# BACKGROUND INFORMATION ON THE PROCEDURE

## Submission of the dossier

The applicant GlaxoSmithKline Biologicals S.A. submitted on 07 March 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Cervarix, through the centralised procedure falling within the Article 3(1) and point 1 of Annex of Regulation (EC) No 726/2004 . The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 28 July 2005

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 indication prevention of cervical cancer.

**Scientific Advice:**

The applicant received Scientific Advice from the CHMP on 17 March 2005.

**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 and the evaluation teams were:

Rapporteur: **Pieter Neels** Co-Rapporteur: **Manfred Haase**

## Steps taken for the assessment of the product

- The application was received by the EMEA on 07 March 2006.
- The procedure started on 29 March 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 3 July 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 21 June 2006.
- 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.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 20 February 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 6 April 2007.
- During the CHMP meeting on 23-26 April 2007, the CHMP agreed on a List of Outstanding issues to be addressed by the applicant.
- During a meeting of the Vaccines Working Party on 2-4 May 2007, experts were convened to address questions raised by the CHMP.

- During the meeting on 16 – 19 July 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 Cervarix on 19 July 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 17 July 2007 and revised later on 23 July 2007.