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Guidance document

Authorisation of Homeopathics, anthroposophics and other complementary medicinal products

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1 Definitions, terms, abbreviations

1.1 Abbreviations

Ann.	Annex
B.Hom.P.	British Homeopathic Pharmacopoeia
HAS List	List of homeopathic and anthroposophic substances (Annex 6 KPTPO)
HAB	Deutsches homöopathisches Arzneibuch [German Homeopathic Pharmacopoeia]
HMP	Human Medicinal Products
KPTPO	Ordinance of 7 September 2018 of the Swiss Agency for Therapeutic Products on the Simplified Licensing of Complementary and Phytotherapeutic Products (Complementary and Phytotherapeutic Products Ordinance, KPTPO; SR 812.212.24)
Let.	Letter
Para.	Paragraph
Ph. Eur.	Pharmacopoea Europaea
Ph. F.	Pharmacopée Française [French Pharmacopoeia]
Ph. Helv.	Pharmacopoea Helvetica [Swiss Pharmacopoeia]
SC List	List of Schüssler salts (Annex 7 KPTPO)
Sec.	Section
TPLRO	Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the Licensing Requirements for Therapeutic Products (SR 812.212.22)
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)
VMP	Veterinary medicinal products

2 Introduction and objective

This guidance document describes the requirements relating to the documentation for the submission and simplified authorisation of homeopathic and anthroposophic medicinal products (MP) according to Chapter 4, section 5 KPTPO, as well as complementary medicines used in alternative treatments according to Chapter 6 KPTPO. As 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 on authorisation in a uniform and equitable manner. The intention of publishing this guidance document is to show third parties what requirements have to be fulfilled, according to Swissmedic practice, to ensure that corresponding applications can be processed as quickly and efficiently as possible.

3 Scope

This guidance document applies to the simplified authorisation of homeopathic and anthroposophic human and veterinary medicinal products (HMP and VMP) according to Chapter 4, section 5 KPTPO,

and other complementary medicines according to Chapter 6 KPTPO. It applies to new authorisation applications for the corresponding MP.

The guidance document also applies to the requirements relating to the quality documentation for applications for the authorisation of homeopathic and anthroposophic HMP and VMP according to Art. 14 para. 1 a^{bis} – a^{quater} TPA and Art. 11 TPA. As regards the rest of the requirements for the corresponding applications, the guidance document *Authorisation of human medicinal product with new active substance* and the guidance document *Authorisation in accordance with Art. 14 para. 1 let. $a^{bis-quater}$ TPA* are applicable.

The guidance document does not apply to the authorisation of homeopathic and anthroposophic medicinal products and other complementary medicines by the notification procedure according to Chapter 7 KPTPO or to the authorisation of Asian medicinal products according to Chapter 5 KPTPO. The guidance document *Authorisation of Homeopathics, anthroposophics and medicinal products for gemmotherapy without an indication in the notification procedure* or the guidance document *Authorisation of Asian medicinal products* apply to these medicinal products.

4 Legal framework

The procedures for authorising homeopathic and anthroposophic HMP and VMP according to Chapter 4, section 5 KPTPO and complementary medicines for alternative treatments according to Chapter 6 KPTPO are based primarily on the following legislative texts:

TPA

Art. 9	Marketing authorisation
Art. 10	Conditions for granting a marketing authorisation
Art. 11	Application for a marketing authorisation
Art. 14	Simplified authorisation procedures

TPLRO

Art. 2	General preconditions
Art. 3	Documentation on the analytical, chemical and pharmaceutical tests
Art. 4	Documentation on the pharmacological and toxicology tests
Art. 5	Documentation on clinical trials
Art. 6	Special requirements for fixed-dose combination medicinal products
Art. 7	Documentation on the analytical, chemical and pharmaceutical tests (veterinary medicinal products)
Art. 8	Documentation on innocuousness (veterinary medicinal products)
Art. 9	Additional documentation on innocuousness and residues for tests on livestock
Art. 10	Admissibility of pharmacologically active substances and proposed withdrawal periods
Art. 11	Documentation on preclinical and clinical trials (veterinary medicinal products)
Ann. 1	Information and texts on containers and packaging materials for human medicinal products

Ann. 1a	Information and text on containers and packaging materials for homeopathic and anthroposophic medicinal products without indication and medicinal products for gemmotherapy without indication
Ann. 3	Requirements for the declaration of active substances and pharmaceutical excipients in human medicinal products
Ann. 3a	List of excipients subject to declaration
Ann. 4	Requirements for the Information for healthcare professionals for human medicinal products
Ann. 5.2	Requirements for the Patient information for homeopathic and anthroposophic medicinal products

KPTPO

Art. 5	Principle of simplified authorisation
Art. 6	Documentation on the pharmacological and toxicology tests
Art. 7	Proof of therapeutic efficacy and safety
Art. 9	Analytical, chemical and pharmaceutical documentation
Art. 10	Toxicological and pharmacological documentation
Art. 11	Clinical documentation

5 Description / General requirements / Assessment principles

5.1 Selection of the appropriate authorisation procedure

Homeopathic and anthroposophic medicinal products and other complementary medicines can be authorised under various procedures, depending on the composition of the medicinal product in question and its intended use. The annex to this guidance document gives an overview of these procedures and also serves as a decision-making tool that can be used for identifying the procedure to be employed for a particular preparation.

5.2 Formal requirements

The formal requirements are based on the guidance document *Formal requirements* and the corresponding directory overview of *documents to be submitted.*

5.3 Declaration requirements

5.3.1 Full declaration form

The following information is required according to the sections as shown below:

5.3.1.1 Active substances produced according to a homeopathic manufacturing process

5.3.1.1.1 Active substances in homeopathic and spagyric medicinal products

The active substances in medicinal products with and without indication should be listed under this heading in accordance with Ann. 1a no. 1, para. 1 let. e, no. 1 and 2, and Ann. 1a no. 1 para. 2 and 3 TPLRO.

Active substances with a pharmacopoeia monograph

If a monograph exists for the active substance in a recognised homeopathic pharmacopoeia or in the “Homeopathic preparations and substances for homeopathic preparations” chapter of the European Pharmacopoeia or in the homeopathic section of Ph.F., the main name of the substance should be used in the title of the monograph. The pharmacopoeia must be referenced immediately after the substance name.

e.g.

Aralia racemosa (HAB) D6

Galium odoratum spag. Zimpel (HAB) D1

Active substances with a pharmacopoeia monograph without (clear) reference to a manufacturing specification

If a monograph exists for the active substance, but the monograph does not specify manufacturing instructions or several different substances are listed, the Ph. Eur. or HAB manufacturing instructions

used must be added after the potency. A special specification that is listed only in the relevant HAB monograph should be stated with "HAB SV".

e.g.

Belladonna (Ph.Eur.Hom.) D6

Crocus (Ph.Eur.Hom.) D6 (Ph.Eur.Hom. 1.1.8)

Acidum salicylicum (HAB) D6 (HAB 5a)

Acidum arsenicosum (HAB) D12 (HAB SV)

Active substances without a pharmacopoeia monograph

If no monograph exists for the active substance in a recognised homeopathic pharmacopoeia, it has to be specified in greater detail in accordance with Ann. 1a no. 1 para. 3 let. c TPLRO.
This means that the following have to be provided for mother tinctures and potencies of plant or animal origin:
– Primary plant(s) or animal(s) with genus and species
– Plant/animal parts used; indication of their condition (fresh/frozen). If the condition is defined in the manufacturing instructions, the additional indication can be omitted.
– Manufacturing instructions and the pharmacopoeia containing the instructions. This information should be inserted after the potency. While it is usually sufficient to state the manufacturing specification for the first manufacturing step, it is also permissible to state the following specifications as well. If a manufacturing specification is recognised by Swissmedic according to Art. 23 para. 3 KPTPO, this should be stated with "SV".
– Any manufacturing method-related labelling required by the HAB (e.g. “spag. Zimpel”, “Rh”) must also be inserted.
e.g.
Calendula officinalis e floribus D4 (Ph.Eur.Hom. 1.1.3) or
Calendula officinalis e floribus D4 (HAB 2a)

Aranea diadema ex animale toto rec. D8 (Ph.Eur.Hom. 1.1.9) or

Aranea diadema ex animale toto rec. D8 (HAB 4b)

Bufo bufo e veneno sicco D8 (HAB 8a)

Melissa officinalis ex herba Rh D6 (HAB 21)

Atropa belladonna ex planta tota spag. Peka D4 (HAB 47a)

Active substances without a pharmacopoeia monograph, starting material with Ph. Eur. monograph (non-homeopathic section)

If the non-homeopathic section of Ph. Eur. includes a monograph for the starting material but not the active substance, this monograph is binding for quality and must also be referenced in the form *Full declaration*.
e.g.

Magnesium asparticum (Magnesii aspartas dihydricus Ph.Eur.) D6 (HAB 5a)

Ipecacuanha e radice (Ipecacuanhae radix Ph.Eur.) D6 (HAB 4a)

Active substance without a pharmacopoeia monograph, starting material with a monograph in the HAB or Ph. Eur. (homeopathic section)

If, in a homeopathic monograph in the HAB or Ph. Eur. (homeopathic section), only the section for the starting material is applicable to the active substance, the starting material must be specified as for active substances without a monograph in a pharmacopoeia. The homeopathic monograph referred to for the starting material should be stated according to the corresponding plant part.

e.g.

Bellis perennis ex planta tota (HAB) spag. Zimpel TM (HAB 25)

Atropa belladonna ex herba rec. (Ph.Eur.Hom.) spag. Baumann D1 (SV)

5.3.1.1.2 Active substances in Schüssler salts

For these active substances, the number of the salt appears at the beginning of the active substance name. The active substance names given in the SC List apply. The remaining requirements are the same as those for homeopathic active substances.

e.g.

№ 11 Silicea (HAB) D12

№ 12 Calcium sulfuricum (HAB) D3 (HAB 6)

№ 13 Kalium arsenicosum D12 (HAB 6)

5.3.1.1.3 Active substances in medicinal products for gemmotherapy

The requirements for homeopathic medicinal products apply to medicinal products for gemmotherapy.

e.g.

Plant part - bud:	Castanea sativa e gemma recenti D1 (Ph.Eur.Hom. 2.1.3)
Plant part - young shoot tip:	Rubus idaeus e germine recenti D1 (Ph.Eur.Hom. 2.1.3)
Plant part - root tip:	Secale cereale e radicella recenti D1 (Ph.Eur.Hom. 2.1.3)

5.3.1.2 Active substances in anthroposophic medicinal products

The requirements stated in 5.3.1.1.1 apply to active substances produced according to a homeopathic manufacturing process.

Anthroposophic active substances that are derived from plant-based starting materials but not manufactured and potentised according to a homeopathic process or for which the homeopathic section of a recognised pharmacopoeia contains no manufacturing instructions are subject to the requirements for herbal substances and preparations stated in the guidance document *Authorisation of phytotherapeutic products*. In addition to the plant drugs used, the botanical name of the primary plant and the plant part used and, for extracts, the type of extract (e.g. dry extract, fluid extract), the drug-extract ratio and the extractant should be listed. Further details concerning these requirements, illustrated with examples, can be found in the guidance document *Authorisation of phytotherapeutic products* (see section 5.1.3).

As regards plant drugs and preparations derived from these drugs without a monograph in Ph. Eur., the species used, and not just the plant genus, should be included in the description of the preparations. Exceptions can only be accepted if just one species of the genus for use in medicinal products or other products is known and thus the generic designation is sufficiently precise for identifying the extract.

e.g.

Citri limonis fructus recentis succus (Citrus limon (L.) BURM., fructus)

Menthae piperitae aetheroleum (Mentha x piperita L., aetheroleum)

Cydoniae fructus recentis extractum aquosum (Cydonia oblonga MILL., fructus), DER 1:2.1, extractant: Aqua purificata

Bryophylli pinnati massa siccata 5-12 mg ex bryophylli folii recentis succus (Bryophyllum pinnatum (LAM.) OKEN., folium) 170 mg, DER: 1:0.67-0.83

As regards anthroposophic active substances for which several starting materials are compounded in a special process to form a mother substance, the starting materials stated in the monograph for the mother substance should be listed qualitatively in the *Full declaration* form. If these starting materials are monographed in a pharmacopoeia, the pharmacopoeia reference for the starting materials processed in the mother substance should be stated. These requirements apply irrespective of whether the active substance is the mother substance or whether the mother substance is potentised to form the active substance.

5.3.1.3 Excipients

Contents from manufacture/potentisation:

The quantities of vehicles or excipients used during manufacture/potentisation (e.g. ethanol 96%, water, lactose monohydrate, glycerol) and accounting for at least 1% of the finished product should be listed under this heading.

In the case of potentisation with an isotonising agent, the sodium-containing substances contained in oral and parenteral medicinal products must also be listed, regardless of the quantity. The quantities should be stated in mg.

The calculated total quantity of sodium should be rounded to one decimal point.

Excipients for the pharmaceutical form must be listed separately (see below).

The constituents of excipient mixtures such as ethanol/water mixtures or sodium chloride solution must be listed separately.

Excipients for the pharmaceutical form:

The quantity and quality of excipients that are used, in addition to the active substance, in the manufacture of the pharmaceutical form should be listed under this heading. The constituents of excipient mixtures such as ethanol/water mixtures or sodium chloride solution must be listed separately. The function of the excipients should be stated.

5.3.1.4 Further requirements

For pharmaceutical forms that contain ethanol, the ethanol content in the finished product should also be stated as a percentage by volume.

The total sodium content of oral and parenteral medicinal products that contain sodium (e.g. solutions for injection containing sodium chloride) must be listed separately.

For liquid pharmaceutical forms, the required figures should be stated in ml. If, as a result of the manufacturing process, the gram is selected as the reference value in the declaration, but the quantity of the medicinal product is stated in ml, the number of millilitres corresponding to 1 g of the medicinal product should additionally be stated.

Liquid homeopathic and anthroposophic preparations should not be described as "solutions". Rather than using this term, which can lead to confusion particularly for medicinal products with potentised active substances, the term "liquid" should be used.

If any medicinal product is dosed in drops, the drop equivalent should also be stated, as should the number of spray pumps per ml for sprays and the number of globules per gram for globules. The only exception from this requirement applies to eyedrops in single-dose containers since repeated withdrawal is not envisaged.

If an anthroposophic medicinal product contains only herbal active substances that are not manufactured according to a homeopathic manufacturing process, the section on "Contents from manufacture/potentisation" is omitted, and all excipients should be listed as for herbal medicinal products.

5.3.2 Packaging and patient information

For medicinal products without an indication that are authorised with a reduced dossier or in the notification procedure and whose packaging material is not checked and approved by Swissmedic, the statements under 7.2.3 should be observed. In particular, the Latin active substances names must not be translated into the national languages.

5.3.2.1 Active substances manufactured according to a homeopathic manufacturing process

5.3.2.1.1 Active substances in homeopathic and spagyric medicinal products

Active substances for which a monograph exists in a recognised homeopathic pharmacopoeia or in the "Homeopathic preparations and substances for homeopathic preparations" chapter of the European Pharmacopoeia or in the homeopathic section of Ph.F should be stated in accordance with the *Full declaration* form:

e.g.

Aralia racemosa (HAB) D6

Galium odoratum spag. Zimpel (HAB) D1

Crocus (Ph.Eur.Hom.) D6 (Ph.Eur.Hom. 1.1.8)

If a monograph for the starting material exists in the non-homeopathic part of the pharmacopoeia, it is not mandatory – contrary to the information in the *Full declaration* form – to specify the quality monograph for the starting material.

e.g.

Magnesium asparticum D6 (HAB 5a)

However, if it is easier to declare the starting material by referencing the Ph. Eur. monograph – particularly if there are several possible primary plants – this can be done as follows using the Ph.Eur monograph names.

e.g.

Senna foliolum (Ph.Eur.) D6 (HAB 4a)

Ipecacuanhae radix (Ph.Eur.) D12 (Ph.Eur.Hom 1.1.8)

In addition to the scientific name, the Latin name commonly used in the respective school of therapy can optionally be stated.

e.g.

Atropa bella-donna (Belladonna) (HAB) D4 (Ph.Eur.Hom. 1.1.3)

Although a translation of the Latin active substance names commonly used in the school of therapy into German (or French/Italian) is unusual for potentised active substances manufactured according to a homeopathic manufacturing process, this may be included as additional information in the Patient information, provided the active substances are unambiguously and fully characterised in the translation. Only translations approved by Swissmedic for the corresponding medicinal product may be used.

The active substances in a medicinal product should be declared in a linguistically consistent manner. If the product contains both active substances manufactured according to a homeopathic manufacturing process and other active substances, all active substances should be listed, first in

Latin and, if necessary, supplemented by details of the primary plant and/or translations into the official Swiss languages.
Mother tinctures can be stated with "mother tincture", "TM" or with "Ø".

5.3.2.1.2 Active substances in Schüssler salts

Proceeding from the active substance name in the *Full declaration* form (section 5.3.1.1.2), the other requirements concerning the information in packaging texts and patient information are the same as those for homeopathic active substances (section 5.3.2.1.1).

e.g.

№ 11 Silicea (HAB) D12

№ 12 Calcium sulfuricum D3 (HAB 6)

5.3.2.1.3 Active substances in medicinal products for gemmotherapy

The active substances should be stated as they appear in the *Full declaration* form (section 5.3.1.1.3).

e.g.

Castanea sativa e gemma recenti D1 (Ph.Eur.Hom. 2.1.3)

5.3.2.2 Active substances in anthroposophic medicinal products

The information above applies to active substances manufactured using a homeopathic manufacturing process.

For anthroposophic active substances from plant-based starting materials that are not manufactured according to a homeopathic process, the requirements for herbal substances and preparations apply in accordance with the guidance document *Authorisation of phytotherapeutic products*.

As regards anthroposophic medicinal products with an indication and containing active substances that are declared exclusively according to the requirements for herbal substances and preparations, the active substance name in the patient information is translated into the official languages according to the requirements of the guidance document *Authorisation of phytotherapeutic products* and approved by Swissmedic. If the space available for entering the medicinal product composition on the packaging materials is insufficient, the abbreviated Latin form can be used for medicinal products with an indication (see section 5.1.3 of the guidance document *Authorisation of phytotherapeutic products*). Translations or abbreviated forms are not possible for medicinal products without an indication: the Latin active substance name shown on the *Full declaration HMV* form should be adopted.

If active substances with a homeopathic manufacturing process and active substances with a non-homeopathic manufacturing process are combined in an anthroposophic medicinal product, all active substances should be listed in Latin in both the patient information and the packaging texts. In this case, the details in the patient information for those active substances that are not produced according to a homeopathic manufacturing process must match the declaration in the *Full declaration* form.

As regards anthroposophic active substances for which several starting materials are combined in a special process to form a mother substance, the starting materials stated in the monograph for the mother substance should be listed qualitatively as in the *Full declaration* form. However, the inclusion of a reference to a pharmacopoeia should be omitted for these starting materials.

5.3.2.3 Excipients

Excipients should be listed in accordance with Ann. 3 and 3a TPLRO. If a medicinal product requires neither Information for healthcare professionals nor Patient information, the requirements for the Information for healthcare professionals apply to the full declaration of the excipients on the external packaging or, if there is no packaging, the container (quantities of excipients of particular interest should be specified; all other excipients should be stated qualitatively).

If vehicles or excipients are used in the manufacture/potentisation of the active substances (e.g. ethanol 96 %, water, lactose monohydrate, glycerol) and account for at least 1 % of the finished product, these should be listed among the excipients. As regards potentisation with an isotonising agent, the sodium-containing substances present in oral and parenteral medicinal products should also be listed quantitatively regardless of the amount and taken into account when stating the total sodium content. The optional mention of other excipients used during manufacture is permitted only if these have also been listed accordingly on the *Full declaration* form.

5.3.2.4 Further requirements

For medicinal products containing ingredients of animal origin as described in chapter 5.2.8 of Ph.Eur., the requirements relating to the declaration of the relevant substances stated in the guidance document *Minimising the risk of TSE* should also be observed.

If the medicinal product is dosed in drops, the drop equivalent should also be stated in the patient information, as should the number of spray pumps per ml for sprays and the number of globules per gram for globules. Stating the drop equivalent is also required for eyedrops in multi-dose containers. However, this is not necessary for eyedrops in single-dose containers since repeated withdrawal is not envisaged.

Liquid homeopathic and anthroposophic preparations should not be described as "solutions". Rather than using this term, which can lead to confusion particularly for medicinal products with potentised active substances, the term "liquid" should be used.

If the gram is selected as the reference value for liquid pharmaceutical forms, but the content of the container is stated in ml, the number of grams corresponding to 1 ml of the medicinal product should additionally be stated.

5.4 Documentation requirements

The requirements relating to the documentation of the procedures described in this guidance document are described in Chapters 6, 7 and 8.
Evidence must also be provided to show that medicinal products for livestock only contain active substances listed as permitted pharmacologically active substances in foodstuffs legislation. If necessary, withdrawal periods (waiting times) should be proposed and substantiated accordingly.

5.5 Document protection

No document protection is granted for authorisations of complementary medicines according to the procedures for simplified authorisation described in this guidance document. Such protection is possible only for authorisations according to Art. 11 TPA (see guidance document *Authorisation of human medicinal product with a new active substance*).

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

5.6.1 Paediatric population

5.6.1.1 General requirements relating to the dosage recommendation in the product information

If the dosage recommendation distinguishes between different paediatric populations, the respective age ranges with specific figures should be stated. The age group classification is based on the definitions in the ICH Guideline "*Clinical Investigation of Medicinal Products in the Pediatric Population E11*":

Preterm newborn infants:	before the end of the 37th week of pregnancy
Term newborn infants:	0 – 27 days
Infants and toddlers:	28 days – 23 months
Children:	2 – 11 years
Adolescents:	12 – 18 years
Adults:	from 18 years

Age groups excluded from the dosage instruction must be listed both in the **"Do not take/use … or take/use only with caution"**) and **"How to take/use …"** sections.

5.6.1.2 Homeopathic and anthroposophic medicinal products according to Chapter 4 KPTPO

According to Ann. 2 no. 5 KPTPO, the following requirements apply to homeopathic and anthroposophic medicinal products:

- Data on paediatric populations must be submitted if dosage recommendations are requested for these age groups. Otherwise, use in these age groups should be ruled out with the standard texts provided in Ann. 5.2 no. 5, 6 and 8 TPLRO, or permitted on a prescription-only basis.
- A Paediatric Investigation Plan according to Art. 54a TPA is not required for the simplified authorisation procedures described in this guidance document.

5.6.1.3 Complementary medicines used in alternative treatments according to Chapter 6 KPTPO

As regards the paediatric population, medicines used in gemmotherapy and Schüssler therapy are subject to the same requirements as homeopathic and anthroposophic medicinal products.

For complementary medicines used for alternative treatments, the Agency specifies what documents are needed on a case-by-case basis.

5.6.2 Geriatric population

Any data available on the geriatric population should be described. As with the provisions for the paediatric population, any missing data should be mentioned.

5.7 Pharmacovigilance Plan

5.7.1 Homeopathic and anthroposophic medicinal products according to Chapter 4 KPTPO

A Pharmacovigilance Plan according to Art. 11 para. 2. let. a no. 5 TPA is not required for the simplified authorisation procedures described in this guidance document.

5.7.2 Complementary medicines used in alternative treatments according to Chapter 6 KPTPO

As regards the Pharmacovigilance Plan, the same requirements apply as for homeopathic and anthroposophic medicinal products.

5.8 Time limits

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

5.9 Fees

The fees specified in the Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic; SR 812.214.5) apply.

6 Homeopathic and anthroposophic medicinal products with indication (Art. 24 para. 1 KPTPO)

6.1 Precondition for the application of the procedure

According to Art. 24 para. 1 KPTPRO, a homeopathic or anthroposophic medicinal product with indication can be authorised if it fully satisfies the definition of a medicinal product in the corresponding school of therapy and if the quality, safety, innocuousness and therapeutic effect are adequately documented.
The following points in particular must be fulfilled:

- The starting materials correspond with Chapter 4, section 2 KPTPO
- All active substances are manufactured according to a homeopathic, anthroposophic or spagyric process (sections 3 and 4 KPTPO).
- The pharmaceutical form is known in the corresponding school of therapy (Art. 23 para. 2 KPTPO).
- Adequate safety is documented for the active substances and their use.
- The indications are substantiated according to the therapeutic principle in question.

6.2 Medicinal product name

Selection of the medicinal product name is subject to the requirements of the guidance documents *Medicinal product name* and *Packaging for human medicinal products*. In particular, it should be noted that an indication may be mentioned only as a name extension (suffix), e.g. to the company name (core brand / prefix) and approved only if the indication completely covers the approved indication.

If the name of a mother tincture is part of the medicinal product name, this should be stated with "mother tincture". Stating "TM" is not permitted since this can also mean "trademark". As stated under 6.3 of the guidance document *Packaging for human medicinal products,* special characters may be used only if they are part of a registered trademark logo. This does not apply to "Ø" which is rather a special character with a substantive meaning.

6.3 Application documentation requirements

The principles concerning the requirements and scope of documentation are defined in Ann. 2 KPTPO.

For medicinal products containing active substances that are not hitherto known in homeopathy, anthroposophy or spagyrics, or that employ a homeopathic therapeutic principle that differs from classical homeopathy, the compliance with the relevant definition in Art. 4 para. 3 KPTPO should be explained in a separate section.

For active substances that are not included in the HAS List, documentation demonstrating their familiarity in the corresponding school of therapy should be submitted, e.g. published analyses of homeopathic medicinal products (see also Ann. 3 no. 2 KPTPO).

6.4 Documentation on quality

6.4.1 Documentation on the quality of the active substance (Module 3.2.S)

Starting materials, active substances

Starting materials

The starting materials used must comply with the Pharmacopoeia monographs applicable to homeopathics and anthroposophics (Ph. Eur., Ph. Helv.) and satisfy the general requirements for starting materials stated in the Pharmacopoeia, HAB and Ph. F.

If an individual monograph exists in a recognised pharmacopoeia for a starting material, the requirements documented therein must be fulfilled. If a corresponding monograph does not exist for a starting material, the company must prepare its own monograph. Quality criteria, as defined in similar monographs of recognised pharmacopoeias, must be specified taking into account the nature of the relevant starting material (for example, herbal, animal, mineral or human origin). Reasons must be given for the choice of test and the methods must be validated.

As regards testing for contaminants in plant-based starting material, the requirements of the general Ph. Eur. monograph *Herbal Drugs for Homoeopathic Preparations/Plantae medicinales ad praeparationes homoeopathicas* must be taken into account.

In the case of herbal starting materials, precise details of the primary plant/primary plants and the plant parts used must be provided.

Organ preparations

In the case of organ preparations, documentation showing how the requirements relating to organ preparations are observed must also be provided (Art. 18 KPTPO).

Nosodes

In the case of nosodes, documentation showing how the requirements relating to nosodes are observed must also be provided (Art. 19 KPTPO).

Mother tinctures/Solutions/First triturations

If an individual monograph exists in a recognised pharmacopoeia for a mother tincture, solution or first trituration, the requirements documented in the monograph must be fulfilled.

If a corresponding monograph does not exist for a mother tincture, solution or first trituration, the company must prepare its own monograph characterising the quality of the preparation. The structure and content of the company’s monograph must be based on existing monographs included in the recognised pharmacopoeias.

Where applicable, assays must be carried out and limits specified (as for defined constituents, including inorganic substances, or for pharmacologically active substances such as alkaloids, cardiac glycosides, etc.).

The description of the manufacture of the mother tinctures, solutions and first triturations must prove that the manufacturing instructions, as described in Ph. Eur. or – where applicable – in other recognised pharmacopoeias, are followed.

Active substances

For active substances, the quality of the starting materials, mother tinctures, solutions, first triturations and lowest preparable dilutions used, see above, and the quality of the active substances, must be documented, where meaningful or useful.

If the preparations are potentised, the process of potentisation must also be documented (see also *Batch documentation*). Compliance with the manufacturing instructions as described in the Swiss Pharmacopoeia and in HAB, Ph. F. and B.Hom.P is essential.

Stability documents

If they do not immediately undergo further processing, the stability of the mother tinctures, solutions and first triturations must be tested. The recorded data – including colour illustrations of the fingerprints obtained by thin-layer chromatography and/or images of the GC/HPLC fingerprints, where applicable – as well as a critical evaluation of the data must be submitted. A substantiated retest period must be requested.

Primary container

If mother tinctures, solutions or first triturations or active substances are stored, documentation on the primary container used – particularly specifications– and documentation on the suitability of the materials used must be submitted. The required declarations of conformity must likewise be submitted. Potential interactions with the container materials must also be discussed.

Excipients

Specifications and test methods must be documented. If excipients are the subject of a monograph in the pharmacopoeia, the documented requirements must be satisfied; in these cases, a reference to the monograph is sufficient.

The same requirements apply to excipients used in the manufacture of the finished product (see CTD Module 3.2.P).

6.4.2 Documentation on the quality of the finished product (Module 3.2.P)

Composition of the finished product

The full (qualitative and quantitative) composition of the finished product must be documented. Where applicable, the active substances must be designated in accordance with the Pharmacopoeia, HAB, Ph.F. or B.Hom.P. For pharmaceutical forms whose composition (particularly the choice of excipients) is not defined in HAB, Ph.F., in the recognised manufacturing instructions in B.Hom.P or in the Pharmacopoeia, the choice of excipients must be justified

Manufacture of the finished product

The manufacture of the finished product must be described in both narrative and schematic form. The implemented in-process controls must be documented (specifications, analytical methods and test frequencies, if possible in tabular form). A standard batch size and/or batch size range must be defined.

The documentation must prove that the homeopathic or anthroposophic manufacturing instructions, as documented in Ph. Eur. or in other recognised pharmacopoeias, are followed.

The manufacturing process must be validated and the corresponding validation report submitted.

If validation is omitted, the reason for omitting it must be justified, taking into account the pharmaceutical form.

Procedures designed to achieve sterility must be described in detail.

Validation documents must be submitted for the corresponding manufacturing steps.

Control of the finished product

The specifications and analytical methods must be submitted, as must the validation documents, where applicable. The requirements of the respective Ph. Eur. monograph for the pharmaceutical form must be taken into account during the preparation of the specifications.

The following parameters – depending on the composition and pharmaceutical form – form part of the finished product specification:

- organoleptic aspects
- physical parameters
- identity tests (particularly chromatographic procedures for lower potencies and mother tinctures contained in the finished product)
- assays and/or limit tests for inorganic substances and herbal components with pharmacologically active/toxicologically relevant constituents
- dry residue or loss on drying
- alcohol content
- content of preservative(s)

The respective tests relating specifically to the pharmaceutical form must also be carried out.

Primary container

Documentation on the primary container must be submitted. This includes specifications, test methods and design drawings, plus documentation on the materials used and their suitability for the intended use. The required declarations of conformity must likewise be submitted. Particularly for liquid and semi-solid pharmaceutical forms, potential interactions with the container materials must be discussed.

Stability documentation for the finished product

The stability of the finished product must be investigated in accordance with ICH and EMA guidelines, and reasons for the proposed shelf life must be provided.

A shelf-life specification must be submitted.

The stability tests must be carried out on at least two batches and cover the entire shelf life. At least one of the two batches must be a production batch.

At the time of submission, the stability data covering a storage period of at least 6 months for at least 2 pilot batches must be available.

The recorded data must be documented clearly in tabular form. For the stability batches, the manufacturing date, batch size and the primary container used must be stated. If applicable, the colour illustrations of the fingerprints obtained at the individual test times by thin-layer chromatography and/or the images of the GC/HPLC fingerprints must be enclosed.

The submitted data must be discussed: *Out of specification* results, tendencies and statistically significant deviations, for example changes in the fingerprints, must be considered

Stability after opening should be tested if applicable and depending on the pharmaceutical form. A use-by period backed by appropriate reasons must be requested.

6.4.3 Batch documentation

Complete batch documentation must be submitted. The documentation must include all the records from the testing of the starting material, via the testing of the mother tincture, solution or first trituration, through to the manufacture and testing of the finished product. The batch documentation should be as coherent as possible.

6.5 Non-clinical documentation

6.5.1 Type and scope of documentation for toxicologically known starting materials, active substances or excipients

The familiarity of a starting material, active substance or excipient should be verified according to Ann. 2 no. 3.4 KPTPO.
The toxicological innocuousness of the starting material or the proposed potency/dilution should be demonstrated by submitting scientific findings.

6.5.2 Type and scope of documentation for toxicologically new starting materials, active substances or excipients

For toxicologically new starting materials, active substances and excipients, all aspects of safety and possible pharmacokinetic substance interactions should be addressed. These include information on general toxicity, genotoxicity, reproductive toxicity, carcinogenicity, immunotoxicity or local tolerance (e.g. allergenic potential). This information can be based on publications or experimental data generated with a starting material, active substance or excipient that is comparable with the substance to be authorised. If possible, preference should be given to the use of validated/qualified alternative methods rather than animal studies. The documentation should be discussed in the Nonclinical Overview (CTD Module 2.4), for example; experimental data should be prepared accordingly in summary form (CTD Module 2.6). All documents should be submitted in full (CTD Module 4).

The following should also be taken into account for homeopathic and anthroposophic medicinal products:

- Toxicological tests on animals are not required for new starting materials, active substances or excipients in dilutions or concentrations that exclude a possible risk of allergy or toxicity.
- Specifically, documents and studies on the allergenic potential of new starting materials, active substances or excipients are required only if these substances are present in the medicinal product in potencies up to, and including, D7. Any omission of such documentation must be justified.
- Specifically, documents on the interaction potential of new starting materials, active substances or excipients are required only if these are present in the medicinal product as active substances in a final dilution below D4. Any omission of such documentation must be justified.

6.6 Clinical documentation

6.6.1 Bibliographic clinical documentation

- Bibliographic documentation should demonstrate that:
  a) the composition can be sufficiently justified by use in the respective school of therapy, and familiarity in homeopathy or anthroposophic medicine can be proved for the requested indication;
  b) sufficient knowledge exists concerning possible adverse effects;
- If submitting bibliographic documentation to demonstrate therapeutic benefit, literature on the indication in the proposed school of therapy must be submitted for each individual active substance. In the case of books, at least the relevant chapter, the title page and publication details must be submitted. The literature must be assessed and referenced in the Summary (CTD Module 2.5.).
- The recognised sources for demonstrating therapeutic benefit are the monographs published by the German Commission D for homeopathic medicinal products and the monographs of the German Commission C for anthroposophic medicinal products, as well as the primary literature of the respective school of therapy. The Agency will verify on a case-by-case basis whether other literature sources can be recognised.
- Company publications, non-fiction books, articles not issued by specialist publishers, and books and publications that are not expressly concerned with the respective school of therapy will not be recognised as a matter of course.

6.6.2 Requirements for clinical documentation relating to use

- Apart from literature references, the evidence can also consist, for example, of scientifically prepared documentation on case reports, open trials or controlled clinical studies.
- For new homeopathic active substances, analyses of new homeopathic medicinal products can also be submitted.
- The case reports, open trials or controlled studies must involve the corresponding school of therapy, and the results must be clearly attributable to the corresponding active substance or medicinal product.
- Results of clinical trials (open trials/controlled clinical studies) are required in the case of a new use that is not adequately documented in the specialist literature for the respective school of therapy.
- Demonstration by means of case reports or open trials requires at least 50 reports/open trials from several investigating physicians. Trials must be prepared, conducted and assessed in accordance with the requirements stated in Art. 14 paragraph 4 of the Ordinance on Clinical Trials (ClinO). Furthermore, trials must be conducted and assessed by qualified medical study investigators.
- If the notified medicinal product is directly comparable with a medicinal product that has already been authorised, reference can be made to the published results of observational studies of the authorised medicinal product.
- Sales figures on the documentation of patient exposure will not be accepted as proof for an indication, but they will be used for the purpose of calculating the incidence of adverse effects.

6.6.3 Requirements for the indication wording

- Indications are recognised only if adequate evidence has been obtained from the corresponding school of therapy.
- Requested indications may not be derived from the findings of other schools of therapy, nor may they be mixed with findings from phytotherapy or findings from allopathy.
- Formulations on indications always start with “According to homeopathic pharmacology…” or “According to anthroposophical knowledge of humans and nature…” etc.
- Indications that are considered to be obsolete on the basis of the latest medical and therapeutic findings for a complementary medicine cannot be recognised as such (e.g. immune disorders, defined psychiatric illnesses, cancers).
- If a medicinal product is intended to be used in addition to another treatment for a particular indication, this should be specified accordingly (e.g. “in addition to a medically required treatment for..”)

6.6.4 Requirements for documentation on tolerability

6.6.4.1 Basic information

Any adverse effects that occur during investigations designed to demonstrate therapeutic benefit should be prepared and reported to the Agency in accordance with *Instruction BW101 22 001e MB Safety relating to clinical trials – Compulsory notification*.

- Any adverse effects of the medicinal product or one of its constituents that are known from the literature or postmarketing experience should be described and assessed.
- This requirement also applies if new, previously unknown adverse effects or risks emerge for substances and potencies included in the HAS List.
- Swissmedic can determine, in individual cases, that documentation on tolerability does not need to be submitted if the medicinal product
    - contains sufficiently diluted active substances that are known in homeopathy or anthroposophic medicine. In this case, substances included in the HAS List for the respective method of administration can be taken into account in the dilutions stated under “Notification procedure as of” or higher dilutions, as can substances not on this list in potencies from D12/C6, provided the HAS List accords with the latest scientific and technical findings for the corresponding substance
    - and only contains known excipients, or carrier substances commonly used in homeopathic or anthroposophic medicine.
- Swissmedic decides whether documentation is not required on the basis of corresponding reasons.

6.6.4.2 Scope of documentation

For preparations with substances and potencies that are not included on the HAS List for the respective method of administration, or whose familiarity and efficacy cannot be adequately demonstrated in the corresponding school of therapy, the following documents relating to safety are expected:

- Provided the medicinal product is marketed in another country, the findings obtained in that country from postmarketing experience must be documented in a Safety Update Report and a risk assessment undertaken based on this report:
    - sales figures (packages or units sold per country and year)
    - information on how long the preparation has been on the market in the country in question and whether (and if so, what and why) quality-related changes have been made
    - known side effects, contraindications and interactions, as well as documentation of a corresponding systematic literature search
    - submission of the current or most recent valid medicinal product information from the country in question
    - submission of existing Periodic Safety Update Reports (PSUR).

- Provided the substances concerned are known from their use in other areas (e.g. medical device, foods, cosmetics), the findings obtained in these areas must be documented and a risk assessment undertaken based on these findings.
- If sufficient data and findings on the use of the substances or medicinal product are not available, the following documents must be submitted:
  - Medicinal products for topical use on the skin or mucous membranes require single and repeated testing for local tolerance and sensitising properties. To this end, at least 50 open trials by several investigating physicians are required as proof of clinical tolerance.
  - For medicinal products intended for parenteral administration, safety data in the form of clinical trials (open trials) with humans or the proposed target animal species and relating to the respective method of administration must be submitted.
  - For nosodes and organ preparations, safety in humans or in the proposed target animal species must also be investigated in addition to the testing of local tolerance in animals (for preparations for local or parenteral administration), taking account of immunological parameters for determining the risk of sensitisation.

6.6.5 Requirements for the summary of the clinical documentation (Clinical Expert Statement, e.g. in a CTD Module 2.5)

- This part should give a clear picture of the therapeutic benefit and clinical tolerability of the notified medicinal product. The name of the medicinal product, pharmaceutical form, method of administration, dosage and therapeutic use must be stated in an introduction. The summary should include a clear overview of the assessment of the clinical documentation with reference to all claimed uses and should be adequately referenced. It should present all results from clinical trials and the systematic literature search – including positive and negative findings – and assess the possible benefit and risks.
- If clinical trials (e.g. open trials) are submitted, the corresponding Study Reports must be submitted and a summary evaluation carried out. The author of the Expert Statement should be an expert who is qualified and trained in the relevant subject area.

6.7 Medicinal product information and package texts

6.7.1 Special situations

In addition to the requirements of Ann. 2 no. 1 KPTPO, as well as Annexes 1 and 5.2 TPLRO, the requirements of the guidance document *Product information for human medicinal products*, the guidance document *Product information for veterinary medicinal products*, the guidance document *Packaging for human medicinal products and the guidance document Packaging texts for veterinary medicinal products,* as well as any Swissmedic publications that apply to the product information and package texts of complementary medicines, also apply.

The following applies to the information in Annex 5.2, section 3 TPLRO: Indications must always be introduced with formulations such as "According to homeopathic pharmacology, …" or "According to anthroposophical knowledge of humans and nature...". The merging of different schools of therapy is not permitted.
Only if there is clinically controlled evidence of efficacy or scientific proof of the mode of action may the properties of the active substances or medicine also be mentioned as follows:
" (the active substances contained in) are effective in ..."
" (medicine XY) is effective in ..."

If there is no clinically controlled evidence of efficacy, the following additional statement can be approved if this is adequately substantiated:
"(e.g. anti-inflammatory) properties are attributed in (school of therapy) to (the active substances contained in ...)"

Packaging texts for medicine cabinets or family pharmacies that deviate from the TPLRO are not approved by Swissmedic.

6.7.2 Standard text concerning the indication:

The standard text included in the template *Patient information for homeopathic and anthroposophic medicinal products* is part of the drug-specific indication and explains the underlying basis. It applies to all those homeopathic and anthroposophic medicinal products for which proof of efficacy was not provided by means of clinical trials conducted to current scientific standards (at least AHCPR level of evidence III).

7 Authorisation of homeopathic and anthroposophic medicinal products without indication

7.1 Authorisation without indication with complete documentation (Art. 25 para. 2 KPTPO)

The statements on the authorisation of medicinal products with indication contained in Art. 24 KPTPO apply to the documentation to be submitted on quality and safety.

The labelling and medicinal product information should be based on the requirements of Art. 26 para. 1 KPTPO.

As well as Ann. 1a no. 1 para 2 and 3 TPLRO, the detailed information in section 5.3 of this guidance document should also be observed when declaring active substances. Examples can be found in Ann. 9.2.

7.2 Authorisation with Reduced Dossier (Art. 25 para. 1 KPTPO)

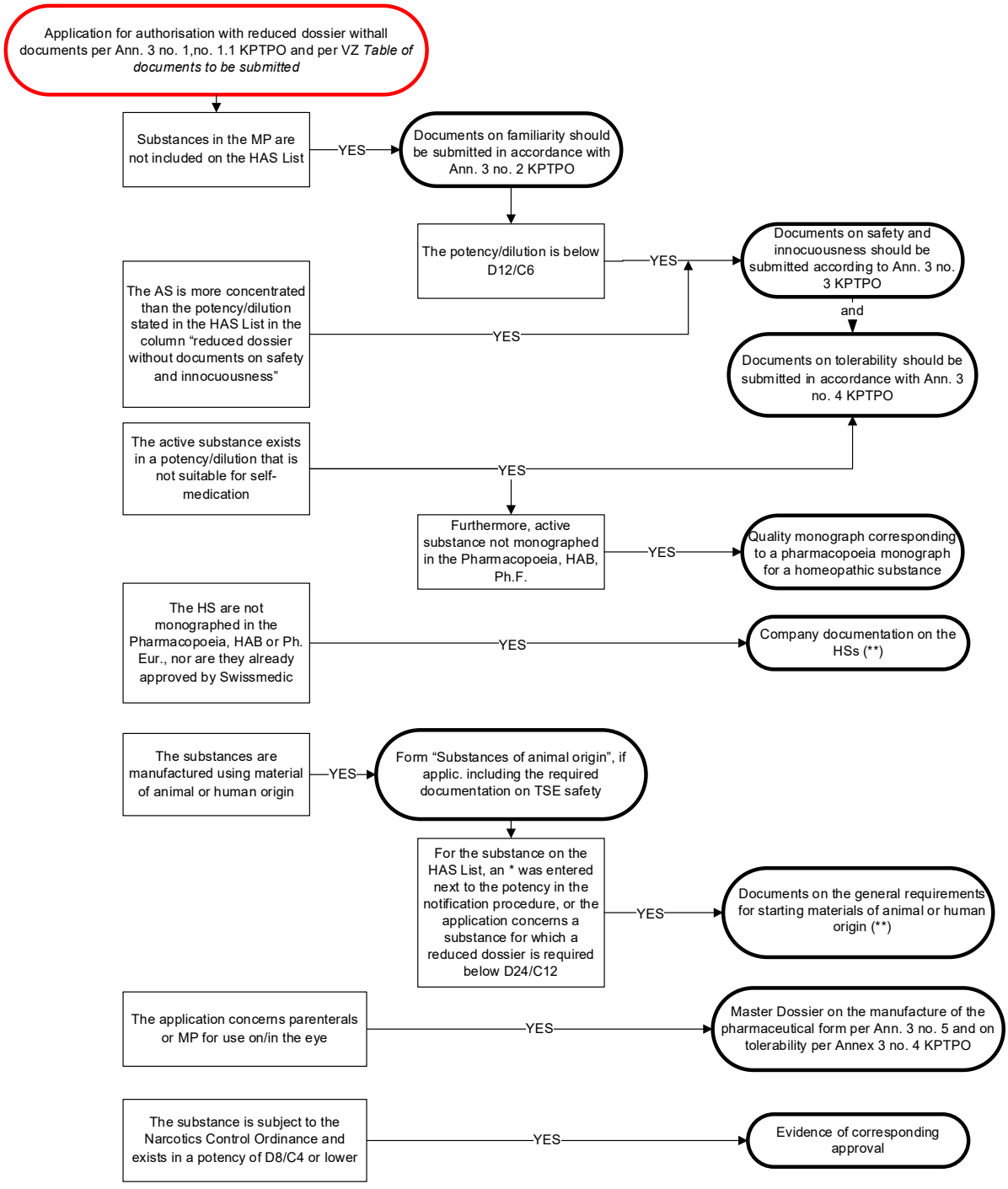
7.2.1 Preconditions for the application of the procedure

The preconditions set out in Art. 25 para. 1 KPTPO apply.

7.2.2 Required documentation

Only the documentation specified in Ann. 3 KPTPO needs to be submitted for an application with a reduced dossier. Applications containing additional documents do not satisfy the formal requirements.

The following graphic is intended to facilitate the compilation of the required documents:



Note: The documents listed in the oval boxes must be submitted with the application for authorisation with a reduced dossier.

** If applicable for several products, a template in the form of Master Dossiers is possible. For Master Dossiers the corresponding information stated in the WL *Notification procedure for homeopathics and anthroposophics* should be observed. It is also possible to submit Master Dossiers that apply both to products in the notification procedure and those with a reduced dossier. A reference to other valid Master Dossiers should be included in the documentation.

Authorisation with a reduced dossier is also possible for substances not included in the HAS List and for substances to be authorised at a lower potency than envisaged for a notification procedure.

As part of an application with reduced dossier, it is also possible to apply for a dispensing category other than that stated in the HAS List.

An application for authorisation with a reduced dossier can be accompanied by a simultaneous request to add the substances or potencies contained in the proposed preparation to the HAS List. (see guidance document *Authorisation for homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy without indication in the notification procedure*)
A separate application with reduced dossier is required for each pharmaceutical form. It is not possible to change the pharmaceutical form at a later date by means of a variation application.

If a medicinal product is to be authorised as both a human and a veterinary medicinal product, separate applications are required for this purpose.

7.2.3 Information and texts on containers and packaging materials

Ann. 1a TPLRO applies. The following should be noted in particular:

- only scientific names are permitted as product names
- no indications or dosages may be stated. Instead, the following standard text should be stated: “For individual therapy, use and dosage as directed by the advising professional”
- all restrictions on use and warnings included in the HAS List for the respective substances, and any other known restrictions on use and warnings, must be listed.
- no other information beyond that specified in Ann. 1a TPLRO or not approved by Swissmedic is permissible.

According to Art. 26 para. 1 TPO, the information on the packaging must be drafted in at least two of Switzerland's official languages.

The scientific name of the medicinal product approved by Swissmedic must not be modified and translations into the Swiss national languages must not be added.

If the space available on the container/packaging material is insufficient for all the information required by Ann. 1a TPLRO, the information stated in Ann. 1a no. 1 para 1 let. h and j TPLRO can be omitted from the packaging texts. In this case, the missing information should be summarised in a package leaflet for enclosure with the medicinal product in the form of an information sheet in two of Switzerland's official languages (Art. 44 para. 2 KPTPO). However, this information sheet may not contain additional information or figures that go beyond the scope of Ann. 1a TPLRO or that are not ordered by Swissmedic.

If all information is presented in the form of a wrap-around label, all the information required by Annex 1a TPLRO, excluding number 1 para. 1 let. h and j, should appear on the part of the label that is visible without unrolling.

The active substances should be declared in Latin. As well as Annex 1a no. 1 paras. 2 and 3 TPLRO, the detailed information in section 5.3 of this guidance document should also be observed. Examples can be found in Annex 9.2.

Even if the composition of the preparation is repeated on an enclosed information leaflet, a translation of the active substance names commonly used in the relevant school of therapy into the national languages may be omitted. This also applies to anthroposophic active substances from plant-based starting materials that are not produced and potentised according to a homeopathic manufacturing process or for which no corresponding manufacturing specification exists in the homeopathic section of a recognised pharmacopoeia.

In addition to the active substances, all excipients contained in the preparation should also be declared in qualitative terms, regardless of their quantity. Furthermore, the vehicles used during manufacture/potentisation and other excipients (e.g. ethanol 96 %, water, lactose monohydrate, glycerol) should be listed as excipients if they account for at least 1% of the finished product. As regards potentisation with an isotonising agent, the sodium-containing substances present in oral and parenteral medicinal products should also be listed regardless of the amount. The quantities of excipients of particular interest according to Ann. 3a TPLRO should be listed. The constituents of excipient mixtures such as ethanol/water mixtures or sodium chloride solution must be listed separately. The total quantity of sodium in oral and parenteral medicinal products that contain sodium (e.g. solutions for injection containing sodium chloride) must be listed separately.

If the composition is repeated on an enclosed information sheet, the excipients may be listed in the official languages on the information sheet only and in Latin on the packaging materials.

For liquid pharmaceutical forms, the required figures should be stated in ml. If, as a result of the manufacturing process, the gram is selected as the reference value in the declaration, but the quantity of the medicinal product is stated in ml, the number of millilitres corresponding to 1 g of the medicinal product should additionally be stated.

If the medicinal product is dosed in drops, the drop equivalent should also be stated, as should the quantity delivered per spray pump for sprays and the number of globules per gram for globules. Stating the drop equivalent is also required for eyedrops in multi-dose containers. However, this is not necessary for eyedrops in single-dose containers since repeated withdrawal is not envisaged.

Negative declarations (e.g. “lactose-free”) are not permitted.

For excipients of particular interest according to Ann. 3a TPLRO, the specified warnings should be adopted. Since a dosage is not stated for medicinal products without an indication, the relevant thresholds and information required by Ann. 3a TPLRO should be selected as a reference value per ml or g rather than as a dose.

The warnings for ethanol should be stated according to the ethanol content as follows:

Threshold less than 100 mg ethanol per ml:

This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per ml.

Threshold more than 100 mg ethanol per ml:

This medicinal product contains x mg of alcohol (ethanol) per millilitre or per gram (y% m/m or y%m/V). The amount in 1 ml corresponds to A ml of beer or B ml of wine.

Health risk for patients who suffer form alcoholism. This should be taken into account in pregnant or breastfeeding women or in children who are at an increased risk of liver disease or epilepsy.

The labelling of medicinal products containing narcotics in dilutions up to, and including, D8/C4, must display the text "*Subject to the Federal Act on Narcotics and Psychotropic Substances"*. If an information leaflet is provided, this text should be placed immediately after the product name.

The marketing authorisation holder is responsible for the design and correct content of the packaging texts and any information leaflet. The texts should be submitted as part of the authorisation application only in response to a specific request from Swissmedic.

The basic aspects of packaging materials design are subject to the requirements of the Guidance document *Packaging materials for human medicinal products* or the Guidance document *Packaging texts for veterinary medicinal products*.

8 Authorisation of complementary medicines used in alternative treatments

Chapter 6 KPTPO applies.

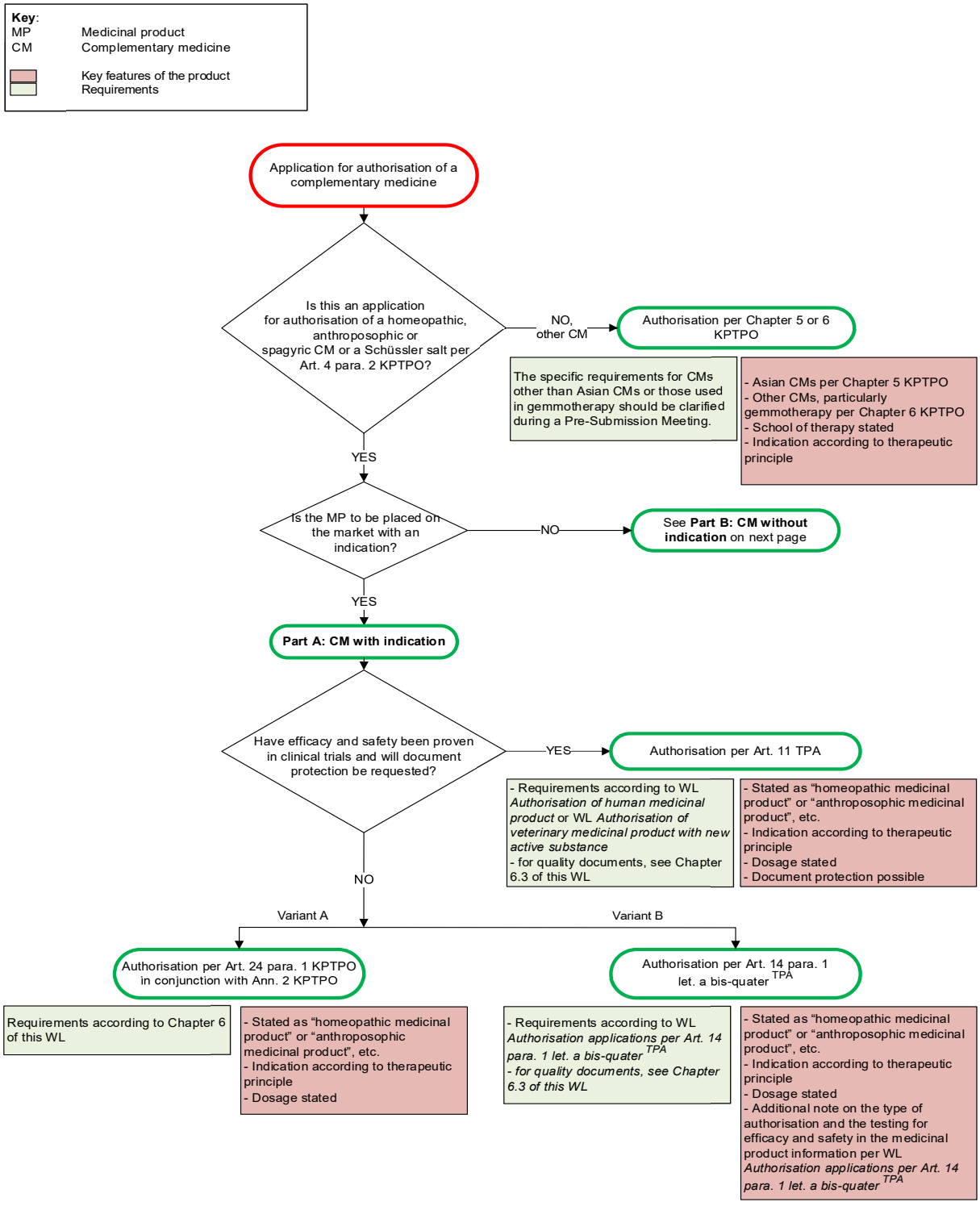
In addition to the medicinal products for gemmotherapy named in Art. 35 KPTPO, complementary medicines used in alternative treatments may, in principle, also be authorised according to Art. 35 KPTPO.

The application for these alternative treatments must be accompanied by adequate evidence showing that these are part of complementary medicine and established in corresponding professional circles. The applicant must also prove that the active substances, the combinability of active substances, the pharmaceutical form and the indications have been used and known for many years in the corresponding school of therapy. Corresponding evidence can be provided primarily through professional publications (reference books, publications in specialist journals).

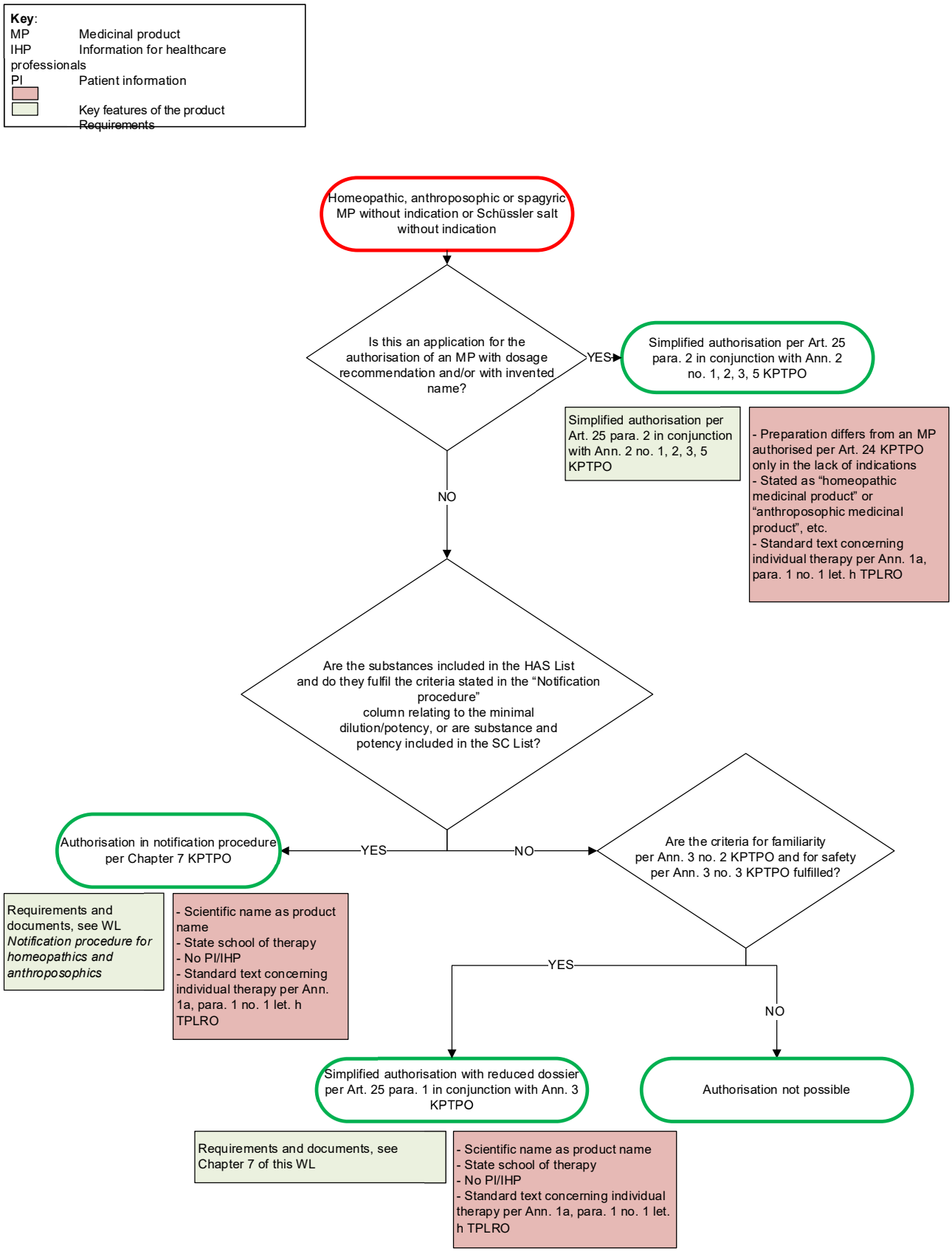
9 Annex

9.1 Decision tree for the application type for the authorisation of a complementary medicine

Part A: Complementary medicine with indication



Part B: Complementary medicine without indication



9.2 Sample declarations for medicinal products with and without indication

1. Medicinal product with indication and medicinal products without indication in the simplified authorisation procedure (Art. 25 para. 2 KPTPO)

A. Drops containing 3 active ingredients and additional excipients

- *Full declaration* form:

  1 ml of liquid contains:

Belladonna (Ph.Eur.Hom.) D4 (Ph.Eur.Hom. 1.1.3)	0.1 ml
Arnica montana ex planta tota (HAB) D3	0.1 ml
Calcium fluoratum (HAB) D6	0.3 ml

  Contents from manufacture/potentisation:

Ethanol 96 % (Ph.Eur.)	x mg
Purified water (Ph.Eur.)	q.s
Lactose monohydrate (Ph.Eur.)	x mg

  Excipients:

Ethanol 96 % (Ph.Eur.)	y mg
Purified water (Ph.Eur.)	y mg

  corresp. to Ethanolum xxx % (V/V)

  1 ml is equivalent to xxx drops.

- Medicinal product information (3 official languages)

  Composition
  1 ml of liquid (xxx drops) contains:
  Active substances:

Belladonna (Ph.Eur.Hom.) D4 (Ph.Eur.Hom. 1.1.3)	0.1 ml
Arnica montana ex planta tota (HAB) D3	0.1 ml
Calcium fluoratum (HAB) D6	0.3 ml

  Excipients: Ethanol 96 %, purified water, lactose monohydrate x mg. Contains xxx vol% alcohol.
  Warning for ethanol and lactose monohydrate in accordance with Ann. 3a TPLRO.

- Packaging materials to match (2 official languages, Latin names permissible for excipients) but without warning in accordance with Ann. 3a TPLRO.

B. Solution for injection containing 2 active ingredients and additional excipients

- *Full declaration* form:

  1 ml ampoule contains:
  Active substances:

Colchicum autumnale (HAB) D12	0.6 ml
Crotalus horridus (HAB) D6	0.2 ml

  Contents from manufacture/potentisation:

Sodium chloride (Ph.Eur.)	x mg
Water for injection purposes (Ph.Eur.)	y ml
Glycerol (Ph.Eur.)	z ml

  Excipients:

Water for injection purposes (Ph.Eur.)	0.2 ml
Sodium chloride (Ph.Eur.)	xx mg (isotonising agent)

  Equivalent to sodium x mg

- Medicinal product information (3 official languages)

  Composition:
  1 ml ampoule contains:
  Active substances:

Colchicum autumnale (HAB) D12	0.6 ml
Crotalus horridus (HAB) D6	0.2 ml

  Excipients: Water for injection purposes, sodium chloride, glycerol.

  Warning for sodium in accordance with Ann. 3a TPLRO.

- Packaging materials to match (2 official languages, Latin names permissible for excipients) but without warning in accordance with Ann. 3a TPLRO.

C. Globules containing 2 active substances

- *Full declaration* form:

  1 g of globules contains, in processed form:
  Active substances:

Apocynum cannabinum (HAB) D12	5 mg (or 0.005 g)
Calcium sulfuricum (HAB) D12	5 mg

  Excipients:

Sucrose (Ph.Eur.)	1 g (vehicle)

  1 g is equivalent to 110 – 130 globules.

  It is no longer possible to state percentages in full declarations.

- Medicinal product information (3 official languages)

  1 g of globules contains, in processed form:
  Active substances: Apocynum cannabinum (HAB) D12 10 mg, Calcium sulfuricum (HAB) D12 5 mg
  Excipient: 1 g sucrose

  1 g is equivalent to 110 – 130 globules.

  It is no longer possible to state percentages in full declarations.

  Warning for sucrose in accordance with Ann. 3a TPLRO.

- Packaging materials to match (2 official languages, Latin names permissible for excipients) but without warning in accordance with Ann. 3a TPLRO.

If insufficient space is available, the statement "1 g of globules contains, in processed form" can either be replaced by the statement "1 g of globules contains" [in French and German] at the start of the declaration or by "per 1 g of globules" [in French and German] following the list of ingredients.

D. Eyedrops in single-dose containers

- *Full declaration* form:

  1 ml of liquid contains:
  Active substances:
  Euphrasia (HAB) D6 1ml

  Sodium chloride (Ph.Eur.) x mg
  Water for injection purposes (Ph.Eur.) y ml

- Medicinal product information (3 official languages)

  Composition:
  1 ml of liquid contains:
  Active substance:
  Euphrasia (HAB) D6 1ml
  Excipients: Water for injection purposes, sodium chloride, glycerol.

- Packaging materials to match (2 official languages, Latin names permissible for excipients) but without warnings in accordance with Ann. 3a TPLRO.

2. Medicinal product without indication authorised with reduced dossier (Art. 25 para. 1 KPTPO) or by the notification procedure (chap. 7 KPTPO)

Principles: As regards requirements for active substance names, the requirements and examples listed under 5.3 should be observed in addition to Ann. 1a para. 1 no. 2 and 3 TPLRO.

If the active substances' scientific names commonly used in the school of therapy are to be listed as well, only the scientific names or synonyms listed in the HAS List (Ann. 6 KPTPO) and gemmotherapy list (Ann. 8 KPTPO) are permissible (cf. sample packaging texts B and C). Names must not be translated into the official languages.

Example for homeopathy:

Belladonna (Ph.Eur.Hom.) D6 (Ph.Eur.Hom. 1.1.3) *or*
Belladonna (Atropa belladonna) (Ph.Eur.Hom.) D6 (Ph.Eur.Hom. 1.1.3)

Example for gemmotherapy:

Castanea sativa e gemma recenti D1 (Ph.Eur.Hom. 2.1.3) *or*
Castanea sativa e gemma recenti (Castanea vesca e gemma recenti) D1 (Ph.Eur.Hom. 2.1.3)

A. Homeopathic medicinal product with 4 active substances and excipients from manufacturing, drops

- Declaration on packaging texts (in 2 official languages, Art. 25 para. 1 TPO):

  Zusammensetzung/Composition:
  1 ml Flüssigkeit/liquide (xxx Tropfen) enthält/contient :
  Wirkstoffe/Principes actifs :

Belladonna (Ph.Eur.Hom.) D6 (Ph.Eur.Hom. 1.1.3)	0.3 ml
Arnica montana ex planta tota (HAB) D8	0.3 ml
Calcium fluoratum (HAB) D12	0.2 ml
Senna foliolum (Ph.Eur.) D8 (Ph.Eur.Hom. 1.1.8)	0.2 ml

  Hilfsstoffe/Excipients: Ethanol 96 %/éthanol à 96 %, Gereinigtes Wasser/eau purifiée
  Enthält/Contient: … Vol.-% Alkohol/d'alcool

  1 ml entsprechen/correspond à xxx Tropfen/gouttes

  Warning for ethanol in accordance with the requirements stated in 7.2.3.

B. Homeopathic medicinal product with 1 active substance and excipients from manufacturing, globules

- Declaration on packaging texts (in 2 official languages, Art. 26 para. 1 TPO)

  Composition:

  1 g of globules contains, in processed form:
  Active substance: Belladonna (Ph.Eur.Hom.) D6 (Ph.Eur.Hom. 1.1.3) 10 mg
  Excipient: Sucrose 1 g
  1 g is equivalent to 110 – 130 globules.
  Composition:
  1 g de globules contient :
  Principe actif: Belladonna (Ph.Eur.Hom.) D6 (Ph.Eur.Hom. 1.1.3) 10 mg
  Excipient : Saccharose 1 g

  1 g correspond à 110 – 130 globules.

  Warning for sucrose in accordance with Ann. 3a TPLRO.

C. Homeopathic medicinal product with 1 active substance, excipients exclusively from the manufacture/potentisation of the active substance, oral drops

- Declaration on packaging texts (in 2 official languages, Art. 26 para. 1 TPO):

  Zusammensetzung/Composition :

  1 ml Flüssigkeit/liquide (xxx Tropfen/gouttes) enthält/contient :
  Wirkstoff/Principe actif :
  Belladonna (Ph.Eur.Hom.) D4 (Ph.Eur.Hom. 1.1.3) 1 ml
  Hilfsstoffe/Excipients : Ethanol 96 %/éthanol à 96 %, Gereinigtes Wasser/eau purifiée
  Enthält/Contient : … Vol.-% Alkohol/d'alcool

  Warning for ethanol per the requirements stated in 7.2.3

D. Medicinal product for use in gemmotherapy containing 3 active substances and excipients from manufacturing, spray for use in the buccal cavity

- Declaration on packaging texts (in 2 official languages, Art. 26 para. 1 TPO)

  Zusammensetzung/Composition:

  1 ml Flüssigkeit/liquide enthält/contient
  Wirkstoffe/Principes actifs :
  Ribes nigrum e gemma recenti D1 (Ph.Eur.Hom. 2.1.3) 0.5 ml
  Rubus idaeus e germine recenti D1 (Ph.Eur.Hom. 2.1.3) 0.3 ml
  Secale cereale e radicella recenti D1 (Ph.Eur.Hom. 2.1.3) 0.2 ml
  Hilfsstoffe/Excipients: Ethanol 96%/éthanol à 96 %, Glycerol/glycérol, Gereinigtes Wasser/eau purifiée

  Enthält/Contient: … Vol.-% Alkohol/d'alcool
  1 ml entsprechen/correspond à xxx Spraystössen/pulvérisations.

  Warning for ethanol per the requirements stated in 7.2.3.

E. Medicinal product for use in Schüssler therapy with 1 active substance and excipients from manufacturing, tablet

- Declaration on packaging texts (in 2 official languages, Art. 26 para. 1 TPO)

  Zusammensetzung/Composition:
  In 1 Tablette à xxx mg ist verarbeitet /1 comprimé à xxx mg contient:
  Wirkstoff/Principe actif :
  № 11 Silicea (HAB) D12 250 mg;
  Hilfsstoffe/Excipients: Lactose-Monohydrat/lactose monohydraté 250 mg,
  Magnesiumstearat/stéarate de magnésium, Kartoffelstärke/amidon de pomme de terre

  Warning for sucrose in accordance with Ann. 3a TPLRO, reference value per g.

F. Anthroposophic medicinal product with active substances derived from plant-based starting materials that are not produced according to a homeopathic process, oral drops

- Declaration on packaging texts (in 2 official languages, Art. 26 para. 1 TPO):

Zusammensetzung/Composition :
1 ml Flüssigkeit/de liquide (xxx Tropfen/gouttes) enthält/contient :
Cydoniae fructus recentis extractum aquosum (Cydonia oblonga MILL., fructus), DEV/RDE 1:2,1,
Auszugsmittel/agent d'extraction: Aqua purificata 1 ml
Hilfsstoff/Excipient : Gereinigtes Wasser/eau purifiée

G. Anthroposophic medicinal product with a composition as active substance, oral drops

- Declaration on packaging texts (in 2 official languages, Art. 26 para. 1 TPO):

Zusammensetzung/Composition :
1 ml Flüssigkeit/de liquide (xxx Tropfen/gouttes) enthält/contient :
Apis cum Levistico (compositio ex: Apis mellifica ex animale toto rec. et Levistici radicis sicc. extractum aquosum (Levisticum officinale W.D.J.KOCH.), DEV/RDE 4:1, Auszugsmittel/agent d'extraction: Aqua purificata) D3 (HAB 11) 1 ml
Hilfsstoffe/Excipients : Glycerol 85 %/glycerol à 85 %, Gereinigtes Wasser/eau purifiée

Change history

Version	Change	sig
6.0	• Additional section inserted on "Further requirements" for the Full declaration form (section 5.3.1.4) and the declaration in Packaging and patient information (section 5.3.2.4). Requirements supplemented and clarified in these sections. • Requirements changed for stating the drop equivalent for eyedrops (sections 5.3.1.4, 5.3.2.4, 7.2.3, and 9.2) • Requirement clarified for the listing of sodium-containing excipients (sections 5.3.1.3, 5.3.1.4 and 5.3.2.3) • Terminology adapted for the paediatric and geriatric population (sections 5.6.1 and 5.6.2) • Section inserted on "Medicinal product name" (section 6.2), with clarification concerning the inclusion of an indication or mother tincture in the medicinal product name • Section on the quality of the active substance moved and revised (section 6.4.1) • Addition concerning packaging texts for medicinal products with indication for medicine cabinets (section 6.7.1.) • Requirements clarified for the listing of the standard text concerning the indication (section 6.7.2) • "HMV4" removed from document titles	spm
5.0	• Declaration requirements structured according to the type of treatments (section 5.3). Examples added to the declaration requirements for spagyric medicinal products (sections 5.3.1.1.1 and 5.3.2.1.1) and for medicinal products for gemmotherapy (sections 5.3.1.1.3 and 5.3.2.1.3). Declaration requirements for anthroposophics supplemented and clarified (sections 5.3.1.2, 5.3.2.2 and 7.2.3). Requirements added concerning the sodium content and equivalent on the packaging texts (section 5.3.2.3). • Clarification of the indication-related information (section 6.6.1) • Clarification of the requirements for the ethanol warning for medicinal products without an indication (section 7.2.3). • Additional information on the wrap-around labels for medicinal products without an indication (section 7.2.3). Examples added relating to declaration on the *Full declaration* form, medicinal product information and the packaging texts (section 9.2)	spm
4.0	• Introduction of a new section *8 Authorisation of complementary medicines used in alternative treatments* • Renumbering of the following sections • Addition to section *6.2. Application documentation requirements* with information on active substances or therapeutic principles that were previously unknown in the school of therapy. • Further details in section 6.3.1 on primary containers and batch documentation. • Declaration requirements supplemented and explained in greater detail in the following sections: *5.3. Declaration requirements* *9.2 Sample declarations for medicinal products with and without indication*	spm

3.0	Declaration requirements for homeopathics and anthroposophics supplemented and explained in greater detail in the following sections: 5.3 Declaration requirements 7.2.3 Information and texts on container and packaging materials (only applies to medicinal products without indication) Second annex inserted: 8.2 Sample declarations for medicinal products with and without indication	spm
2.0	Declaration requirements modified for homeopathics and anthroposophics in the following sections: Section 5.6.1.1 General requirements relating to the dosage instruction in the product information Section 5.3 Requirements relating to the declaration a) *Full declaration* form; b) Folding carton and Patient information Section 7.2.3 Information and text on containers and packaging materials	spm
1.0	Implementation of TPO4	spm