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Committee on Herbal Medicinal Products (HMPC)

Concept paper on the revision of the Guideline on Good agricultural and collection practice for starting materials of herbal origin

Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	24 November 2021
Start of public consultation	1 March 2022
End of consultation (deadline for comments)	1 June 2022

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

Keywords	Committee on Herbal Medicinal Products; HMPC; herbal medicinal products; HMPs; traditional herbal medicinal products; THMPs; herbal substances; good agricultural and collection practice; GACP

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1. Introduction

The "Guideline on Good agricultural and collection practice for starting materials of herbal origin" (EMEA/HMPC/246816/2005) was published on 20 February 2006. In order to guarantee that the guideline reflect the state of the art and practical experiences, a revision is proposed.

2. Problem statement

The quality and safety of herbal medicinal products should be guaranteed and demonstrated in accordance with the existing requirements. The Good Agricultural and Collection Practices (GACP) for medicinal plants recommended in the EMA guideline are the first step in quality assurance, on which safety and efficacy of herbal medicines directly depend. To obtain consistent and reproduceable "starting materials of herbal origin" of an appropriate standard, an adequate quality assurance system for the collection and/or cultivation, harvest, and primary processing is required. With the growing number of companies involved in the cultivation of medicinal plants, several improvements can be envisaged. Furthermore, and since the publication on 1 September 2009 of the revised Annex 7 to the EC GMP Guide, some questions about the applicability of GACP or the GMP-Annex 7 have emerged. Therefore, an update to the GACP guideline is required.

3. Discussion (on the problem statement)

The GACP guideline provide a basis for standards for the collection and for cultivation of medicinal plants and should therefore be viewed as an effective "working tool" whose benefits are to reduce waste, ensure quality of raw material, and contribute to the sustainable management of available resources and environmental protection. Therefore, the revision of the guideline will address the need for clarification and consistency (e.g. demarcation/overlap GMP *vs* GACP, diverse practice in Member States, uncertainty about requirements, certification and dossier submission, comparison to other GACP standards such as those established by World Health Organisation (WHO). Further, improving the current guideline will also enhance coherence with other EU Directives and Regulations (e.g. water, soil, pesticides). It should make a positive contribution for sustainable management of resources and quality control of harvested wild medicinal plants. Finally, it is expected that understanding and compliance by the interested parties will be facilitated, supporting the submission of dossiers that are in accordance with the existing requirements.

Given the nature of this revision, a concept paper and a public consultation are required.

4. Recommendation

With regard to the questions raised on the application of the existing "Guideline on Good agricultural and collection practice for starting materials of herbal origin" (EMEA/HMPC/246816/2005), the HMPC recommends to revise this guideline to address the matters described under section 3.

The revised guideline will be applicable to registration applications for traditional herbal medicinal products (THMPs) for human use and will also be applicable to marketing authorisation applications for herbal medicinal products (HMPs).

5. Proposed timetable

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

6. Resource requirements for preparation

The Rapporteur should prepare a draft of the revised guideline and mainly involve the HMPC members and also seek the contributions from the GMP/GDP Inspectors Working Group (GMDP IWG). Member States are invited to provide comments via their Committee and Working Party Members.

7. Impact assessment (anticipated)

The revised guideline is expected to facilitate a better understanding of applicable requirements for assuring and demonstrating that herbal starting materials were collected and/or cultivated in compliance with GACP. Benefits are expected for applicants in the preparation of their dossiers and for competent authorities in their assessment of these dossiers.

8. Interested parties

During the consultation period on the revised guideline, comments from parties concerned with the use of THMPs and HMPs will be welcome.

9. References to literature, guidelines, etc.

1. Guideline on Good agricultural and collection practice for starting materials of herbal origin (EMEA/HMPC/246816/2005)

2. EU Guidelines to Good Manufacturing Practice - Medicinal Products for Human and Veterinary Use GMP Annex 7. Manufacture of Herbal Medicinal Products

3. ICH Topic Q 7 - Good Manufacturing Practice for Active Pharmaceutical Ingredients

4. WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants, 2003 http://apps.who.int/iris/bitstream/10665/42783/1/9241546271.pdf