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

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AD HOC WORKING GROUP ON HERBAL MEDICINAL PRODUCTS

Final Comments on Notice to Applicants Volume 2B Part IC2 'Expert Report on Toxico-pharmacological Documentation' and Part III 'Toxico-pharmacological Documentation'

RELEASE FOR CONSULTATION BY THE EMEA	January 1998
DEADLINE FOR COMMENTS	April 1998
RELEASE OF FINAL PROPOSALS	September 1998

Note:

Modifications from the original texts proposed by the group are in *bold italic.*

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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Part III "Toxico-pharmacological Documentation"

These parts are found adequate for herbal medicinal products. It was confirmed that the Expert Report has to address all aspects of Part 3 of the Annex to Council Directive 75/318/EEC of 20 May 1975 'Toxicological and pharmacological tests'.