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

London, 30 June 2003
EMEA/CPMP/3736/03

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS (CPMP)

SUMMARY INFORMATION ON A REFERRAL OPINION FOLLOWING AN ARBITRATION PURSUANT TO ARTICLE 30 OF DIRECTIVE 2001/83/EC

For

LEDERFOLINE AND ASSOCIATED NAMES (See Annex I)

International Nonproprietary Name (INN): calcium folinate

BACKGROUND INFORMATION

Calcium folinate is the calcium salt of 5-formyl tetrahydrofolic acid. It is an active metabolite of folinic acid and an essential coenzyme for nucleic acid synthesis in cytotoxic therapy.

National Marketing Authorisations for Lederfoline and associated names had been granted in all 15 Member States, based on national decisions. Some of the Marketing Authorisations (e.g. all presentations in Italy, Denmark, Finland, France, Sweden and The Netherlands) have been withdrawn upon Marketing Authorisation Holders' requests.

France presented to the EMEA a referral under Article 30 of Directive 2001/83/EC, (corresponding to Article 11 of Directive 75/319/EEC, as amended, to referrals presented before 18 December 2001) in order to harmonise the nationally authorised summaries of product characteristics of the medicinal product Lederfoline and associated names, (calcium folinate, solution for injection). In their notification, the French agency noted that there were divergences relating to various sections of the SPCs, particularly with respect to "indications", "posology" and "contra-indications".

At its 23-25 April 2002 meeting, the CPMP adopted a list of questions and initiated the procedure.

During the meeting on 18-19 March 2003, the CPMP, in the light of the overall submitted data and the scientific discussion within the Committee, was of the opinion that the proposal for the harmonisation of the SPC was acceptable and that the SPC should be amended. A positive opinion was therefore adopted by the CPMP on 19 March 2003.

The list of product names concerned is given in the Annex I. The scientific conclusions are provided in the Annex II, together with the amended Summary of Product Characteristics in the Annex III.

The final opinion was converted into a Decision by the European Commission on 30 June 2003.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.eu.int http://www.emea.eu.int