# I. BACKGROUND INFORMATION ON THE PROCEDURE

## 1. Submission of the dossier

Further to the submission of a letter of intent by Novartis Healthcare A/S on 18 March 2008, the CVMP accepted on 15-17 April that ZOLVIX was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure.

The company Novartis Healthcare A/S submitted an application to the EMEA on 2 September 2008 for the granting of a Community marketing authorisation in accordance with Article 31 of Regulation (EC) No 726/2004 of 31 March 2004.

The application was validated on 16 September 2008.

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

Rapporteur: Prof. Christian Friis from Denmark: Co-Rapporteur Mr Johan Schefferlie from Netherlands

## 2. Steps taken for the assessment of the product

Supplementary information was provided by the applicant on 16 April 2009.
Written explanations were provided by the applicant on 22 June 2009.

The procedure was finalised with adoption of the opinion according to Article 31 of Regulation (EC) No 726/2004 on 15 July 2009.