BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Amgen Europe B.V. submitted on 28 April 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Vectibix, 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 applicant applied for the following indication: treatment of metastatic carcinoma of the colon or rectum after failure of oxaliplatin- and/or irinotecan- containing chemotherapy regimens.

Scientific Advice
The applicant did not seek scientific advice at the CHMP.

Licensing status
Vectibix has been given first a Marketing Authorisation in United States of America for the treatment of Epidermal Growth Factor Receptor EGFR-expressing (EGFR Epidermal Growth Factor Receptor), metastatic colorectal carcinoma with disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens in September 2006.

A new application was filed in the following countries: Switzerland, Canada and Australia.

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

Rapporteur: Frances Rotblat Co-Rapporteur: Eva Skovlund

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 28 April 2006.
- The procedure started on 24 May 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 7 August 2006 (Annex 4.1). The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 11 August 2006 (Annex 4.2).
- During the meeting on 19-21 September 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 21 September 2006 (Annex 4.3).
- Inspections were carried out:
  - Inspections of active Substance Manufacturers:
    At Amgen Inc. - Building 7 One Amgen Center Drive - Thousand Oaks, CA - USA
    Inspection requested by CHMP in September 2006 meeting and performed by Dutch inspectorate on 25-27 October 2006.
    And at Amgen Inc. - 6701 Kaiser Drive - Fremont, CA - USA
    Inspection requested by CHMP in September 2006 meeting and performed by Dutch inspectorate on 17-19 October 2006.
  - Inspection of Finished Product Manufacturer:
    At Cardinal Health, PTS, LLC - 4757 Nexus Centre Drive - San Diego, CA - USA
    Inspection requested by CHMP in September 2006 meeting and performed by Dutch inspectorate on 20-24 October 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 15 December 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 26 January 2007 (Annex 4.4).

- During the CHMP meeting on 19-22 February 2007, the CHMP agreed on a List of Outstanding Issues to be addressed in writing by the applicant (Annex 4.5).
- The applicant requested an oral explanation and submitted the responses to the CHMP List of Outstanding Issues on 19 March 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 17 April 2007 (Annex 4.6).
- During the CHMP meeting on 23-26 April 2007, outstanding issues were addressed by the applicant during an oral explanation.
- During the meeting on 21-24 May 2007, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a negative opinion for granting a Marketing Authorisation to Vectibix on 24 May 2007.

1.3 Steps taken for the re-examination procedure

- The applicant submitted written notice to the EMEA on 06 June 2007 to request a re-examination of the Vectibix CHMP opinion of 24 May 2007.
- During its meeting on 19-21 June 2007, the CHMP appointed Dr P. Demolis as Rapporteur. Dr G. Calvo Rojas Co-Rapporteur.

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

  Rapporteur: Pierre Demolis Co-Rapporteur: Gonzalo Calvo Rojas

- The detailed grounds for the re-examination request were submitted by the applicant on 24 July 2007 (Appendix 2 of Final Opinion). The re-examination procedure started on 25 July 2007.
- During its meeting on 17-19 July 2007, the CHMP adopted the List of Questions and List of Participants to the SAG on Oncology to be held on 05 September 2007.
- The Rapporteur's Assessment Report was circulated on 28 August 2007 (Annex 4.7). The Co-Rapporteur's Assessment Report was circulated on 28 August 2007 (Annex 4.8).
- During a meeting of the CHMP Scientific Advisory Group on Oncology on 05 September 2007, experts were convened to consider the grounds for re-examination. During this meeting the applicant presented an oral explanation. A report of this meeting was forwarded to the CHMP on 20 September 2007 (Annex 4.9).
- During the meeting on 18-20 September 2007, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a final Opinion recommending the granting of the conditional Marketing Authorisation for Vectibix.
- During the meeting on 13-15 November 2007, the CHMP, upon the European Commission's request dated 12 November 2007, adopted a revised CHMP assessment report for the conditional Marketing Authorisation for Vectibix granted on 20 September 2007.