BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant BioMarin Europe Ltd submitted on 03 December 2004 an application for Marketing Authorisation to the European Medicines Agency (EMEA) through the centralised procedure for Naglazyme, which was designated as an orphan medicinal product EU/3/01/025 on 14 February 2001.

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

Rapporteur: Dr Ian Hudson Co-Rapporteur: Prof Beatriz Silva Lima

Orphan Drugs:

Naglazyme was designated as an orphan medicinal product in the following indication: Treatment of Mucopolysaccharidosis, type VI (Maroteaux-Lamy Syndrome). The calculated prevalence of this condition was 0.024 per 10,000 EU population.

Scientific Advice:

The applicant did not seek scientific advice at the CHMP.

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

- The application was received by the EMEA on 03 December 2004.
- The procedure started on 20 December 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 1 March 2005 The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 07 March 2005
- During the meeting on 18-21 April 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 21 April 2005
- The applicant submitted the responses to the CHMP consolidated List of Questions on 20 May 2005.
- The summary report of the inspection carried out at the manufacturing site: BioMarin Pharmaceuticals, 46 Galli Drive, Novato USA, between 20-24 June 2005 was issued on 21 July 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 01 July 2005
- During the CHMP meeting on 25-28 July 2005, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant .
- The applicant submitted the responses to the CHMP List of Outstanding Issues on 08 August 2005.
- During the meeting on 12-15 September 2005 , 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 Naglazyme on 15 September 2005. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 15 September 2005.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 24 January 2006.