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Change history

Version	Valid and binding as of	Description, comments (by author)	Author's initials
6.0	01.09.2021	Section 6.2. Swissmedic now accepts submission of the application documentation on the basis of study reports or EU dossiers. Sections 6.4, 7.3 and 8.2: The requirements of the Guidance document *Medicinal product information for human medicinal products HMV4* must be taken into account in the dosage recommendation for human medicinal products. Section 8.3.2: Applicants may use their discretion to decide whether or not to provide Information for healthcare professionals.	mag, ham
5.0	15.9.2020	Section 7.3. "Medicinal product information": Clarification of the "date of revision of the text". If, at the company's discretion, information for healthcare professionals is drawn up based on foreign information for healthcare professionals, only safety-related aspects may be added in terms of content. Section 8.3. "Medicinal product information": Clarification of disclaimer text: In accordance with Art. 17d para. 3 TPLO the correct term is "longstanding experience" (previously: longstanding use")	dts
4.2	01.06.2020	Sections 7.2 and 8.2 "Application documentation requirements": Explanation of the documentation requirements where there are discrepancies between the medicinal product for which authorisation has been applied for and the reference medicinal product.	dts
4.1	04.05.2020	Section 6.2 "Application documentation requirements": As an addition to the bibliographical documentation, Swissmedic accepts findings from non-published clinical study reports as supporting evidence. Section 6.4.1 "Information for healthcare professionals": Clarification of the requirements in section 16 "Other information" of the Information for healthcare professionals.	dts, ham
4.0	01.02.2020	Section 6.1 "Preconditions for the application of the procedure": Active substance must have been authorised in the EU/EFTA for ten years. How long the chosen foreign reference/comparator product has been authorised is not relevant. Section 7.3.1: Companies can use their discretion to decide whether or not to issue Information for healthcare professionals for applications under the procedure according to Art. 14 para. 1 let. a^{ter} TPA. Sections 6.4, 7.3 and 8.3: Clarification of the wording of the notes to be included in medicinal product information and of the date of revision of the text.	dts
3.0	08.08.2019	Section 6.2: More precise requirements regarding the application documentation: separate proof of 10-year authorisation of active substance and authorisation of comparator medicinal product in EU/EFTA.	dts
2.0	08.04.2019	Chapter Chapters 6.1 and 6.5: Deletion Requirement according to Art. 14a para. let. b TPA Chapter 7.2: Inclusion of "Documentation on therapeutic effect" (Art. 11 para. 2 let. a, sec. 3 TPA) Chapter 8.2: Harmonisation of the wording regarding the documents to be supplied	dts
1.1	01.01.2019	Section 3 "Scope": The therapeutic equivalence (interchangeability) of the medicinal product proposed for authorisation with a Swiss reference product is not examined in the procedure according to Art. 14 para. 1 letter a$^{bis-quater}$ TPA. Section 5.1 "Formal requirements": Further details concerning the entries on the application form Section 6.1 "Precondition for the application of the procedure", inclusion of an additional precondition according to Art. 14a para. 2 TPA	dts

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		Chapter 6.2: "Application documentation requirements": If there are any differences compared to the foreign comparator product, a corresponding confirmation should be submitted. Subsection to 6.4 "Product information": Further details on the structure and translation of the product information, on the submission of applications for modification of the product information and on the information and documentation after authorisation. Sections 7.2 and 8.2 "Application documentation requirements": Further details on the assessment of the risks Sections 7.3.1 and 8.3.1 "Information for healthcare professionals". Further details on the Information for healthcare professionals	
1.0	01.01.2019	Implementation of TPO4	dts

1 Definitions, terms, abbreviations

1.1 Abbreviations

Art.	Article
FeeO-Swissmedic	Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products of 14 September 2018 (SR 812.214.5)
HMP	Human Medicinal Products
Let.	Letter
Para.	Paragraph
Sec.	Section
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, SR 812.21)
TPLO	Ordinance of the Swiss Agency for Therapeutic Products of 22 June 2006 on the Simplified Licensing of Therapeutic Products and the Licensing of Therapeutic Products by the Notification Procedure (SR 812.212.23)
TPLRO	Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the Licensing Requirements for Therapeutic Products (SR 812.212.22)
VMP	Veterinary medicinal products

2 Introduction and objective

This guidance document describes the requirements pertaining to the documentation for the submission and simplified authorisation of medicinal products according to Art. 14 para. 1 letter a$^{bis-quater}$ TPA. Since this involves a guidance document aimed at administrative bodies, it does not directly specify the rights and obligations of private individuals. Swissmedic uses this document first and foremost as a resource for applying the legal provisions on authorisation in a uniform and equitable manner. The publication of the Instruction is designed to make it clear to third parties what requirements must be fulfilled according to the practice of Swissmedic.

3 Scope

This guidance document applies to the authorisation of human and veterinary medicinal products (HMP and VMP). It sets out the requirements for new applications and variation applications according to Art. 14, para. 1 a$^{bis-quater}$ TPA.

Variation applications according to Art. 14 para. 1 letter a$^{bis-quater}$ TPA are possible only for clinical and preclinical aspects, and only if the first authorisation of the medicinal product has been granted according to Art. 14 para. 1 letter a$^{bis-quater}$ TPA.

Regulatory variations and variations affecting quality are processed in the standard procedure and according to the requirements of the guidance document *Variations and extensions HMV4*. Combining Art. 13 and Art. 14 para. 1 letter a$^{bis-quater}$ TPA is not possible.

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The therapeutic equivalence (interchangeability) of the medicinal product proposed for authorisation with a Swiss reference product is not examined in the procedure according to Art. 14 para. 1 letter $a^{bis-quater}$ TPA. If the therapeutic equivalence is to be assessed, the applicant can follow the authorisation procedure according to Art. 14 para. 1 letter a TPA (Medicinal products with known active substances).

4 Legal framework

4.1 Medicinal products whose active substances are used in a medicinal product that has been authorised in an EU or EFTA country for at least 10 years (Art. 14 para. 1 letter $a^{bis-quater}$ TPA)

The procedure according to Art. 14 para. 1 letter a^{bis} TPA is based, in particular, on the following legal provisions:

4.1.1 Human medicinal products

TPA

- ***Art. 11 Application for a marketing authorisation***
  - Para. 1
  - Para. 2 letter a, sec. 1 - 4
- ***Art. 14 Simplified authorisation procedures***
  - Para. 1 letter a^{bis}
- ***Art. 14a Authorisation application in the simplified authorisation procedure***
  - Para. 1 letter a
  - Para. 2

TPLO

- ***Art. 17a Principle***
- ***Art. 17b Application***

4.1.2 Veterinary medicinal products

TPA

- ***Art. 11 Application for a marketing authorisation***
  - Para. 1
  - Para. 2 letter a sec. 1 - 4 and 2 b
- ***Art. 14 Simplified authorisation procedures***
  - Para. 1 letter a^{bis}
- ***Art. 14a Authorisation application in the simplified authorisation procedure***
  - Para. 1 letter a
  - Para. 2

TPLO

- ***Art. 17a Principle***
- ***Art. 17b Application***

4.2 Non-prescription medicinal products with a 30-year medical life (Art. 14 para. 1 a^{ter} TPA)

The procedure according to Art. 14a para. 1 letter a^{ter} TPA is based, in particular, on the following legal provisions:

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4.2.1 Human medicinal products

TPA

- ***Art. 11 Application for a marketing authorisation***
  - Para. 1
  - Para. 2 letter a, sec. 1, 3 and 4
- ***Art. 14 Simplified authorisation procedures***
  - Para. 1 letter a^{ter}
- ***Art. 14a Authorisation application in the simplified authorisation procedure***
  - Para. 1 letter b

TPLO

- ***Art. 17c***

4.2.2 Veterinary medicinal products

TPA

- ***Art. 11 Application for a marketing authorisation***
  - Para. 1
  - Para. 2 letter a, sec. 1, 3 and 4
  - Para. 2 letter b
- ***Art. 14 Simplified authorisation procedures***
  - Para. 1 letter a^{ter}
- ***Art. 14a Authorisation application in the simplified authorisation procedure***
  - Para. 1 letter b

TPLO

- ***Art. 17c***

4.3 Medicinal products that have been authorised in a canton for at least 15 years (Art. 14 para. 1 a^{quater} TPA)

The procedure according to Art. 14a para. 1 letter a^{quater} TPA is based, in particular, on the following legal provisions:

4.3.1 Human medicinal products

TPA

Art. 11 Application for a marketing authorisation

- Para. 1
- Para. 2 letter a, sec. 1, 3 and 4

Art. 14 Simplified authorisation procedures

- Para. 1 letter a^{quater}

Art. 14a Authorisation application in the simplified authorisation procedure

- Para. 1 letter c

TPLO

- ***Art. 17d***

4.3.2 Veterinary medicinal products

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TPA

- ***Art. 11 Application for a marketing authorisation***
  - Para. 1
  - Para. 2 letter a, sec. 1, 3 and 4
  - Para. 2 letter b
- ***Art. 14 Simplified authorisation procedures***
  - Para. 1 letter a^{quater}
- ***Art. 14a Authorisation application in the simplified authorisation procedure***
  - Para. 1 letter c

TPLO

- ***Art. 17d***

5 General requirements

5.1 Formal requirements

The formal requirements are based on the guidance document *Formal requirements HMV4* and the associated directory *Overview of documents to be submitted HMV4.*

For the procedures according to Art. 14 para. 1 letter a$^{bis-quater}$ TPA, in addition to the desired simplified procedure, the applicant must also check the relevant boxes in the form *New authorisation of human medicinal product HMV4* or the form *Variations and extensions HMV4* to specify the type of application involved (New active substance, Known active substance with innovation, Known active substance without innovation, etc.).

5.2 Technical documentation requirements

The requirements of the guidance documents *Authorisation of human medicinal product with new active substance HMV4* and guidance documents *Authorisation of veterinary medicinal products HMV4*. For authorisation extensions and variation applications, the requirements of the guidance document *Variation and extensions HMV4* also apply.
As regards the quality of particular medicinal product categories (e.g. homeopathics, herbal medicinal products), the requirements of the respective guidance documents should be taken into account.
The requirements specified in the guidance documents on *Product information for human medicinal products HMV4* and *Product information for veterinary medicinal products HMV4 as well as Packaging for human medicinal products HMV4 or Packaging texts for veterinary medicinal products HMV4* also apply, and the special aspects and exceptions in the procedures according to Art. 14 para. 1 letter a$^{bis-quater}$ TPA are described in this guidance document.

5.3 Document protection

No document protection is granted for authorisations according to Art. 14 para. 1 letter a$^{bis-quater}$ TPA.
Additional information on the requirements concerning document protection can be found in the guidance document *Document protection HMV4*.

5.4 Requirements concerning the investigation of the medicinal product in specific age groups

A Paediatric Investigation Plan according to Art. 54a TPA is not required.

5.5 Pharmacovigilance Plan

A Pharmacovigilance Plan according to Art .11 para. 2 letter a sec. 5 TPA is not required.

5.6 Authorisation extensions and variation applications

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Variation applications in the simplified procedure according to Art. 14 para. 1 letter a$^{bis-quater}$ TPA are possible only for medicinal products that were also first authorised according to Art. 14 para. 1 letter a$^{bis-quater}$ TPA, and provided the clinical or preclinical documentation is affected by the variation. Quality-related variation applications and regulatory variations are processed in the standard processes according to the guidance document *Variation and extensions HMV4* and are subject to the standard fees.

5.7 Time limits

The time limits are based on the guidance document *Time limits for authorisation applications HMV4*.

5.8 Fees

The fees specified in the Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic) apply.

6 Medicinal products with active substances that have been authorised in an EU or EFTA country for at least 10 years (Art. 1 para. 1 letter a^{bis} TPA)

6.1 Preconditions for the application of the procedure

According to Art. 14 para. 1 letter a^{bis} and Art. 14a para. 1 letter a TPA in conjunction with Art. 17a and 17b TPLO, a medicinal product can be authorised

a) if its active substances have been contained in an authorised medicinal product in an EU or EFTA country for at least ten years[1];

and

b) if it is comparable with the medicinal product authorised in the foreign country in respect of indication, dosage (dosage strength and dosage recommendation), administration route and – additionally for veterinary medicinal products – in respect of the target animal species, and if, according to the latest scientific findings, any difference would not be expected to lead to any change in the assessment of its safety and efficacy.

The applicant must be able, throughout the period in which its medicinal product is authorised, to spontaneously and promptly present all internationally recorded safety signals relating to the foreign reference medicinal product (Art. 14a para. 2 letter a TPA).

6.2 Application documentation requirements

The following application documentation requirements must be met:

- Proof that, at the time of submission, the active substances have been authorised as a medicinal product in the indication applied for in an EU or EFTA country for at least 10 years.
- Proof of the EU/EFTA authorisation of the medical product to which the authorisation application refers and whose product information texts are to be adopted.
- Complete documentation on quality according to the latest scientific findings in accordance with Art. 3 TPLRO and in accordance with Art. 7 TPLRO. This must, for example, meet the requirements of Ph.Eur, Ph.Helv, TPA 2 and the current provisions of international guidelines (in particular ICH and VICH guidelines). In addition, the current published Swissmedic requirements in terms of quality must be met (e.g. requirements concerning potential nitrosamine contamination).
- As regards the quality of particular medicinal product categories (e.g. homeopathics, herbal medicinal products), the requirements of the respective guidance documents should be taken into account.

[1] The key requirement is that the active substance must have been authorised for ten years. How long the chosen foreign reference/comparator product has been authorised is not relevant.

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- Documentation on the pharmacological, toxicological and clinical investigations in accordance with Art. 4 and 5 TPLRO or, for VMP, in accordance with Art. 8 and 11 TPLRO. This can be submitted in bibliographical form if sufficient proof of the safety and efficacy of the medicinal product exists in the published literature (see also section 6.3). Swissmedic also accepts submissions on the basis of study reports or EU dossiers.
  Irrespective of which documentation the application is based on, the evidence submitted by the applicant must be summarised in a scientifically sound way and, for example, evaluated critically by means of expert statements. For human medicinal products, this may also be in the form of a non-clinical / clinical overview (Module 2.4 / 2.5), or an expert report or detailed and critical summaries (DACS) for veterinary medicinal products.
  The summary and critical evaluation must correspond to current scientific knowledge. Non-clinical and clinical overviews, experts reports and DACS prepared in the past must be updated. The results of safety-relevant reviews and procedures (e.g. signal procedures) by foreign authorities are also included in the “current knowledge”. The evaluation reports of the relevant authorities on such procedures should be attached as a reference.
- Table showing differences between the medicinal product to be proposed in Switzerland and the foreign comparator medicinal product. If there are no differences, a confirmation stating that the medicinal product to be authorised and the foreign comparator product are identical should be submitted
- Scientific explanation by an expert stating that differences between the medicinal product to be proposed and the foreign comparator medicinal product are not expected to affect the assessment of safety and efficacy, and that the findings on preclinical and clinical safety and efficacy obtained with the foreign comparator medicinal product can be applied to the medicinal product be proposed with sufficient reliability.
- Additionally for veterinary medicinal products for animals that are kept for food production: Information and documentation on the attestation of residues and the required withdrawal periods.
- Additionally for veterinary medicinal products containing antibiotics: Documentation on the risk of resistance.

6.3 Requirements pertaining to the consulted scientific data on the proof of safety and efficacy (bibliographical documentation)

In the procedure in accordance with Art. 14 para. 1 letter a^{bis} TPA, an applicant can refer to published scientific data in order to document the pharmacological and toxicological investigations (Art. 4 or Art. 8 TPLRO for VMP) and the clinical investigations (Art. 5 or Art. 11 TPLRO for VMP).

The following are recognised as scientific data:

- Decisions of foreign authorities (Assessment Reports)
- Specialist scientific literature
- Extracts from databases on pharmacology, toxicology and clinical side effects relating to the comparator medicinal product authorised in the foreign country
- Collection of individual case reports that are amenable to scientific evaluation
- Current expert reports and therapeutic guidelines issued by professional associations
- Findings resulting from the use of the comparator medicinal product authorised in the foreign country (e.g. PSUR data)

The evidential value of the scientific data used depends primarily on the quality and scope of the material and on the consistency of the derived conclusions. The following quality attributes are considered to be guiding factors for the review:

- The selection criteria for the literature compilation (search strategy, list of searched databases, service providers) are presented in a transparent and comprehensible manner. Additionally used, unfocused search strategies are also documented.

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- Both advantageous and less advantageous results are considered in the analysis and contradictory findings are discussed.
- The cited publications – usually original publications – correspond to the latest scientific and technical findings and are predominantly published in peer-reviewed journals.
- The results of any epidemiological studies (particularly those with a comparative design) must be submitted to supplement data from published, controlled clinical trials. The transferability of the key data (e.g. indication, dosage strength, dosage recommendation, administration route) to the medicinal product to be authorised is verifiably presented.
- Scientific publications and literature data are complete, i.e. not just submitted and referenced as abstracts.

If more than 12 months have elapsed between the search and the submission date of the authorisation application, a supplement updating the main document is expected, or an explanation as to why newer data and findings were not included.

6.4 Product information

6.4.1 General remarks

The requirements of the Guidance document *Medicinal product information for human medicinal products HMV4* (section on “Requirements for specific medicinal product groups and procedures”) must be taken into account in the dosage recommendation for human medicinal products.

6.4.2 Information for healthcare professionals

The structure (section titles) should satisfy the requirements of TPLRO. The content of sections 1-3 must also satisfy the requirements of TPLRO. Sections 4–16 or, for VMP, sections 4–6 of the Information for healthcare professionals – must include a translation into the official languages stated in Art. 14 para. 2 and 3 TPO of the corresponding texts taken from the latest version of the approved product information for the authorised medicinal product in the foreign country to which the application refers. However, the excipient composition does not need to be listed again in section 16 “Other information” for human medicinal products, and the shelf life (according to the product information of the foreign comparator product) does not need to be stated in this section. By contrast, the storage instructions (including storage temperature) must be stated in accordance with Swiss requirements.

The applicant is responsible for the correctness of all translations.

The following note must be included directly beneath the product name:

The efficacy and safety of NAME OF THE MEDICINAL PRODUCT X have only been summarily reviewed by Swissmedic. The authorisation of NAME OF THE MEDICINAL PRODUCT X is based on NAME OF THE MEDICINAL PRODUCT Y, date of revision of the text MONTH YYYY, which contains the same active substance(s) and is authorised in COUNTRY Z.

The “Date of revision of the text” section must specify the date on which the information for the foreign reference/comparator product was last revised and state whether Swissmedic has added safety-relevant information.

Date of revision of the text
Foreign reference/comparator medicinal product: Month YYYY
With safety-relevant additions by Swissmedic: Month YYYY
or
Without safety-relevant additions by Swissmedic: Month YYYY

6.4.3 Package leaflet and packaging

The structure (section titles) should satisfy the requirements of TPLRO. Sections 3–9 of the Patient information or, for VMP, sections 4–13 of the package leaflet, must include a certified translation into the official languages stated in Art. 14 paras. 2 and 3 TPO of the corresponding texts taken from the

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latest version of the approved product information for the authorised medicinal product in the foreign country to which the application refers.

The applicant is responsible for the correctness of all translations.

The following note must be included directly beneath the product name:

The efficacy and safety of NAME OF THE MEDICINAL PRODUCT X have only been summarily reviewed by Swissmedic. The authorisation of NAME OF THE MEDICINAL PRODUCT X is based on NAME OF THE MEDICINAL PRODUCT Y, date of revision of the text MONTH YYYY, which contains the same active substance(s) and is authorised in COUNTRY Z.

In accordance with section 16 in Annex 5.1, 5.2 or 5.3 TPLRO, the text must specify when the Patient information was last reviewed by the foreign reference authority and state whether Swissmedic has added any safety-relevant information:

This package leaflet was last reviewed by the foreign reference authority in MONTH YYYY.
With safety-relevant additions by Swissmedic: Month YYYY
or
Without safety-relevant additions by Swissmedic: Month YYYY

For veterinary medicinal products, the information provided in accordance with section 14 of Annex 6 no. 5 TPLRO must read as follows:

Package leaflet approval date
Approval by foreign reference authority: Month YYYY
With safety-relevant additions by Swissmedic: MONTH YYYY
or
Without safety-relevant additions by Swissmedic: Month YYYY

The packaging must satisfy the requirements of TPLRO.

6.4.4 Updating the product information

The product information authorised in Switzerland is essentially based on the product information of the country issuing the authorisation on which the new authorisation application is based. Applications for an update to the Swiss product information that are based on an update of the product information of the foreign comparator product can be submitted to Swissmedic as a type IB variation (Variation A.100 according to Annex 7 TPLRO). Since, after authorisation, the Swiss product information continues to be based on the product information of the foreign comparator product, applications of type C.I.2 are not possible.

6.5 Information and documentation after authorisation by Swissmedic

Pursuant to Art. 14a para. 2. letter a TPA, the authorisation holder of the medicinal product authorised for sale in Switzerland is obliged, throughout the period of authorisation of its product, to spontaneously and promptly present all internationally recorded safety signals relating to the foreign comparator product.

If the authorisation of the foreign comparator product is rejected, the authorisation holder is obliged to notify Swissmedic accordingly.

7 Medicinal products that have been used for many years (Art. 14 para. 1 letter a^{ter} TPA)

7.1 Preconditions for the application of the procedure

In accordance with Art. 14 para. 1 letter a^{ter} and Art. 14a para. 1 letter b TPA, in conjunction with Art. 17c TPLO, a medicinal product can be authorised if it is a non-prescription medicinal product with a stated indication and which has been used medically for at least 30 years, including at least 15 years in countries of the EU and EFTA.

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7.2 Application documentation requirements

- State the countries in which the comparator medicinal product has been used medically for at least 30 years.
- Proof of medical use in the requested indication, pharmaceutical form and dosage in the specified countries for at least 30 years.
- State the EU/EFTA countries in which the comparator medicinal product has been used medically for at least 15 years.
- Proof of medical use in the requested indication, pharmaceutical form and dosage in the named EU/EFTA countries for at least 15 years.
  The following factors are decisive in proving the medical use in the requested indication, pharmaceutical form and dosage:
  - the period during which a substance has been used,
  - the quantitative use of the comparator medicinal product among the user groups (exposure data)
- Any minor differences that exist between the medicinal product to be authorised and the medicinal product that has been used for many years should be presented and discussed. Minor differences in the pharmaceutical form, for example, are permissible as long as they are not expected to have any effect on safety or efficacy. The extent to which differences will be accepted depends on the medicinal product in question, and will be assessed from case to case.
- Documentation on therapeutic effect
- Documentation on undesirable effects
- An assessment of the risks (tolerability and safety) based on the recorded post-marketing pharmacovigilance data. If no pharmacovigilance data are available, the applicant should specify which corresponding investigations have been conducted.
- Complete documentation on quality according to the latest scientific findings in accordance with Art. 3 TPLRO and, for VMP, in accordance with Art. 7 TPLRO. As regards the quality of particular medicinal product categories (e.g. homeopathics, herbal medicinal products), the requirements of the respective guidance documents should be taken into account.
- Additionally for VMP for animals that are kept for food production:
  Information and documentation on the attestation of residues and the required withdrawal periods.
- There is no need to submit documentation on the pharmacological, toxicological or clinical investigations in accordance with Arts. 4 and 5 TPLRO – or, for VMP, in accordance with Arts. 8 and 11 TPLRO – or the Information for healthcare professionals.

7.3 Product information

7.3.1 General remarks

The requirements of the Guidance document *Medicinal product information for human medicinal products HMV4* (section on “Requirements for specific medicinal product groups and procedures”) must be taken into account in the dosage recommendation for human medicinal products.

7.3.2 Information for healthcare professionals

Applicants may use their discretion to decide whether or not to provide Information for healthcare professionals.
If the Swiss information for healthcare professionals is drawn up based on foreign information for healthcare professionals, the applicant may only add safety-related aspects in terms of content.

The following note must also be included directly beneath the product name:

PRODUCT NAME X was authorised exclusively on the basis of its longstanding use. Its efficacy and safety have not been checked by Swissmedic. (To be included if the texts are based on foreign Information for healthcare professionals:) *The Information for healthcare professionals is based on*

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NAME OF THE MEDICINAL PRODUCT Y from COUNTRY Z, date of revision of the text MONTH YYYY.

The date of revision of the text section must specify what the Information for healthcare professionals is based on and when the Information for healthcare professionals was last reviewed by the foreign reference authority (Variant 1) or by the marketing authorisation holder (Variant 2). If the Swiss Information for healthcare professionals is based on foreign information for healthcare professionals and the marketing authorisation holder adds safety-related aspects, this must also be dated (Variant 1).

Variant 1– if texts are based on foreign Information for healthcare professionals

Date of revision of the text
Foreign reference/comparator medicinal product: Month YYYY
With additions by MARKETING AUTHORISATION HOLDER X: MONTH YYYY
or
Without additions by MARKETING AUTHORISATION HOLDER X: Month YYYY
Content not reviewed by Swissmedic.

Variant 2 – if texts are not based on foreign Information for healthcare professionals

Date of revision of the text
Marketing authorisation holder's text: MONTH YYYY. Content not reviewed by Swissmedic.

7.3.3 Package leaflet and packaging

The structure (section titles) of the package leaflet should satisfy the requirements of TPLRO.

The following note must be included in the package leaflet directly beneath the name of the medicinal product name:

NAME OF THE MEDICINAL PRODUCT X was authorised exclusively on the basis of its longstanding use. Its efficacy and safety have not been checked by Swissmedic.

In the case of veterinary medicinal products for animals that are kept for food production, the following note must be included:

NAME OF THE MEDICINAL PRODUCT X was authorised exclusively on the basis of its longstanding use. With the exception of food safety (withholding period), its efficacy and safety have not been checked by Swissmedic.

In accordance with section 16 in Annex 5.1, 5.2 or 5.3 TPLRO, the text must specify what the Patient information is based on, when the Patient information was last reviewed by the foreign reference authority (Variant 1) or by the marketing authorisation holder (Variant 2) and, where applicable, whether Swissmedic has added any safety-relevant information. If the Swiss Patient information is based on foreign Patient information and the marketing authorisation holder adds safety-related aspects, this must also be dated (Variant 1).

Variant 1– if texts are based on foreign Patient information

This package leaflet was last reviewed by the foreign reference authority in MONTH YYYY.
(With additions by MARKETING AUTHORISATION HOLDER X: MONTH YYYY
or
Without additions by MARKETING AUTHORISATION HOLDER X: Month YYYY
Content not reviewed by Swissmedic.

Variant 2 – if texts are not based on foreign Patient information

This package leaflet was last updated by the marketing authorisation holder in (MONTH YYYY).
Content not reviewed by Swissmedic.

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For veterinary medicinal products, the information provided in accordance with section 14 “Package leaflet approval date” in Annex 6 no. 5 TPLRO should read as follows:

Variant 1 – if texts are based on a foreign veterinary medicinal product package leaflet

Package leaflet approval date
Approval by foreign reference authority: Month YYYY
With additions by MARKETING AUTHORISATION HOLDER X: MONTH YYYY
or
Without additions by MARKETING AUTHORISATION HOLDER X: Month YYYY
Content not reviewed by Swissmedic.

Variant 2 – if texts are not based on a foreign veterinary medicinal product package leaflet

Package leaflet approval date
This package leaflet was last updated by the marketing authorisation holder in MONTH YYYY.
Content not reviewed by Swissmedic.

The packaging must satisfy the requirements of TPLRO.

8 Medicinal products with cantonal authorisation (Art. 14 para. 1 letter a^{quater} TPA)

8.1 Preconditions for the application of the procedure

According to Art. 14 para. 1 letter a^{quater} and Art. 14a para. 1 letter c TPA, in conjunction with Art. 17d TPLO, a medicinal product can be authorised if it has been authorised as a medicinal product in a canton for at least 15 years.

8.2 Application documentation requirements

- Proof of authorisation of the medicinal product in the requested indication, pharmaceutical form and dosage for 15 years in the canton to which the authorisation application refers.
- Any minor differences that exist between the medicinal product to be authorised and the medicinal product approved by cantons should be presented and discussed. Minor differences in the pharmaceutical form, for example, are permissible as long as they are not expected to have any effect on safety or efficacy. The extent to which differences will be accepted depends on the medicinal product in question, and will be assessed from case to case.
- Complete documentation on quality according to the latest scientific findings in accordance with Art. 3 TPLRO and, for VMP, in accordance with Art. 7 TPLRO. As regards the quality of particular medicinal product categories (e.g. homeopathics, herbal medicinal products), the requirements of the respective guidance documents should be taken into account.
- Documentation on therapeutic effect
- Documentation on undesirable effects
- An assessment of the risks (tolerability and safety). If no pharmacovigilance data are available, the applicant should specify which corresponding investigations have been conducted.
- Additionally for veterinary medicinal products for animals that are kept for food production: Information and documentation on the attestation of residues and the required withdrawal periods.
- There is no need to submit complete documentation on the pharmacological, toxicological or clinical investigations in accordance with Art. 4 and 5 TPLRO or, for VMP, in accordance with Art. 8 and 11 TPLRO.

8.3 Product information

8.3.1 General remarks

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The requirements of the Guidance document *Medicinal product information for human medicinal products HMV4* (section on “Requirements for specific medicinal product groups and procedures”) must be taken into account in the dosage recommendation for human medicinal products.

8.3.2 Information for healthcare professionals

Swissmedic does not generally check and approve the Information for healthcare professionals in this simplified procedure.
Applicants may use their discretion to decide whether or not to provide Information for healthcare professionals. However, if the medicinal product is classed in dispensing category A or B, Swissmedic may require Information for healthcare professionals on a case-by-case basis.
The following note must also be included directly beneath the product name:

NAME OF THE MEDICINAL PRODUCT X was authorised exclusively on the basis of its longstanding experience in CANTON X. Its efficacy and safety have not been checked by Swissmedic. (To be included if the texts are based on foreign Information for healthcare professionals:) *The Information for healthcare professionals is based on NAME OF THE MEDICINAL PRODUCT Y from COUNTRY Z, date of revision of the text MONTH YYYY.*

In the case of veterinary medicinal products for animals that are kept for food production, the following note must be included:

NAME OF THE MEDICINAL PRODUCT X was authorised exclusively on the basis of its longstanding experience in CANTON X. With the exception of food safety (withholding period), its efficacy and safety have not been checked by Swissmedic.

The date of revision of the text section must specify what the Information for healthcare professionals is based on and when the Information for healthcare professionals was last reviewed by the foreign regulatory authority (Variant 1) or by the marketing authorisation holder (Variant 2). If the Swiss Information for healthcare professionals is based on foreign information for healthcare professionals and the marketing authorisation holder adds safety-related aspects, this must also be dated (Variant 1).

Variant 1 – if texts are based on foreign Information for healthcare professionals

Date of revision of the text
Foreign medicinal product on which this Information for healthcare professionals is based: MONTH YYYY
With additions by MARKETING AUTHORISATION HOLDER X: MONTH YYYY
or
Without additions by MARKETING AUTHORISATION HOLDER X: Month YYYY
Content not reviewed by Swissmedic.

Variant 2 – if texts are not based on foreign Information for healthcare professionals

Date of revision of the text
Marketing authorisation holder’s text: MONTH YYYY. Content not reviewed by Swissmedic.

8.3.3 Packaging elements

The structure (section titles) of the package leaflet should satisfy the requirements of TPLRO. The following note must be included in the package leaflet directly beneath the name of the medicinal product:

NAME OF THE MEDICINAL PRODUCT X was authorised exclusively on the basis of its longstanding experience in CANTON X. Its efficacy and safety have not been checked by Swissmedic.

In the case of veterinary medicinal products for animals that are kept for food production, the following note must be included:

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NAME OF THE MEDICINAL PRODUCT X was authorised exclusively on the basis of its longstanding experience in CANTON X. With the exception of food safety (withholding period), its efficacy and safety have not been checked by Swissmedic.

In accordance with section 16 in Annex 5.1, 5.2 or 5.3 TPLRO, the text should specify when the marketing authorisation holder last updated the patient information.

This package leaflet was last updated by the marketing authorisation holder in (month/year). Content not reviewed by Swissmedic.

For veterinary medicinal products, the information provided in accordance with section 14 “Package leaflet approval date” in Annex 6 no. 5 TPLRO should read as follows:

Package leaflet approval date
This package leaflet was last updated by the marketing authorisation holder in MONTH YYYY. Content not reviewed by Swissmedic.

The packaging must satisfy the requirements of TPLRO.

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