BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Glaxo Group Limited submitted on 21 July 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Avamys, through the centralised procedure under Article 3 (2) (a) of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 28 April 2006.

The legal basis for this application refers to:

Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application

The application submitted is a complete dossier:

composed of administrative information, complete quality data, non-clinical and clinical data based on applicants' own tests and studies and/or bibliographic literature substituting/supporting certain tests or studies.

The applicant applied for the following indications

Adults / Adolescents (12 years and over)

Treatment of the symptoms of seasonal allergic rhinitis:
In patients with seasonal allergic rhinitis, fluticasone furoate nasal spray is effective for the treatment of nasal symptoms (rhinorrhoea, nasal congestion, nasal itching and sneezing) and ocular symptoms (itching/burning, tearing/watering, and redness of the eye).

Treatment of the symptoms of perennial allergic rhinitis:
In patients with perennial allergic rhinitis, fluticasone furoate nasal spray is effective for the treatment of nasal symptoms (rhinorrhoea, nasal congestion, nasal itching and sneezing).

Children (2 to 11 years)

Treatment of the symptoms of seasonal allergic rhinitis:
In patients with seasonal allergic rhinitis, fluticasone furoate nasal spray is effective for the treatment of nasal symptoms (rhinorrhoea, nasal congestion, nasal itching and sneezing).

Treatment of the symptoms of perennial allergic rhinitis:
In patients with perennial allergic rhinitis, fluticasone furoate nasal spray is effective for the treatment of nasal symptoms (rhinorrhoea, nasal congestion, nasal itching and sneezing).

Following the CHMP assessment the following indication was granted:

Adults, adolescents (12 years and over) and children (6-11 years)
Avamys is indicated for the treatment of:

- the symptoms of allergic rhinitis

Scientific Advice
The applicant received Scientific Advice from the CHMP on 30 July 2004. The Scientific Advice pertained to clinical aspects of the dossier.

Licensing status
At the time of submission a new application was filed in the following countries: U.S.A.
The product was not licensed in any country at the time of submission of the application.

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

Rapporteur: Michal Pirozynski (PL) Co-Rapporteur: David Lyons (IRL)

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 21 July 2006.
- The procedure started on 16 August 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 5 November 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 31 October 2006.
- During the meeting on 11-14 December 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 14 December 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 16 March 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 26 April 2007.
- During the CHMP meeting on 21 – 24 May 2007, the CHMP agreed on a list of outstanding issues to be addressed in writing and in an oral explanation by the applicant.
- The summary report of the inspection carried out at the following site: Huntingdon Research Centre, Woolley Road, Alconbury, Cambridgeshire UK on 6-7 June 2007 was issued on 23 July 2007.
- The applicant submitted the responses to the CHMP consolidated List of Outstanding Issues on 03 August 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 26 August 2007, and an updated Overview on 11 September 2007.
- During the CHMP meeting on 17-20 September 2007, outstanding issues were addressed by the applicant during an oral explanation before the CHMP.
- The applicant submitted a clarification, draft SPC and draft letter of undertaking on 25 September 2007.
- The Rapporteurs circulated the Joint Assessment on the clarification to all CHMP members on 11 October 2007.
- During the meeting on 15-18 October 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 Avamys on 18 October 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 16 October 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 11 January 2008.