) Packaging texts Medicinal products manufactured in Switzerland: Drafts texts in accordance with Swiss requirements Medicinal products manufactured abroad: Copies of the texts approved abroad and drafts of the additional adhesive labels (in German and French) that will be placed on the foreign packaging and that show the authorisation number and packaging code, plus the approval mark A, the area of application (short form), the contact data for Tox Info Suisse and the note: "ANTIDOTE: only use in emergencies and with medical supervision. The indication is defined by the professional prescribing this product". Confirmation from Tox Info Suisse stating the average annual figure for cases of intoxication in Switzerland Confirmation from the Military Pharmacy of the Swiss Confederation stating the estimated number of critical cases	C	
3.22.3.2	Module 3	See the Guidance document *Authorisation of antidote*	C	

3.22.4 Medicinal gases

No.	Subject	Requirement	C / O	Exceptions
3.22.4.1	Application documentation	See the Guidance document Authorisation of medicinal gas	-	

3.22.5 Antivenins

No.	Subject	Requirement	C / O	Exceptions
3.22.5.1	Application documentation	See the Guidance document Authorisation of antivenin	C	

3.22.6 Parallel import

No.	Subject	Requirement	C / O	Exceptions
3.22.6.1	Application documentation	▪ GMP/GDP compliance: official licences, GMP/GDP certificates no more than three years old ▪ Foreign manufacturer in the country of export: GDP certificate ▪ Wholesaler: ➢ domiciled in the country of export, GDP certificate from the authority in the country of export. ➢ domiciled in a third country with comparable control of human medicinal products, GDP certificate and licence to source the medicinal product from the	C	

No.	Subject	Requirement	C / O	Exceptions
		country of export from the foreign authority in the third country. ▪ Importer: Licence to import ready-to-use medicinal products or wholesale trading licence. ▪ Creating packaging for Switzerland: For the repackaging company, manufacturing licence and GMP certificate for the repackaging process. If the repackaging company is Swiss, a GMP certificate does not have to be submitted. ▪ Photos of the folding carton and primary container of the sample pack per dosage strength as a PDF file ▪ Information for healthcare professionals and patients in the country of export: in the corresponding language of the country of export (with translation if not in an official Swiss language or English) ▪ Information for healthcare professionals and patients for Switzerland: in an official Swiss language, as a Word file ▪ Packaging texts: Swiss packaging or label per dosage strength as a mock-up in a single file with searchable text (OCR)		
	Sample packs	▪ Two sample packs per dosage strength must be submitted directly to the Swissmedic laboratory (OMCL; delivery conditions: see Guidance document *Import of a human medicinal product according to Art. 14 para. 2 and 3 TPA (parallel import)*; address: see form *Import of a human medicinal product according to Art. 14 para. 2 and 3 TPA (parallel import)*).	C	

Should there be a change to the wholesaler or supplier of the medicinal product imported according to Art. 14 para. 2 and 3 TPA, an updated version of the form "Import of a medicinal product according to Art. 14 para 2 and 3 TPA (parallel import)" must be submitted.

3.22.7 Herbal medicinal product with traditional use

No.	Subject	Requirement	C / O	Exceptions
3.22.7.1	Cover letter (in addition to the requirements in section 2.5.1 "Cover letter")	Brief description of the proof of traditional use Information on the directly comparable herbal medicine		
3.22.7.2	Modules 2-5	Additional requirements, see the Guidance document *Authorisation of herbal medicinal products* (in addition to Module 2.5, the clinical documentation must also include Module 2.7.4 (Summary of Clinical Safety) and Module 5.4 with literature references, and the preclinical documentation must include Module 2.4 (Non Clinical Overview) and Module 4.3 with literature references).	C	

3.22.8 Herbal medicinal product with well-established use

No.	Subject	Requirement	C / O	Exceptions
3.22.8.1	Cover letter (in addition to the requirements in section 2.5.1 “Cover letter”)	Brief description of the proof of well-established use.		
3.22.8.2	Modules 2-5	Additional requirements, see the guidance document Authorisation of herbal medicinal products (in addition to Module 2.5, the clinical documentation must also include Module 2.7.4 (Summary of Clinical Safety) and Module 5.4 with literature references, and the preclinical documentation must include Module 2.4 (Non Clinical Overview) and Module 4.3 with literature references).	C	

Change history

Version	Change	sig
13.6	Clarifications in section 2.5.3 regarding language requirements Changes in section 2.5.15 regarding the submission of the documents required for the MedD components Changes in section 3.22.6 due to revision of Art. 14 para. 3 TPA	ski, nma, hv cho
13.5	Sections 2.5.8, 3.8 and 3.9 revised due to RMP changes.	stb
13.4	HMV4 suffixes removed 3.11 Co-marketing: Clarifications regarding eDOK and eCTD. 3.12 Variations and authorisation extensions (end of section): Correction to the submissions deadline for variations without assessment (VMP) following implementation: previously max. 1 month, now max. 60 calendar days.	ski/dsc/vy/mra/stb
13.3	New layout, no content adjustments to the previous version.	dei
13.2	Section 3.11 – Co-marketing: Clarification of documentation to be submitted Section 3.1.3 – Under the revised FeeO-Swissmedic, conditions can now be the subject of collective applications Section 3.21.1.4 – Correction: section 6 instead of section 4	ski/vy/dsc/stb
13.1	Section 2.5.15 – Combination products: Clarification of concepts. Section 1.1.1 – Abbreviations added/updated accordingly	stb/spb/na
13.0	Section 3.9 – Amendment of a note that no RMP has to be submitted for a KAS without innovation. Section 2.5.5 – Clarification that expert CVs should be dated and signed. Section 2.5.8.1 – Clarification on mandatory submission and addition of a note on RMP for KAS without innovation.	cho/stb/fg
12.0	For applications requesting an FTP or temporary authorisation, the decision minutes must also be submitted as a Word file. This is specified accordingly in sections 3.3 and 3.4 of this guidance document. section 3.21.1 at “Please note!” – Deletion of the fix defined submission period for DMF/ASMF before submission of the application (previously 11 CD)	stb/nma
11.0	Adaptation of guidance document due to new structure of VMP variations (early revision of VMP regulations)	fg/ps
10.0	Section 2.5.15: Insertion of sub-heading to improve clarity (explanatory addition) Section 3.22.6: Information regarding change of a wholesaler	stb/hv/mik/ski
9.0	Modification regarding combination products due to new EU MDR and revised MedDO in section 2.5.15	stb
8.0	Section 2.1 – Submission formats: Note added on continuing the submission format when authorisation is transferred. Section 3.3 – Further details concerning applications for temporary authorisation (tempA HMP) Section 3.4 – Further details concerning FTP applications (HMP) Section 3.11 – Co-marketing medicinal products: further details Section 3.13 – Review replaced by assessment	vy
7.0	Change in section 3.3 / 3.4 "AAA". Change below 3.12.5: Editorial changes may also be submitted as an “Other change” B.z, type IA”. Section 2.5.8.1: New reference to guidance document (formerly to information sheet) from Safety of Medicines division. Section 2.5.6.1: Explanation of Environmental Risk Assessment specifications	fg/wer/stb

6.2	Change in section 2.5.4.1 “Submission methods for packaging”: Addition of the term ‘mock-up’ for non-original printouts.	jst
6.1	Section 2.5.2 «Forms»: replacement of the section number 3.11 with 3.12 “Variations and extensions”.	tsj
6.0	Section 3.3.: Addition of requirement for applications for temporary authorisation Section 3.18: Detailed information regarding authorisation of individual teas, cough and throat lozenges and pastilles in dispensing category E by the notification procedure Section 3.21: DMF/ASMF documents can now be submitted via the Portal.	stb/buj/anm
5.1	▪ Section 3.12: Further details on the requirements concerning the submission of documents to fulfil conditions. ▪ 2.5.3.2.8: Changes to the product information that were rejected by Swissmedic for a first authorisation or earlier applications can be requested again only if they are documented by new data (SMJ 03/2009). ▪ Chapter 2.4 Confirmation of receipt: The receipt of type IA, IAIN and IB variations is confirmed if the applicant is not a portal user. A confirmation of receipt is always issued for fast-track requests. ▪ Section 2.5.2 Forms: Unless otherwise explicitly stated by Swissmedic, the default transitional period for forms is 3 months. If additional application requirements are associated with a new version of a form, a default transitional period of 3 months likewise applies to these new requirements. Various corrections to the chapter numbers (incl. deletion of A at the start of the numbers and intervening 0.	dts/stb
5.0	Chapter 3.11 “Variations and extensions”: Inclusion of no. A.3.11.0.8 Chapter 2.5.6 Explanations regarding the documentation of Environmental Risk Assessments (ERA) for biosimilar applications and additional indications that are likely to have a substantial environmental impact.	wer
4.0	Section 3.12 “Conditions imposed by Quality Review, Preclinical Review and Clinical Review”: The fulfilment of a condition imposed in respect of a collective application must entail a separate request for each medicinal product concerned. Collective applications are not permitted in relation to the fulfilment of conditions.	dts
3.1	Point A.2.5.2.6: Further details on the mandatory submission of the form Confirmation regarding substances from GVO HMV4 Chapter 3.11 "Variations and extensions": Further details on the format for specifying the implementation date: “DD.MM.YYYY” (A.3.11.0.2).	dts/stb
3.0	Supplement to Chapter 3.14 “Complementary medicinal products: Reduced dossiers”.	spm
2.0	Chapter 3.11 "Variations and extensions": inclusion of no. A.3.11.0.7 - Number of variations per variation no. Chapter 3.20 “DMF/ASMF and Plasma Master Files” Explanation re no A.3.20.1.2 form DMF HMV4. Chapter 3.2.1 “Recognition of orphan drug status (ODS) for human medicinal products” and Chapter 3.2.2 “Recognition of MUMS status for veterinary medicines”: Swissmedic will cancel the advance payment.	wer/nma/gf

1.1	Chapter 2.4 "Confirmation of receipt" Explanation re no. A.2.5.1.2: Dispatch of the authorisation document is subject to a fee. Explanation re no. A.2.5.1.1: Variation types IA, IAIN and IB can be submitted without cover letters. Chapter 3.9 "Submissions according to Art. 14 para. 1 let. abis-quater TPA": The additional requirements regarding the cover letter have been deleted. Chapter 3.11 "Variations and extensions": • Inclusion of new requirement: "Hybrid collective applications comprising both human and veterinary medicinal products are not admissible." • Clarification concerning the submission and completion of the form Variations and extensions HMV4. Further details on the procedure for dealing with editorial changes and/or updates to documentation.	dts
1.0	Implementation of TPO4	dts