BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Abbott Laboratories Ltd submitted on 6 July 2006 an application in accordance with Article 58 of (EC) No Regulation 726/2004 to the European Medicines Agency (EMEA) for a scientific opinion in the context of cooperation with the World Health Organisation for Aluvia.

The eligibility by the World Health Organisation was agreed-upon on 24 May 2006.

Aluvia will exclusively be intended for markets outside the Community.

The application submitted is a complete dossier composed of administrative information, complete quality data, non-clinical and clinical data with a letter from Abbott Laboratories Ltd, the MAH of the centrally authorised product Kaletra (lopinavir / ritonavir) allowing the cross reference to relevant non-clinical and clinical data of the Kaletra application.

The Rapporteur appointed by the CHMP was:

Rapporteur	E. Abadie

2 Steps taken for the assessment of the product

- The eligibility by the World Health Organisation was agreed upon on 24 May 2006.
- The application was received by the EMEA on 6 July 2006.
- The procedure started on 23 July 2006.
- The Rapporteur's Assessment Report was circulated to all CHMP members on 21 August 2006 and an updated Assessment Report was circulated to all CHMP members on 13 September 2006.
- During the meeting on 18-21 September 2006, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive scientific opinion to Aluvia 200 mg/50 mg film-coated tablets on 21 September 2006.
- The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-opinion on 18 September 2006.