BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Schwarz Pharma AG submitted on 9 March 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Fesoterodine, 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 16 December 2005.

The legal basis for this application refers to:
Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application

Scientific Advice:

The applicant did not seek scientific advice at the CHMP.

Licensing status:

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: Dr. Gonzalo Calvo Rojas Co-Rapporteur: Dr. Tomas Salmonson

1.2 Steps taken for the assessment of the product

- The application was received by the EMEA on 9 March 2006.
- The procedure started on 29 March 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 22 June 2006 (Annex 1). The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 13 June 2006 (Annex 2).
- 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 (Annex 3).
- The applicant submitted the responses to the CHMP consolidated List of Questions on 04 October 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 14 November 2006 (Annex 4).
- During the CHMP meeting on 11-14 December 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant (Annex 5).
- The applicant submitted the responses to the CHMP list of outstanding issues on 17 January 2007.
- The Rapporteurs circulated the Joint Response Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 2 February 2007 (Annex 6).
- During the meeting on 19-22 February 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 TOVIAZ on 22 February 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 20 February 2007 (Annex 7).