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

17 September 1998
EMEA/HMPWP/12/99

AD HOC WORKING GROUP ON HERBAL MEDICINAL PRODUCTS

FINAL COMMENTS ON NOTICE TO APPLICANTS VOLUME 2B PART IB1 – SUMMARY OF PRODUCT CHARACTERISTICS

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.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.eu.int http://www.emea.eu.int

Final Comments on Notice to Applicants Volume 2B Part I B 1:
Summary of Product Characteristics

The requirements are found adequate for herbal medicinal products. It was clarified that marker substances will not be declared in section 2 of the SPC, Qualitative and Quantitative Composition.

The working group provided in July 1998 the CPMP QWP with comments on the draft guidance for revision of the SPC sections 2, 3 and 6, as part of the update of the guidance on SPCs undergone by the CPMP.