BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Genzyme Europe B.V. submitted on 2 September 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Cholestagel, through the centralised procedure. After agreement by the CPMP on 21 February 2002, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 as amended.

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

Rapporteur: Dr Frits Lekkerkerker Co-Rapporteur: Dr Lars Gramstad

Scientific Advice:

The applicant did not seek scientific advice at the CPMP.

Licensing status:

Colesevelam has been given a Marketing Authorisation in USA on 26 May 2000 under the invented name WelChol.

2. Steps taken for the assessment of the product

- The procedure started on 23 September 2002.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 3 December 2002. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 3 December 2002.
- During the meeting on 21 – 23 January 2003, the CPMP 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 23 January 2003.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 13 May 2003.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CPMP members on 23 June 2003.
- During the CPMP meeting on 22 – 24 July 2003, the CPMP agreed on a List of Outstanding Issues to be addressed in writing and, if necessary, in an oral explanation by the applicant. The List of Outstanding Issues was sent to the applicant on 24 July 2003.
- The applicant submitted written responses to the CPMP List of Outstanding Issues on 8 September 2003.
- The Rapporteurs circulated the Joint Review on the applicant's responses to the List of Outstanding Issues to all CPMP members on 1 October 2003.
- During the CPMP meeting on 21-22 October 2003, it was decided that in the light of the written responses provided there was no need for the applicant to address outstanding issues during an oral hearing before the CPMP.
- During the CPMP meeting on 21 – 22 October 2003, the CPMP agreed on a List of Outstanding Issues to be addressed in writing by the applicant. The List of Outstanding Issues was sent to the applicant on 23 October 2003.
- The applicant submitted written responses to the CPMP List of Outstanding Issues on 31 October 2003.
- The Rapporteurs circulated the Joint Review on the applicant's responses to the List of Outstanding Issues to all CPMP members on 10 November 2003.

- During the meeting on 18 - 20 November 2003, the CPMP, 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 Cholestagel on 20 November 2003. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 18 November 2003.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 10 March 2004.