EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 November 2023
EMA/HMPC/888811/2022
Committee on Herbal Medicinal Products (HMPC)

Concept paper on revision of the 'Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products / traditional herbal medicinal products'

Adopted by HMPC for release for consultation	25 January 2023
Start of public consultation	01 March 2023
End of consultation (deadline for comments)	31 May 2023

Comments should be provided using this template. The completed comments form should be sent to hmpc.secretariat@ema.europa.eu@ema.europa.eu

Keywords	Herbal medicinal products[1]; traditional herbal medicinal products; herbal substances[2]; herbal preparations[2]; extracts; declaration; SmPC[3]; package leaflet; labelling; HMPs[4]; THMPs[5]

[1] Throughout the document and unless otherwise specified, the term 'herbal medicinal product' includes 'traditional herbal medicinal product'
[2] The term 'herbal substance' should be considered as equivalent to the term 'herbal drug' as defined in the European Pharmacopoeia and the term 'herbal preparation' should be considered as equivalent to the term 'herbal drug preparation' as defined in the European Pharmacopoeia
[3] SmPC: Summary of Product Characteristics
[4] HMPs: herbal medicinal products
[5] THMPs: traditional herbal medicinal products

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

© European Medicines Agency, 2023. Reproduction is authorised provided the source is acknowledged.

1. Introduction

This concept paper addresses the need for a revision of the 'Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products' (EMA/HMPC/CHMP/CVMP/287539/2005 Rev.1).

Common criteria for the declaration shall ensure clear characterisation of and differentiation between different types of herbal substances/preparations and proper description of their qualitative and quantitative particulars. The declaration is primarily intended to describe the identity and quantity of the herbal substance/preparation, being the active substance of the herbal medicinal product (HMP) and should focus on those characteristics found to be useful in ensuring an adequate and harmonised description of the herbal substance/preparation and the HMP.

Guideline EMA/HMPC/CHMP/CVMP/287539/2005, initially published in 2007 and first revised in 2010, outlines the principles for uniform declaration of herbal substances/preparations in HMPs. It focuses on the different types of herbal substances/preparations in relation to the quality documentation given. Examples of declaration of such active substances are provided. The main guideline describes the declaration in the SmPC, while package leaflets, labelling and other herbal-specific provisions are provided in Annex 1 to the guideline.

2. Problem statement

The main principles in the current guideline are still valid; however, not all aspects and examples reflect the latest state of the art in the light of (I) accumulated experience from marketing authorisation and registration procedures of HMPs/THMPs and (II) updates and revisions of relevant European Pharmacopoeia (Ph. Eur.) provisions and HMPC guidelines related to quality of HMPs after 2010. A revision of the guideline could allow to address all latest developments improving the usability for applicants and assessors.

3. Discussion (on the problem statement)

Based on the issues highlighted in the problem statement above, this guideline needs a new revision, because:

- the guideline has not been updated since 2010,
- more experience and information have been accumulated from marketing authorisation and registration procedures (e.g. Mutual Recognition Procedure, Decentralised Procedure),
- changes and updates in Ph. Eur. after previous guideline revision (some examples have become outdated),
- two important guidelines 'Guideline on quality of herbal medicinal products/traditional herbal medicinal products' and 'Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products' have been revised recently,
- modified examples on new or specifically challenging cases of herbal preparations could provide better guidance for use in national and European marketing authorisation procedures.

4. Recommendation

The HMPC recommends revising the guideline to address the matters described under the 'Problem Statement' and 'Discussion (on the problem statement)' (see points 2 and 3 above), ensuring a continued harmonised approach for declaration of HMPs. The revised guideline shall apply to HMPs both for human and veterinary use and to THMPs for human use.

5. Proposed timetable

It is anticipated that a draft guideline could be available within one year after publication of the concept paper. The draft guideline will be released for external consultation for three months. The guideline could be finalised within six months after external consultation.

6. Resource requirements for preparation

The Rapporteurs should prepare a draft of the revised guideline for discussion and agreement at the Herbal Quality Drafting Group of the HMPC. Members States are invited to provide comments via their Committee Members. After HMPC agreement further coordination is foreseen with the Quality Working Party, Committee for Medicinal Products for Human Use (CHMP) and Committee for Veterinary Medicinal Products (CVMP), since in few cases HMP declaration principles are also applicable for medicinal products outside the remit of the HMPC.

7. Impact assessment (anticipated)

The revision of this 'Guideline on declaration of herbal substances and herbal preparations in herbal products / traditional herbal medicinal products' (EMA/HMPC/CHMP/CVMP/287539/2005 Rev.1) is expected to benefit all users of patient information (SmPCs, package leaflets and labelling). For declaration purposes of SmPCs, package leaflets and labelling, the revised guideline will better clarify the required information to be declared for active substances of HMPs and focus on useful characteristics. The updated guideline is also expected to help competent authorities and industry by harmonising declaration requirements and thus enabling a more consistent approach for a coherent declaration for patient information.

8. Interested parties

The interested parties include regulators, pharmaceutical industry, academic groups, and Ph. Eur. expert groups. Interested parties are initially invited to provide suggestions and examples on this concept paper. Secondly, specific comments on the draft revised guideline can be provided during public consultation and will be addressed in an overview of comments that will be published together with the final revised guideline.

9. References to literature, guidelines, etc.

Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products /traditional herbal medicinal products" (EMA/HMPC/CHMP/CVMP/287539/2005 Rev.1)

Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/CHMP/CVMP/201116/2005 Rev. 3)

Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/CHMP/CVMP/162241/2005 Rev. 3)

A Guideline on Summary of Product Characteristics (SmPC) (Human Medicinal Products), Eudralex Vol. 2C, Notice to Applicants (current version)

Guideline on Summary of the Product Characteristics (SPC) – Pharmaceuticals (Veterinary Medicinal Products), Eudralex Volume 6C, Notice to Applicants (current version)

Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668) (EMA/CHMP/302620/2017 Rev. 2)

European Pharmacopoeia (Ph. Eur.) general monographs Herbal drug extracts 04/2019:0765, Herbal drug preparations 07/2010:1434, Herbal drugs 07/2017:1433, Herbal teas 01/2013:1435

European Pharmacopoeia (Ph. Eur.) Information chapter 5.23. Monographs on herbal drug extracts (04/2019:52300)