I BACKGROUND INFORMATION ON THE PROCEDURE

Submission of the dossier

The Applicant, Abbott Laboratories Ltd, submitted on 2 July 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for SevoFlo, through the centralised procedure.

After agreement by the CVMP on 14 March 2001, 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 CVMP appointed Dr J. G. Beechinor from Ireland as Rapporteur and Prof R. Kroker from Germany as Co-Rapporteur for the assessment of the application for SevoFlo.

Licensing status:
Sevoflurane (from Abbott Laboratories) had been granted Marketing Authorisations for human use in all EU Member States at the time of submission of the application.

Steps taken for the assessment of the product

- The procedure started on 11 July 2001.
- The Rapporteur's Assessment Report was circulated to all CVMP members on 18 September 2001. The Co-Rapporteur's critique was circulated to all CVMP members on 1 October 2001.
- During the meeting on 7 November 2001 the CVMP 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 7 November 2001.
- The summary report of the inspection carried out at the Central Glass Company Limited, Japan manufacturing site (the manufacturer of the active substance) between 22 – 24 April 2002 was issued on 22 May 2002.
- The company submitted the responses to the CVMP consolidated List of Questions on 6 June 2002.
- The Rapporteur circulated the joint response Assessment Report on the company’s responses to the List of Questions to all CVMP members on 16 July 2002 .
- CVMP Members, in a written procedure, agreed by 5 August 2002 with the joint (Co)Rapporteur's recommendation that no Oral Explanation was required, and with the List of Outstanding Issues.
- During the meeting on 3 - 5 September 2002 the CVMP, 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 SevoFlo on 4 September 2002.
- The CVMP Opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 11 December 2002.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

II.1 MANUFACTURING AUTHORISATIONS AND INSPECTION STATUS

Manufacturers of the active substance:

Central Glass Company Ltd;
5253 Oaza Okiyube,
Ube City,
Yamaguchi Prefecture - 755,
Japan

Abbott S.p.A ;
Via Pontina Km 52,
04010 Campoverde di Aprilia (LT),
Italy

Manufacturer of the finished product and responsible for batch release:

Abbott Laboratories Ltd;
Queenborough,
Kent,
ME11 5EL,
UK

Manufacturing Authorisation issued on 22 February 1999 by the Medicines Control Agency, (on behalf of the Department of Health), Market Towers, I Nine Elms Lane, Vauxhall, London, SW8 5NQ, UK.

II.2 PROPOSED CONDITIONS OR RESTRICTIONS OF SUPPLY AND USE

Veterinary medicinal product subject to prescription.

II.3 STATEMENT OF THE MRLs

Not applicable.