European Medicines Agency

London, 30 September 2008
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PUBLIC STATEMENT ON

Protopy
(Tacrolimus)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 28 February 2002 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Protopy (Tacrolimus), 0.03% and 0.1% ointment for cutaneous use, which have been approved for treatment of moderate to severe atopic dermatitis.

The marketing authorisation holder (MAH) responsible for Protopy is Astellas Pharma GmBH. The European Commission was notified by the MAH of its decision through the MAH's letter dated 27 June 2008 to voluntarily withdraw the marketing authorisation for Protopy for commercial reasons.

Protopy was never marketed anywhere in the European Union (EU). Protopic is an identical product available in the EU.

On 22 August 2008 the European Commission issued a decision to withdraw the marketing authorisation for Protopy. Pursuant to this decision the European Public Assessment Report for Protopy will be updated to reflect that the marketing authorisation is no longer valid.

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