BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company SBL Vaccin AB submitted on 1 March 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Dukoral, in accordance with the centralised procedure falling within the scope of Part A of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:
Rapporteur: Per Nilsson Co-Rapporteur: Manfred Haase

Licensing status:

Dukoral has been granted national Marketing Authorisations in Sweden in 1991 and in Norway in 1997. Additionally, Dukoral has been approved in 12 countries such as Peru and Guatemala (1996), Argentina, El Salvador, Honduras and Nicaragua (1997), Madagaskar (1999), Estonia (2000), Mexico, Kenya, Mauritius and the Philippines (2001). An application is pending in 11 countries including among others Switzerland, Canada, New Zealand, Thailand and South Africa. Since 2001 Dukoral is recommended by the WHO for immunisation against cholera in endemic areas and is the only cholera vaccine included in the list of "United Nations Prequalified Vaccines" for the prevention of cholera in endemic regions.

2. Steps taken for the assessment of the product

- The procedure started on 26 March 2002.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 4 June 2002. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 7 June 2002.
- During the meeting on 23 – 25 July 2002 the CPMP 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 25 July 2002.
- The company submitted the responses to the CPMP consolidated List of Questions on 16 January 2003.
- The joint response Assessment Report on the company's responses to the List of Questions was circulated to all CPMP members on 19 February 2003.
- During the meeting on 18 – 20 March 2003 the CPMP adopted the List of Outstanding Issues.
- The company submitted the written responses to the List of Outstanding issues on 30 May 2003.
- The joint response Assessment Report on the company's responses to the List of Outstanding Issues was circulated to all CPMP members on 13 June 2003.
- During the CPMP meeting on 24 – 26 June 2003 outstanding issues were addressed by the applicant during a hearing before the CPMP.
- A Rapporteur's pre-opinion report was circulated to all CPMP members on 16 July 2003.
- During the meeting on 22-24 July 2003 the CPMP, 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 Dukoral on 24 July 2003.
- The European Commission returned the initial CPMP Opinion of July 2003 to the EMEA, requesting to reconsider this application according to a different legal basis.

- During the meeting on 24- 26 February 2004 the CPMP, in the light of the overall data and justification submitted and the scientific discussion within the Committee, issued a revised positive Opinion for granting a Marketing Authorisation for Dukoral.