BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Merck Sharp & Dohme Ltd., submitted on 04 April 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Silgard, through the centralised procedure falling within the Article 3(1) and point 1 of Annex of Regulation (EC) No 726/2004.

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 test(s) or study(ies).

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

Rapporteur: **Bengt Ljungberg** Co-Rapporteur: **Eric Abadie**

Scientific Advice:

The applicant received Scientific Advice from the CHMP on 21 January 2004. The Scientific Advice pertained to clinical aspects of the dossier.

Licensing status:
The product was not licensed in any country at the time of submission of the application.

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 04 April 2006.
- The procedure started on 27 April 2006. This application forms part of a multiple application for Human Papillomavirus Vaccine Quadrivalent [Types 6, 11, 16,18], Recombinant, Adsorbed. The initial application was submitted by Sanofi Pasteur MSD (EMEA/H/C/703). The review process for both applications were integrated at the time of List of Questions, allowing the CHMP opinion to be adopted in the same timeframe as EMEA/H/C/703.
- During the meeting on 24-27 April 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 April 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 18 May 2006.
- The Rapporteurs circulated the D150 Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 30 June 2006.
- The Vaccine Working Party during its meeting of 4-6 July 2006 adopted a VWP Report to be transmitted to the CHMP for endorsement.
- The Biologics Working Party during its meeting of 17-19 July 2006 adopted a BWP Report to be transmitted to the CHMP for endorsement.

- The Rapporteurs circulated the D180 Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 20 July 2006.

- During the meeting on 24-27 July 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 Silgard on 27 July 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 27 July 2006.

- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 20 September 2006.