



09 August 2005  
EMA/CHMP/145829/2005

**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE  
(CHMP)**

**OPINION FOLLOWING AN ARTICLE 29(2)<sup>1</sup> REFERRAL FOR**

**Crestor 5 mg**

International Non-Proprietary Name (INN): Rosuvastatin calcium

**BACKGROUND INFORMATION**

Crestor (rosuvastatin calcium) is a selective 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitor (statin) that has been approved for use as a lipid-regulating agent in the management of patients with dyslipidaemia.

A Marketing Authorisation for Crestor (10 to 40 mg) was originally granted to AstraZeneca in The Netherlands on 6 November 2002 and a Mutual Recognition Procedure was started on 7 December 2002. The application was withdrawn in Germany, Norway and Spain, but the procedure was positively ended in all other Member States on 7 March 2003. As part of the marketing authorisation for rosuvastatin within Europe, AstraZeneca committed to apply for a 5-mg dose of rosuvastatin together with any necessary variations within 12 months of completion of the Mutual Recognition Process for the 10 mg, 20 mg and 40 mg formulations.

On the basis of the marketing authorisation for Crestor (5 mg) granted by The Netherlands, on 21 July 2004 the applicant submitted an application for Mutual Recognition to 13 Concerned Member States. This procedure started on 04 August 2004. The approved use in The Netherlands was a 5 mg start dose for patients with predisposing factors to myopathy, and 10 mg as the recommended start dose for patients without these predisposing factors. The main issue during the procedure was whether the 5 mg strength should be the recommended start dose for all patients. The issue was referred for arbitration by the UK on 1 November 2004 (day 89).

The arbitration procedure started on 18 November 2004. The Rapporteur and Co-Rapporteur appointed were Dr P. Nilsson and Dr. G. Calvo, respectively. Written explanations were provided by the Marketing Authorisation Holder on 07 February 2005.

During its April 2005 meeting, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, was of the opinion that the benefit/risk ratio is favourable for Crestor 5 mg or Crestor 10 mg as start dose. The choice of start dose in the individual patient should take into account aspects of efficacy and safety, as detailed in the SPC. Changes to SPC section 4.2 (Posology and method of administration) and 4.4 (Special warnings and special precautions for use) arising from the arbitration process were agreed by CHMP and a positive opinion was adopted on 21 April 2005.

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

The final opinion was converted into a Decision by the European Commission on 09 August 2005.

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<sup>1</sup> Article 29(2) of Directive 2001/83/EC, as amended.