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2 EMA/HMPC/217753/2015
3 Committee on Herbal Medicinal Products (HMPC)

4 Concept paper on the revision of the guideline on 5 specifications: test procedures and acceptance criteria for 6 herbal substances, herbal preparations and herbal 7 medicinal products/traditional herbal medicinal products

8 (CPMP/QWP/2820/00 Rev. 2; EMEA/CVMP/815/00 Rev. 2, EMA/HMPC/162241/2005 Rev. 2)

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1. Introduction (background)

A simplified registration procedure was established for traditional herbal medicinal products (THMPs) for human use with Directive 2004/24/EC of the European Parliament and of the Council. Herbal medicinal products (HMPs) contain exclusively as active ingredients one or more herbal substances or herbal preparations or combinations thereof.

For human and veterinary HMPs (authorised in accordance with Directives 2001/83/EC and 2001/82/EC, respectively) there are a number of specific herbal quality guidelines for example; 'Guideline on quality of HMPs/THMPs' (1) and 'Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and HMPs/THMPs' (2), as well as, general quality guidance for medicinal products.

A new revision of the 'Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and HMPs/THMPs' (CPMP/QWP/2820/00 Rev.2; EMEA/CVMP/815/00 Rev.2, EMA/HMPC/162241/2005 Rev.2) is proposed to take into account new and revised standards and guidance applicable for HMP/THMPs related to quality such as the European Pharmacopoeia revised general text on the Microbiological Quality of HMPs for Oral Use (5.1.8) (3), the general monograph 'Herbal Drug Extracts' (4) and the information chapter on this monograph (5). So far new developments have partially been addressed in 'Questions & Answers on quality of HMPs/THMPs' (6).

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

2. Scope

The proposed revision of the 'Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and HMPs/THMPs' will be applicable to registration applications for THMPs for human use and will also be applicable to marketing authorisation applications for HMPs for human and veterinary use.

3. Problem statement

In the light of experience and with the publication of recent revisions to various guidance documents a need appeared to update the 'Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and HMPs/THMPs'. This includes the need to take account of the following: the updated 'Questions & Answers on quality of HMPs/THMPs' (6), the European Pharmacopoeia revised general text on the 'Microbiological Quality of HMPs for Oral Use and Extracts used in their preparation' (5.1.8) (3), the revised general monograph 'Herbal Drug Extracts' (4) and the new information chapter on this monograph (5), the 'Guideline on quality on combination HMPs/THMPs' (7) and the 'Reflection paper on markers used for quantitative and qualitative analysis of HMPs/THMPs' (8).

4. Discussion (on the problem statement)

The quality of human and veterinary HMPs should be guaranteed and demonstrated in accordance with the existing requirements as set out in Annex I of Directive 2001/83/EC, as amended, Annex I of Directive 2001/82/EC, as amended, with specific herbal quality guidelines such as 'Guideline on quality of HMPs/THMPs' (CPMP/QWP/2819/00 Rev. 2), 'Guideline on specifications: test procedures and

acceptance criteria for herbal substances, herbal preparations and HMPs/THMPs' and, in addition, with current EU/(V)ICH general quality guidelines for medicinal products that are applicable to HMPs/THMPs.

Following the revision of the European Pharmacopoeia general monograph 'Herbal Drug Extracts' and the publication of additional guidelines as well as the updated 'Questions & Answers on quality of HMPs/THMPs', the need for the revision of the 'Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and HMPs/THMPs' was identified.

5. Recommendation

With regard to the questions raised on the application of the existing 'Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and HMPs/THMPs' (CPMP/QWP/2820/00 Rev.2; EMEA/CVMP/815/00 Rev.2, EMA/HMPC/162241/2005 Rev.2), the Committee on Herbal Medicinal Products (HMPC) recommends revision of this guideline to address the matters described under section 3.

The revised guideline shall apply to HMPs both for human and veterinary use and to THMPs for human use.

6. 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 six months after external consultation.

7. Resource requirements for preparation

The Rapporteur should prepare a draft of the revised guideline and mainly involve the Quality Drafting Group of the HMPC. Members States are invited to provide comments via their Committee and Working Party Members.

8. Impact assessment (anticipated)

The revised guideline is expected to provide a better understanding of the requirements for specifications for HMPs/THMPs. It will therefore provide benefits to applicants in the preparation of their submission and to competent authorities for the assessment of the applications.

The proposed third revision will replace 'Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products' (CPMP/QWP/2820/00 Rev.2; EMEA/CVMP/815/00 Rev.2).

9. Interested parties

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

10. References to literature guidelines, etc

1. 'Guideline on quality of herbal medicinal products/traditional herbal medicinal products' (CPMP/QWP/2819/00 Rev.2; EMEA/CVMP/814/00 Rev.2, EMA/HMPC/201116/2005 Rev.2).
2. 'Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products'. (CPMP/QWP/2820/00 Rev.2; EMEA/CVMP/815/00 Rev.2, EMA/HMPC/201116 Rev. 2).
3. European Pharmacopoeia General Chapter: 'Microbiological Quality of HMPs for Oral Use and Extracts used in their preparation' (5.1.8)
4. Monograph 'Herbal drug extracts' European Pharmacopoeia (0765).
5. Monographs on herbal drug extracts (Information chapter) European Pharmacopoeia (5.23).
6. 'Questions & Answers on quality of herbal medicinal products/traditional herbal medicinal products' (EMA/HMPC/41500/2010 Rev. 5).
7. Guideline on quality on combination herbal medicinal products/traditional herbal medicinal products' (EMA/HMPC/CHMP/CVMP/214869/2006)
8. Reflection paper on markers used for quantitative and qualitative analysis of herbal medicinal products/traditional herbal medicinal products' (EMEA/HMPC/253629/2007).