BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant GlaxoSmithKline Biologicals S.A. submitted on 22 December 2005 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Daronrix, through the centralised procedure falling within the Article 3(1) and point 1 of Annex of Regulation (EC) No 726/2004.

The Rapporteur and Co-Rapporteur appointed by the CHMP were:

Rapporteur: Dr Manfred Haase Co-Rapporteur: Dr Pieter Neels

Licensing status:

The product was not licensed in any country at the time of submission of the application.

2. Steps taken for the assessment of the product

- Accelerated Assessment procedure was agreed-upon by CHMP on 15 December 2005.
- The procedure started on 1 February 2006.
- The Rapporteur's first assessment report was circulated to all CHMP Members on 31 March 2006. The Co-Rapporteur's first assessment report was circulated to all CHMP Members on 10 April 2006.
- The BWP discussed Daronrix during their meeting on 19-20 April 2006 and adopted an Interim BWP report to the CHMP.
- During the meeting on 24-27 April 2006, the CHMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 27 April 2006.
- The company submitted the responses to the consolidated list of questions on 5 October 2006.
- The Rapporteurs circulated the response assessment report on the company's responses to the list of questions to all CHMP Members on 15 November 2006.
- The VWP discussed Daronrix during their meeting on 28-30 November 2006 and adopted a Report to the CHMP.
- The BWP discussed Daronrix during their meeting on 4-6 December 2006 and adopted a Report to the CHMP.
- During the meeting on 11-14 December 2006 the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation under exceptional circumstances to Daronrix on 14 December 2006.
- On request of the European Commission, in order to increase clarity and transparency of the scientific reasoning behind the evaluation of Daronrix, the CHMP revised its Assessment report in the sections on conditions, or restrictions, regarding supply and use, introduction, overall conclusion and the benefit-risk assessment and the recommendations. The Annex II of the opinion was revised to reflects that Daronrix can only be marketed when there is an official WHO/EU declaration of an influenza pandemic and on the condition that the Marketing Authorisation Holder takes due account of the officially declared pandemic strain. During the meeting of 22-24 January 2007 the CHMP readopted the positive opinion for granting a Marketing Authorisation under exceptional circumstances to Daronrix on 24 January 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 21 March 2007.

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