



European Medicines Agency
Evaluation of Medicines for Human Use

London, 3 April 2006
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**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
(CHMP)**

OPINION FOLLOWING AN ARTICLE 29(2) REFERRAL

Adartrel

International Non-Proprietary Name (INN): **Ropinirole**

BACKGROUND INFORMATION

Adartrel is a selective dopamine agonist at the D₂- and D₃-dopamine receptor subtypes and is active both centrally and peripherally.

A Marketing Authorisation for Adartrel was granted to GlaxoSmithKline by France on 30 June 2004. The application for Mutual Recognition for Adartrel were submitted to Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden and United Kingdom. The Mutual Recognition Procedure started in September 2004.

The referral procedure was triggered by Spain and The Netherlands, who were of the opinion that this medicinal product might present a risk to public health since the safety and efficacy in long-term treatment of ropinirole in restless legs syndrome had not been demonstrated.

The arbitration procedure started on 15 December 2004. Supplementary information was provided by the Marketing Authorisation Holder on 18 March 2005.

During its 12-15 September 2005 meeting, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee was of the opinion that a marketing authorisation should be granted subject to certain conditions considered essential for the safe and effective use of the medicinal product. A positive opinion was therefore adopted on 15 September 2005.

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

The final opinion was converted into a Decision by the European Commission on 3 April 2006.