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3 Committee on Herbal Medicinal Products (HMPC)

4 Concept paper on the revision of the guideline on quality 5 of herbal medicinal products/traditional herbal medicinal 6 products (EMA/CPMP/QWP/2819/00 Rev. 2, EMA/CVMP/814/00 Rev. 2, 7 EMA/HMPC/201116/2005 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) are applicable the two main specific quality guidelines: '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), other herbal-specific guidelines as well as general quality guidance for medicinal products.

A new revision of the 'Guideline on quality of HMPs/THMPs' (EMA/CPMP/QWP/2819/00 Rev. 2, EMA/CVMP/814/00 Rev. 2, EMA/HMPC/201116/2005 Rev. 2) is proposed to take into account new and revised quality standards and guidance applicable for HMP/THMPs. So far, new developments have partially been addressed in 'Questions & Answers on quality of HMPs/THMPs' (3).

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

2. Scope

The proposed revision of the 'Guideline on quality of 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 a recent revision of the European Pharmacopoeia general monograph 'Herbal Drug Extracts' (4), of the revision of the 'Guideline on declaration of herbal substances and herbal preparations in HMPs/THMPs' (5) and of updated 'Questions & Answers on quality of HMPs/THMPs' (3), a need appeared to update the 'Guideline on quality of HMPs/THMPs'.

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 quality guidelines such as 'Guideline on quality of HMPs/THMPs', '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 the European Pharmacopoeia general monograph 'Herbal Drug Extracts' with the publication of an information chapter on this monograph (6), the publication of the revision of the 'Guideline on declaration of herbal substances and herbal preparations in HMPs/THMPs' and of updated 'Questions & Answers on quality of HMPs/THMPs', the need for the revision of the 'Guideline on quality of HMPs/THMPs' was identified. Further clarifications on quality data requirements in the existing text should be provided (e.g. concerning the amount of inert and technological excipients in extracts, stability requirements for herbal substances and/or herbal preparations). In addition, some clearer wording and reference to updated guidelines should be done.

5. Recommendation

With regard to the questions raised on the application of the existing 'Guideline on quality of HMPs/THMPs' (CPMP/QWP/2819/00 Rev. 2, EMEA/CVMP/814/00 Rev. 2, EMA/HMPC/201116/2005 Rev. 2), the Committee on Herbal Medicinal Products (HMPC) recommends to revise this guideline to address the matters described under section 3 and 4. 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 within 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 on quality requirements 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 quality of HMPs/THMPs' (CPMP/QWP/2819/00 Rev. 2, EMEA/CVMP/814/00 Rev. 2, EMA/HMPC/201116/2005 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/162241/2005 Rev. 2).
3. 'Questions & Answers on quality of herbal medicinal products/traditional herbal medicinal products' (EMA/HMPC/41500/2010 Rev. 5).
4. Monograph 'Herbal drug extracts' European Pharmacopoeia (0765).
5. '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).
6. 'Monographs on herbal drug extracts (Information chapter)' European Pharmacopoeia (5.23).