

1 BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Novartis Europharm Limited submitted on 28 April 2005 an application for Marketing Authorisation to the European Medicines Agency (EMA) through the centralised procedure for Exjade, which was designated as an orphan medicinal product EU/3/02/092 on 13 March 2002. Exjade was designated as an orphan medicinal product in the following indication: treatment of chronic iron overload requiring chelation therapy. The calculated prevalence of this condition was 102,000 persons in the EU.

The legal basis for this application refers to Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application.

The applicant applied for the following indication: treatment of chronic iron overload due to blood transfusions (transfusional haemosiderosis) in adult and paediatric patients (aged 2 years and over).

Protocol Assistance:

The applicant received Protocol Assistance from the CHMP on 25 July 2002 and 17 December 2003. The Protocol Assistance pertained to non-clinical and clinical aspects of the dossier.

Licensing status:

A new application was filed in the following countries: USA

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

Rapporteur: Eric Abadie

Co-Rapporteur: Giuseppe Nistico

1.2 Steps taken for the assessment of the product

- The application was received by the EMA on 28 April 2005.
- The procedure started on 18 May 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 28 July 2005. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 28 July 2005.
- During the meeting on 12-15 September 2005, 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 15 September 2005.
- A clarification meeting on the List of Questions was held on 16 November 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 11 January 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 27 February 2006.
- During the CHMP meeting on 20-23 March 2006 the CHMP agreed on a list of outstanding issues to be addressed in writing and in an oral explanation by the applicant.
- The applicant submitted the responses to the CHMP list of outstanding issues on 3 May 2006.
- The Rapporteurs circulated the updated Joint Assessment Report on the applicant's responses to the list of outstanding issues to all CHMP members on 19 May 2006.
- During the CHMP meeting on 29 May-1 June the outstanding issues were addressed by the applicant during an oral explanation before the CHMP.
- During the CHMP meeting on 29 May-1 June 2006 the CHMP agreed on a second list of outstanding issues to be addressed in writing by the applicant.
- The applicant submitted the responses to the CHMP second list of outstanding issues following an oral explanation on 6 June 2006.
- The Rapporteurs circulated the revised Joint Assessment Report on the applicant's responses to the second list of outstanding issues to all CHMP members on 26 June 2006.

- During the meeting on 26-28 June 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 to Exjade on 28 June 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 28 June 2006.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 28 August 2006.