BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier


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

Rapporteur: Dr D. Jefferys
Co-Rapporteur: Dr M. Teeling

Licensing status:

At the time of the granting of the initial MA, Puregon had received marketing authorisation in Algeria, Argentina, Australia, Bahrain, Bangladesh, Brazil, Bulgaria, Cameroon, Canada, Chile, Colombia, Costa Rica, Cyprus, Czech Republic, Dutch Antilles, Ecuador, Egypt, Estonia, Gabon, Hong Kong, Hungary, Iceland, India, Israel, Ivory Coast, Jordan, Kenya, Kuwait, Latvia, Lebanon, Lithuania, Malaysia, Mexico, Morocco, New Zealand, Norway, Oman, Pakistan, Peru, Philippines, Poland, Qatar, Rumania, Russia, Saudi Arabia, Slovak Republic, Slovenia, South Africa, Sri Lanka, Switzerland, Syria, Taiwan, Thailand, Tunisia, Turkey, Ukraine, United Arabs, USA, Venezuela, Vietnam, Yugoslavia.

2. Steps taken for the assessment of the product

- The Rapporteur’s initial Assessment Report was circulated to all Members of the previous CPMP on 31 October 1994.
- The Co-Rapporteur initial Assessment Report was circulated to all Members of the previous CPMP on 25 October 1994.
- The consolidated list of comments as agreed by the previous CPMP was sent to the company on 5 December 1994.
- The company submitted the responses to the consolidated list of questions on 8 June 1995.
- The “Responses Assessment Report” on preclinical, clinical and pharmaceutical responses provided by the company was circulated to all CPMP Members by the Rapporteur on 11 September 1995.
- The “Responses Assessment Report” on preclinical and clinical responses provided by the company was circulated to all CPMP Members by the Co-Rapporteur on 12 September 1995.
- The “Responses Assessment Report” on pharmaceutical responses provided by the company was circulated to all CPMP Members by the Co-Rapporteur on 21 September 1995.
- A second list of outstanding quality issues, as agreed by the CPMP was sent to the company on 31 October 1995.
- The company submitted the responses to these points on 1 November 1995.
- The Assessment Report of the Rapporteur on these outstanding points was circulated on 7 November 1995. The unresolved pharmaceutical points were discussed at the CPMP Biotechnology Working Party on 13 and 14 November 1995. The company on 8 November 1995 requested an oral hearing before Biotechnology Working Party on 14 November 1995. The presentation answered most of the outstanding quality issues. However major concerns still remained because of the lack of information on batch analysis for process validation for the finished product generated in the Irish manufacturing site. The Biotechnology Working Party therefore requested the submission of analytical data.

• The CPMP in its meeting on 21-22 November 1995 considered and adopted the report from the Biotechnology Working Party. With reference to the manufacturing process validation for the finished product produced at the Irish manufacturing site, the further data submitted on 15 December 1995 by the company were considered adequate to support batch-to-batch consistency.

• The CPMP issued on 20 December 1995 four opinions for granting a marketing authorisation to the different strengths/presentations of Puregon.