The European Agency for the Evaluation of Medicinal Products
Evaluation of Medicines for Human Use

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EMEA WORKING PARTY ON HERBAL MEDICINAL PRODUCTS

COMMENTS ON THE COMMISSION REGULATION (EC) NO. 541/95 OF 10 MARCH 1995 CONCERNING THE EXAMINATION OF VARIATIONS TO THE TERMS OF A MARKETING AUTHORISATION GRANTED BY A COMPETENT AUTHORITY OF A MEMBER STATE AS AMENDED BY COMMISSION REGULATION (EC) NO. 1146/98)

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The views presented in this document are those of the HMPWP, which has been created as a forum for exchange of experience in the field of herbal medicinal products. This document is released for the purposes of transparency and has no legal force with respect to Directive 2001/83/EC.

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Final Comments on the Commission Regulation (EC) No. 541/95 of 10 March 1995 Concerning the Examination of Variations to the Terms of a Marketing Authorisation Granted by a Competent Authority of a Member State as amended by Commission Regulation (EC) No. 1146/98

The EMEA Working Party on Herbal Medicinal Products suggests amending Annex I and Annex II to the Commission Regulation (EC) No. 541/95 on variations in order to encompass herbal medicinal products in the scope of the Regulation.

Annex I

The working group suggests replacing "no change in dissolution profile" by "no change in ***disintegration time*** *or* in dissolution profile" in sections B.4., B.5., B.7., B.33. of Annex I.

The working group suggests replacing "The specifications, synthetic route and quality control procedures are the same as those already approved or a European Pharmacopoeia Certificate of suitability covering the active substance is submitted" by "The specifications, synthetic route or ***manufacturing route, geographical source* and production of the herbal drug (in the case of herbal medicinal products)***, and quality control procedures are the same as those already approved or a European Pharmacopoeia Certificate of suitability covering the active substance is submitted" in sections B.11. and B.11b.

Annex II

The working group suggests adding a paragraph in section 1.

"***viii) in the case of herbal drug preparations***

- ***change of the herbal drug (e.g. different species, different part of the plant)***
- ***change of the extraction solvent or relevant change in the concentration of the extraction solvent***
- ***relevant change in the ratio of the herbal drug to the herbal drug preparation or the ratio of the herbal drug to the extraction solvent***
- ***change to the physical state (e.g. soft extract to dry extract)***"

**** If a different geographical source has no influence on specifications, a Type I variation might be acceptable***