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Change history

Version	Valid and binding as of	Description, comments (by author)	Author's initials
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1 Definitions, terms, abbreviations

1.1 Definitions and terms

a. Individual teas that satisfy the conditions stated in Art.12 KPTPO for the notification procedure
b. Cough and throat lozenges and pastilles that satisfy the condition stated in Art.13 KPTPO for the notification procedure

1.2 Abbreviations

Art.	Article
CTD	Common Technical Document for the Registration of Pharmaceuticals for Human Use
DER	Drug-extract ratio
DMF	Drug Master File
FeeO-Swissmedic	Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products of 7. September 2018 (SR 812.214.5)
GLP	Good Laboratory Practice
HMPC	EMA Committee on Herbal 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
OGLP	Ordinance of 18 May 2005 on Good Laboratory Practice (SR 813.112.1)
Para.	Paragraph
Ph. Eur.	Pharmacopoea Europaea
Ph. Helv.	Phamacopoea Helvetica
Sec.	Section
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)
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, SR 812.21)
TPLRO	Ordinance of the Swiss Agency for Therapeutic Products of 9. November 2001 on the Licensing Requirements for Therapeutic Products (SR 812.212.22)
VZ	Directory

2 Introduction and objective

This guidance document is aimed at administrative bodies and thus does not directly set out the rights and obligations of private individuals. Swissmedic uses the document as a resource for implementing – in a uniform and equitable manner – the legal provisions for the authorisation of individual teas in dispensing category E via the notification procedure (with corresponding health claim) as well as of cough and throat lozenges and pastilles in dispensing category E via the notification procedure (with a corresponding health claim). 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.
The guidance document applies to new authorisations of individual teas according to Art. 12 KPTPO and of cough and throat lozenges and pastilles according to Art. 13 KPTPO.
Unless otherwise noted in this guidance document, variation applications that concern medicinal products must be submitted in accordance with the guidance document *Variations and extensions HMV4*.

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3 Legal framework

The authorisation in the notification procedure for individual teas and for cough and throat lozenges and pastilles in dispensing category E is based, in particular, on the following legislative texts (provisions of laws and ordinances):

KPTPO

- Chapter 2, Section 2, Art.12 — Notification procedure for teas
- Chapter 3, Art.13 — Cough and throat lozenges and pastilles
- Chapter 7 — Notification procedure
- Annexes to KPTPO — Annex 4 (List of teas drugs) and Annex 5 (List of lozenges)

TPA

- Art. 14, para. 1 — Simplified procedure

TPLO

- Art. 32 para. 1 — Principle of the notification procedure

TPO

Therapeutic Products Ordinance

- Art. 3 — Authorisation application

TPLRO

- Art. 12, Annex 1 — Information and text on containers
- Art. 22 — Notification requirement

4 Description/General requirements/Assessment principles

4.1 General principles

4.1.1 Precondition for submission

Before an application for authorisation of a medicinal product in the notification procedure can be submitted, an approved basic company dossier based on Art. 37 and Art. 38 KPTPO must exist.

4.1.2 Time limits

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

4.2 Fees

The fees specified in FeeO-Swissmedic apply.

5 Authorisation of individual teas in the notification procedure

5.1 General

Individual teas in dispensing category E can be authorised in connection with a notification provided the conditions stated in Art. 15 para. 2 TPA are fulfilled and, according to the information available to the Swissmedic the submission and review of documentation on the quality, efficacy and safety of the ingredients do not appear to be necessary (Art. 32 para.1 TPLO). The tea drugs eligible for this procedure are documented in Annex 4 KPTPO.
According to Art. 32 TPLO, the submission and review of the application (notification) are based on Art. 3 TPO.
The Swissmedic checks the authorisation application for conformity with the requirements of this guidance document, particularly as regards the respective proposed active substance (tea drugs), and also checks the wording of the indication and the health claim in relation to the respective proposed active substance, as well as the dispensing category and packaging. If no objections arise during the check, the medicinal product is authorised without the submission of further documentation.

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5.1.1 Requirements

The requirements are defined in Art. 12 KPTPO.

5.1.2 Permitted indications

The health claims attributed to the individual tea drugs (e.g. helps with flatulence, diuretic, etc.) determine the specific indications that may be claimed. If several properties apply, all of them must be stated. The permitted indications are listed in Annex 4 of KPTPO (list of tea drugs).

5.2 Regulatory documentation (Module 1)

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

5.3 Documentation on quality (Module 3)

The applicant must be able to demonstrate the quality of the medicinal product – at any time when requested by the Swissmedic – by means of analytical, chemical and pharmaceutical documentation.

The following documents must be available:

1st Active substances: Specifications and test methods that demonstrate conformity with the following specifications:
- With the valid Ph. Eur. or Ph. Helv. monograph for the respective herbal drug
- With the general Ph. Eur. monograph Herbal Drugs / Plantae medicinales

2nd Manufacture of finished product: Narrative and schematic description; documentation of the implemented in-process controls.

3rd Container: Description of the container (filter bag, outer bag), specifications and analytical methods and documentation on the safety of the materials employed with reference to the intended use.

4th Medicinal product: Specifications and test methods that demonstrate conformity with the following Ph. Eur. specifications:
- With the general Ph. Eur. monograph *Herbal Drugs / Plantae medicinales*
- With the general Ph. Eur. monograph *Herbal Teas / Plantae ad ptisanam*

5th Documentation on the stability of the product in the proposed packaging. Data must be available for a period corresponding to the proposed shelf life, subject to a maximum of 24 months, which demonstrates that the requirements of Ph. Eur. (see point 4) are observed. A shelf life of more than 24 months may be claimed only if the corresponding data for the medicinal product on finished product stability are submitted for the full proposed shelf life.

5.4 Toxicological documentation (Module 4)

Since the toxicology of the substances listed in Annex 4 of KPTPO (list of tea drugs) is considered to be known, they are exempt from the need to submit toxicological documentation.

5.5 Clinical documentation (Module 5)

The benefit of the tea drugs listed in Annex 4 of KPTPO (list of tea drugs) can be promoted explicitly only for adults with the health claims stated in this Annex. The use of these listed health claims for the substances mentioned therefore means that clinical documentation does not need to be submitted.

5.6 Medicinal product information and packaging materials

The information and texts specified in Annex 1 of TPLRO (see Art. 12 para. 1 TPLRO) and the mandatory information specified in Annex 4 KPTPO should be stated on the container used for dispensing, and the requirements of guidance document *Packaging materials HMV4* must be fulfilled. If all the information can be stated on the carton, a package leaflet is not required.

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5.6.1 Additional requirements

5.6.1.1 Name

Only the company name together with the scientific name is permitted as the medicinal product name of an individual tea.

5.6.1.2 Composition / Declaration

The requirement for the declaration is based on the guidance document *Product information for human medicinal products HMV4.*

5.7 Variations to individual teas

Regulatory variations to authorised individual teas in dispensing category E must be submitted in accordance with the guidance document *Variations and extensions HMV4*, Regulatory variations. An extension of the shelf life beyond 24 months must be submitted in the form of a variation together with the necessary documentation in accordance with the guidance document *Variations and extensions HMV4* (see Art. 10 TPO).

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6 Authorisation for cough and throat lozenges and pastilles in dispensing category E in the notification procedure

6.1 General

Cough and throat lozenges and pastilles in dispensing category E can be authorised in connection with a notification provided the conditions stated in Art. 15 para. 2 TPA and in Art. 38, Chapter 7 KPTPO are fulfilled and, according to the information available to Swissmedic, the submission and review of documentation on quality, efficacy and safety of the ingredients do not appear to be necessary (Art. 32 para.1 TPLO). The permitted ingredients are documented in Annex 5 KPTPO.

The submission and review of the application (notification) are based on Art. 3 TPO in conjunction with Art. 32 TPLO and Chapter 7 KPTPO.

Swissmedic checks the authorisation application for conformity with the requirements of this guidance document, particularly as regards the qualitative and quantitative composition, the wording of the indication and the health claim in relation to the active substances, as well as the dispensing category and packaging. If no objections arise during the check, the medicinal product is authorised without the submission of further documentation.

6.2 Criteria for application of the notification procedure

6.2.1.1 Requirements

The requirements are defined in Art. 13 KPTPO.

6.2.2 Permitted indications and claims

The properties attributed to the various constituents (e.g. expectorant, soothing, disinfectant) are crucial for the indication. If justified on the basis of the composition, several indications may be claimed. The medicinal products may be promoted as emollients. These determine the indication. The permitted indications and claims are listed in the "Lozenges" list (Annex 5 KPTPO).

Not permitted are expressions which may give the impression that the effect of the medicinal product has been proven or that the medicinal product possesses preventive or curative effects (health claims). Also not permitted are trivialising formulations that may tempt a person to use the product excessively.

6.3 Regulatory documentation

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

If applicable, a detailed, qualitative composition of the flavours should be submitted by the flavour manufacturer. The qualitative composition quantities of the flavours should also be stated for excipients of particular interest according to Annex 3a TPLRO.

If the product is to be promoted as "kind to the teeth", an expert report by a recognised dental institute must be submitted.

6.4 Documentation on quality (Module 3)

The applicant must be able to demonstrate the quality of the medicinal product – at any time when requested by Swissmedic – by means of analytical, chemical and pharmaceutical documentation.

The following documents must be available:

1st Composition of finished product (full qualitative and quantitative composition), with details of the function of each individual ingredient (active substance, excipient (aroma, colouring agent, antioxidant, preservative, etc.)).
2nd Manufacture of finished product: narrative and schematic description; documentation of the implemented in-process controls.

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3rd Specifications for the primary drugs used in the manufacture of the individual active substances: If a monograph for a drug is published in the valid pharmacopoeia, the corresponding reference must be stated; the requirements described in the relevant monograph must be fulfilled. If no corresponding monograph exists, the manufacturer must prepare its own monograph for the primary drug concerned. This must correspond to an existing monograph in respect of content and scope and also satisfy the requirements of the Ph. Eur. monograph Herbal Drugs / Plantae medicinales.

4th Active substances: If a monograph for an active substance is published in the valid pharmacopoeia, the corresponding reference must be stated; all the requirements described in the relevant monograph must be fulfilled. If no corresponding monograph exists, the manufacturer must prepare its own monograph based on the requirements documented in the relevant General Monographs in Ph. Eur. (for example Herbal Drug Extracts / Plantarum medicinalium extracta or Essential Oils / Aetherolaea).

5th Excipients: If a monograph for an excipient is published in the pharmacopoeia, the respective reference to this monograph must be stated; the requirements described in this monograph must be fulfilled. If no corresponding monograph exists, reference can be made to foodstuffs legislation; the requirements described in this legislation must be fulfilled.

6th Primary container: Description (incl. design drawing) of the container, specifications and analytical methods and documentation on the safety of the materials employed with reference to the intended use.

7th Medicinal product: Specifications including, as a minimum, information on organoleptic testing (appearance, odour) and formulation testing (dimensions, average mass, consistency) and on the inspection of purity (water content, loss on drying, microbiological quality).

8th Documentation on the stability of the product in the proposed primary container. Organoleptic and purity tests must at least be implemented for a shelf life of up to 24 months. A shelf life of more than 24 months may be claimed only if the corresponding data for the medicinal product on finished product stability are submitted for the full proposed shelf life.

6.5 Toxicological documentation (Module 4)

The toxicological risks of the substances stated in the "Lozenges" list, Annex 5 KPTPO, are considered to be known. Accordingly, reference to the herbal substances and preparations stated in this list exempts the applicant from the need to submit toxicological documentation.

6.6 Clinical documentation (Module 5)

The benefit of the substances stated in the "Lozenges" list (Annex 5 KPTPO) can be promoted using only the health claims stated in this list. The use of these listed health claims for the substances mentioned means that clinical documentation does not need to be submitted.

6.7 Medicinal product information and packaging materials

All mandatory information should be stated on the container used for dispensing to patients. A package leaflet is not envisaged for the medicinal products covered by this guidance document *Authorisation of individual teas, cough and throat lozenges, pastilles in the notification procedure HM4* according to Art. 14 para. 3 TPLRO.

As regards the information and texts on containers and packaging materials, the requirements of Art. 12 para. 1 TPLRO apply; unless otherwise specified in this guidance document, the requirements of the guidance document *Packaging for human medicinal products HMV4* apply.

6.7.1 Additional requirements

6.7.1.1 Pack size

The determined quantity included in a pack must be such that the health of a small child cannot be harmed even after excessive consumption (particularly after the ingestion of the contents of a whole pack).

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The quantity of the pack contents can be stated as the full weight (i.e. the number of lozenges in a pack does not need to be stated), provided the weight per unit (lozenge) is declared in the composition.

The expiry date must be clearly shown. The month and year must always be stated, preceded by one of the following formulations:

- "Use by …";
- "Shelf life / expiry date: …";
- "Expires …";
- "May be used until …".

6.7.1.2 Name

The requirements stated in Art.9 para.4 TPO apply to the medicinal product naming of cough and throat lozenges and pastilles. Moreover, and to differentiate them from foodstuffs, the medicinal products should be designated as "cough lozenges" or "throat lozenges", "drops" or "pastilles". Excipients (flavouring and colouring agents) may not be highlighted specifically, either in the medicinal product name or in the packaging text.

6.7.1.3 Composition / Declaration

The requirement for the declaration is based on the guidance document *Product information for human medicinal products HMV4.*

The composition can be stated either as "per 100 g" or "per unit" (1 lozenge). The declaration can also be stated in Latin. The following requirements apply:

a) All active ingredients should be listed in (decreasing) order of their content
b) All additives subject to declaration according to Art. 14 TPLRO must be stated;
c) Any added sugar, sugar alcohols (mannitol, sorbitol, etc.) or sweeteners (e.g. cyclamate) must be declared.
d) The mention of "kind to teeth" and the display of the corresponding "happy tooth" symbol is permitted only if a corresponding expert report has been prepared by a recognised dental institute.

6.8 Variations to cough and throat lozenges and pastilles

Regulatory variations to authorised cough and throat lozenges and pastilles in dispensing category E must be submitted in accordance with the guidance document *Variations and extensions HMV4*, "Regulatory variations" chapter. If there are variations relating to the active substances contained in the medicinal product, these must be submitted as a new application. Variations relating to the excipients in the medicinal product are categorised as “Other regulatory variations”. If the variation also affects the packaging, the amended packaging must also be submitted for assessment along with the application in addition to the “Full declaration” form.
An extension of the shelf life beyond 24 months must be submitted in the form of a variation together with the necessary documentation in accordance with the guidance document *Variations and extensions HMV4* (see Art. 10 TPO).

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