BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Eli Lilly Nederland B.V. submitted on 02 November 2005 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for BYETTA, through the centralised procedure.

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

The application submitted is a complete dossier, it consists of administrative information, complete quality data, non-clinical and clinical data based on applicants' own tests and studies.

The applicant applied for the following indication: treatment of type 2 diabetes mellitus in combination with metformin, and/or sulphonylureas in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.

Scientific Advice:
The applicant received Scientific Advice from the CHMP on 22 May 2003 and on 3 June 2004. The Scientific Advice pertained to clinical aspects of the dossier.

Licensing status:
BYETTA was given a Marketing Authorisation in USA on 28 April 2005.

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

Rapporteur:	Dr Bengt Ljungberg	Co-Rapporteur	Dr Frits Lekkerkerker

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 02 November 2005.
- The procedure started on 23 November 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 2/2/06
- The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 24/01/06.
- During the meeting of CHMP 20-23 March 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 23/03/06.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 16/05/06.
- Appropriate inspection reports were received
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 30/06/06.
- During the CHMP meeting on 27/07/06, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The applicant submitted the responses to the CHMP consolidated List of outstanding issues on 18/08/06.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of outstanding issues to all CHMP members on 30/08/06.
- During the meeting of CHMP 18-21 September 2006, 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 BYETTA on 21/09/06. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 18/09/06.