European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)

CONCEPT PAPER ON QUALITY OF COMBINATION HERBAL MEDICINAL PRODUCTS[1]/TRADITIONAL HERBAL MEDICINAL PRODUCTS

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END OF CONSULTATION (DEADLINE FOR COMMENTS)	31 September 2006

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1. INTRODUCTION

A simplified registration procedure was established for traditional herbal medicinal products for human use under EU Council Directive 2004/24/EC. Herbal medicinal products can be combinations

[1] Throughout the guideline and unless otherwise specified, the term "herbal medicinal products" includes "traditional herbal medicinal products"

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of herbal substances, herbal preparations and combinations thereof and it is expected that their number will increase with full implementation of the legislation on traditional herbal medicinal products.

At present, for human and veterinary herbal medicinal products (authorised in accordance with Directives 2001/83/EC and 2001/82/EC respectively), both the specific herbal quality guidelines: "Guideline on quality of herbal medicinal products/traditional herbal medicinal products" (1) and "Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products" (2), as well as general quality guidance for medicinal products, are applicable to herbal medicinal products. However, the complex composition of combination products presents additional challenges as to how quality can be ensured and demonstrated. The available guidance documents do not fully address this issue. The concepts described in the future guideline will be applicable to all human and veterinary herbal medicinal products.

2. PROBLEM STATEMENT

During the revision of the "Guideline on quality of herbal medicinal products/traditional herbal medicinal products" (1) and the "Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products" (2), it became clear that the application of the existing quality guidelines to complex combination products needs to be further addressed. Indeed, many questions were raised on how to interpret the requirements in order to demonstrate the quality of combination products.

3. DISCUSSION (ON THE PROBLEM STATEMENT)

The quality of a medicinal product is independent of its use, and therefore all general principles of quality and quality guidance documents also apply to herbal medicinal products. It is recognised that the complexity of combination products may have an important impact on the quality control measures to be put in place. The need for a consensus on how to apply the existing quality guidelines to herbal combination products was identified. A consensus will enhance transparency among both applicants and authorities, and is vital to ensure appropriate and consistent quality of combination herbal medicinal products available within the Community.

4. RECOMMENDATION

With regard to the questions raised on the application of the existing quality guidelines to combination herbal medicinal products, the HMPC recommends the development of a respective guideline.

A guideline on the quality of combination herbal medicinal products shall provide clarification on how the existing guidance documents should be interpreted for herbal combination products. Additional guidance on the quality of herbal combination products may be included in this guideline, if a need is identified. In any case it should be read in conjunction with the "Guideline on quality of herbal medicinal products/traditional herbal medicinal products" (1), the "Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products" (2) and the Annex 7 "Manufacture of herbal medicinal products" of Good Manufacturing Practices (GMP) for medicinal products, Volume 4, Rules governing medicinal products in the European Union (3).

The guideline shall apply to herbal medicinal products both for human and veterinary use and to traditional herbal medicinal products for human use.

5. PROPOSED TIMETABLE

It is anticipated that a draft guideline could be available 1 year after the adoption of the concept paper. The draft will then be released for external consultation for three months. The guideline could be finalised within 6 months after external consultation.

6. RESOURCE REQUIREMENTS FOR PREPARATION

The Rapporteur and co-Rapporteur will prepare a draft guideline. Member States are invited to provide comments via their Committee and/or working party members.

7. IMPACT ASSESSMENT (ANTICIPATED)

Industry attributes great importance on the application of the existing quality guidance documents to herbal combination products. Respective proposals and comments have already reached competent authorities. Further participation of industry and stakeholders is anticipated.

8. INTERESTED PARTIES

Comments from industry could be integrated during the development of the guideline, should industry wish to submit comments at this stage.

9. REFERENCES TO LITERATURE, GUIDELINES ETC

1. "Guideline on quality of herbal medicinal products/traditional herbal medicinal products"
2. "Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products"
3. Annex 7 "Manufacture of herbal medicinal products" of Good Manufacturing Practices (GMP) for medicinal products, Volume 4, Rules governing medicinal products in the European Union

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