BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Elan Pharma International Ltd. submitted on 26 July 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for NeuorBloc, through the centralised procedure. After agreement by the CPMP on 26-29 January 1999, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

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

Rapporteur: Prof. C. Sampaio Co-Rapporteur: Dr. David Lyons

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 procedure started on 27 August 1999.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 8 November 1999. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 9 November 1999.
- The CPMP at its meeting of 16-18 November 1999 decided that there was a need for a GMP inspection of the active substance and finished product manufacturing sites of NeuroBloc.
- During the meeting on 14-16 December 1999 the CPMP agreed on the consolidated list of questions to be sent to the company. The final consolidated list of questions was sent to the Applicant on 15 December 1999.
- The Applicant submitted the responses to the CPMP consolidated list of questions on 23 March 2000. The clock restarted on 14 April 2000.
- The Rapporteur circulated the response assessment report on the Applicant's responses to the list of questions to all CPMP Members on 15 May 2000.
- During the CPMP meeting on 27-29 June 2000, the CPMP issued a list of outstanding questions to be addressed by the Applicant during an oral explanation.
- The Applicant submitted to the EMEA and the CPMP members on 16 August 2000 background documentation for the oral explanation.
- On 19 September 2000, the Applicant addressed the outstanding issues during an oral explanation before the CPMP.
- During the meeting on 19-21 September 2000, the Applicant was requested to provide further data (protocol of a post-marketing study comparing efficacy and safety of NeuroBloc versus Botulinum Toxin Type A) prior to the October CPMP meeting. The CPMP decided that the protocol should be discussed during the October CPMP Scientific Advice group meeting and that feedback on the protocol should be given to the October CPMP.
- The Applicant submitted to the EMEA and the CPMP members on 3 October 2000 the Protocol Synopsis for the proposed post marketing commitment study.
- During the meeting on 17-19 October 2000, in the light of the overall data submitted, the scientific discussion within the Committee and the feedback from the Scientific advice group on the protocol submitted by the Applicant, the Committee issued a positive opinion under exceptional circumstances for granting a Marketing Authorisation to NeuroBloc on 19 October 2000.

Medicinal product no longer authorised

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