

3. Steps taken for the re-examination procedure

- The applicant received the CHMP opinion on 24 February 2006
- The applicant submitted written notice to the EMEA on 2 March 2006 to request a re-examination of the ATryn CHMP opinion of 22 February 2006.
- During its meeting on 20-23 March 2006, the CHMP appointed Dr Bengt Ljungberg as Rapporteur and Dr Gonzalo Calvo Rojas as Co-Rapporteur for the re-examination procedure.
- The detailed grounds for the re-examination request were submitted by the applicant on 24 April 2006. The re-examination procedure started on 25 April 2006.
- The Rapporteur's Assessment Report was circulated to all CHMP members on 9 May 2006. The Co-Rapporteur's Assessment Report was circulated to all CHMP members on 10 May 2006.
- An Ad hoc Expert Group meeting on ATryn was held on 29 May 2006 at the EMEA. During this meeting the applicant presented an oral explanation. A report of this meeting was forwarded to CHMP.
- During the CHMP meeting on 30 May 2006 to 1 June 2006, the applicant presented an oral explanation before the CHMP on the 30 May 2006.
- During the meeting on 30 May 2006 to 1 June 2006, 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 Marketing Authorisation under exceptional circumstances to ATryn on 1 June 2006.
- The CHMP opinion was forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 28 July 2006.