European Medicines Agency

London, 4 July 2006
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

SUMMARY INFORMATION ON REFERRAL OPINION PURSUANT TO ARTICLE 30 OF COUNCIL DIRECTIVE 2001/83/EC FOR

STAMARIL and associated names (See Annex I)

International Non-Proprietary Name (INN): Live attenuated yellow fever virus

BACKGROUND INFORMATION

The active substance of STAMARIL is a live attenuated yellow fever virus. STAMARIL is a viral vaccine and the antigen of the vaccine act prophylactic by stimulating an immune response against the above-yellow fever.

Different Summaries of Product Characteristics (SPC) had been authorised, based on national, divergent decisions from the authorisations in the EU Member States. On 11 August 2005, Sanofi Pasteur MSD on behalf of all the Marketing Authorisation Holders (see Annex I) presented to the EMEA a referral under Article 30 of Directive 2001/83/EC, as amended, in order to harmonise the national SPCs of the medicinal product STAMARIL and associated names.

The referral procedure started on 19 September 2005. The CHMP having considered the Rapporteur and the Co-Rapporteur assessment reports, the scientific discussion within the Committee and the comments from the Marketing Authorisation Holders (MAH), was of the opinion that the benefit/risk ratio of STAMARIL and associated names is considered to be positive in the following indications:

Active immunisation against yellow fever in persons from 9 months of age:

- Travelling to, passing through or living in an endemic area.
- Travelling to any country that requires an International Certificate of Vaccination for entry (which may or may not depend on the previous itinerary).
- Handling potentially infectious materials (e.g. laboratory personnel).

The divergences identified at the start of the referral were resolved.

The CHMP gave a positive opinion on 27 April 2006 recommending the harmonisation of the SPC for STAMARIL and associated names.

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

A Decision was issued by the European Commission on 4 July 2006.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.eu.int http://www.emea.eu.int