



COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

**SUMMARY INFORMATION ON REFERRAL OPINION
PURSUANT TO ARTICLE 31 OF COUNCIL DIRECTIVE 2001/83/EC, AS AMENDED, FOR**

Elidel and associated names (See Annex 1)

International Non-Proprietary Name (INN): pimecrolimus

BACKGROUND INFORMATION

Pimecrolimus is a calcineurin inhibitor approved as cream formulation at a 1% concentration. Pimecrolimus was initially approved for the use in patients with mild to moderate atopic dermatitis aged 2 years and over for short-term treatment of signs and symptoms and intermittent long-term treatment for prevention of progression to flares.

Pimecrolimus was first authorised in the EU in Denmark on 15 March 2002. It was subsequently authorised by Mutual Recognition Procedure in all EU Member States except Ireland. It is also approved in Norway and Iceland.

On 21 April 2005, Denmark presented a referral to the EMEA under Article 31 of Directive 2001/83, as amended. The reasons for referral concerned a review of the benefit/risk profile of medicinal products containing pimecrolimus considering efficacy and safety concerns with regards to the potential risk of cancer.

The referral procedure started on 21 April 2005. The Rapporteur and Co-Rapporteur appointed were Dr. Julia Dunne and Dr. Ingemar Persson, respectively. Written explanations were provided by the Marketing Authorisation Holder by 30 June 2005, 15 July 2005, 19 July 2005, 20 December 2005 and 7 March 2006. Oral explanations were given on 22 March 2006.

Based on evaluation of the available data and the Rapporteurs' assessment reports, the CHMP considered that the benefit/risk profile of pimecrolimus containing medicinal products remains favourable, and therefore adopted an opinion on 23 March 2006 recommending the maintenance of the Marketing Authorisations with amendments to the Summary of Product Characteristics, Labelling and Package Leaflet for pimecrolimus containing medicinal products.

On the grounds of safety and efficacy, the CHMP was of the opinion that pimecrolimus should be limited to second line use. The CHMP recommended the restriction of use to these patients where treatment with topical corticosteroids is either inadvisable or not possible.

The Member States competent authorities will continue to keep the product under regular review.

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, Labelling and Package Leaflet in the Annex III and the conditions of the marketing authorisations in the Annex IV.

The final opinion was converted into a Decision by the European Commission on 29 May 2006.

* **Note:** The information given in this document and Annexes reflect only the CHMP Opinion dated 23 March 2006. The Member States competent authorities will continue to keep the product under regular review.