BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Celgene Europe Ltd. submitted on 28 February 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) through the centralised procedure for Revlimid, which was designated as an orphan medicinal product EU/3/03/177 on 12 December 2003. Revlimid was designated as an orphan medicinal product in the following indication: treatment of multiple myeloma.

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

The applicant applied for the following indication: Revlimid in combination with dexamethasone is indicated for the treatment of multiple myeloma patients who have received at least one prior therapy.

Scientific Advice
The applicant received Protocol Assistance from the CHMP on 19 November 2004. The Protocol Assistance pertained to non-clinical and clinical aspects of the dossier.

Licensing status
Revlimid has been given first a Marketing Authorisation in United States of America for the myelodysplastic syndrome indication on 27 December 2005 and then, for the multiple myeloma indication on 29 June 2006.

A new application for the multiple myeloma indication was filed in the following countries: Switzerland and Australia

The Rapporteur and Co-Rapporteur appointed by the CHMP were:
Rapporteur: Eric Abadie Co-rapporteur: Tomas Salmonson

1.2 Steps taken for the assessment of the product

- The application was received by the EMEA on 28 February 2006.
- The procedure started on 29 March 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 16 June 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 16 June 2006.
- On 6 July 2006 the following meetings took place at the EMEA:
  - an *ad hoc* Pharmacovigilance Expert group meeting to give input on pharmacovigilance measures and Risk Management Plan
  - a consultation meeting of Patients' and Victims' organisations (representing their organisations, based on the agreement from the Applicant to disclose relevant confidential data) to comment on the Risk Management Plan, the package leaflet and the labelling:
- During the meeting on 25-27 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.
- A clarification meeting with the Rapporteurs on the CHMP List of Questions was held at the EMEA on 21 September 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 17 November 2006.
- On 12 December 2006, a second ad hoc Pharmacovigilance Expert group meeting on revised pharmacovigilance measures and Risk Management Plan took place at the EMEA.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 19 December 2006.

- During the CHMP meeting on 22-24 January 2007, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- On 29 January 2007, the second consultation of Patients' and Victims' organisations was held to comment on the revised Risk Management Plan, the package leaflet and the labelling. Following the meeting the list of outstanding issues was amended and adopted via a CHMP written procedure in 22 February 2007.
- The applicant submitted the responses to the CHMP revised list of outstanding issues on 26 February 2007.
- During the meeting on 20-22 March 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 Revlimid on 22 March 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 22 March 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 14 June 2007.