BACKGROUND INFORMATION ON THE PROCEDURE

Submission of the dossier

The applicant Hexal Biotech Forschungs GmbH submitted on 9 March 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for HX575, through the centralised procedure falling within the Article 3(1) and point 1 of Annex of Regulation (EC) No 726/2004.

The legal basis for this application refers to:
Article 10(4) of Directive 2001/83/EC, as amended – relating to applications for similar biological medicinal products.

The application submitted is a complete dossier composed of administrative information, complete quality data and appropriate non-clinical and clinical data for a similar biological medicinal product.

Scientific Advice:
The applicant received Scientific Advice from the CHMP on 22 October 2003. The Scientific Advice pertained to quality, non-clinical and clinical aspects of the dossier.

Licensing status:
New applications were filed in the following countries: South Africa.

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

Rapporteur: Eric Abadie **Co-Rapporteur:** Harald Enzmann

Steps taken for the assessment of the product

- The application was received by the EMEA on 09 March 2006.
- The procedure started on 29 March 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 16 June 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 7 June 2006.
- During the meeting on 24-27 July 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 July 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 22 January 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 2 March 2007.
- During the CHMP meeting on 19-22 March 2007, 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 list of outstanding issues on 24 April 2007.
- During the CHMP meeting on 21 May 2007, outstanding issues were addressed by the applicant during an oral explanation before the CHMP.
- During the meeting on 18-21 June 2007, 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 HX575 on 21 June 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 19 June 2007.