

I BACKGROUND INFORMATION ON THE PROCEDURE

1. STEPS TAKEN FOR THE ASSESSMENT OF THE PRODUCT

Further to the submission of a letter of intent by Novartis Animal Health UK Ltd on 27 February 2007, the CVMP accepted on 13-15 March 2007 that Onsior was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure in accordance to Article 3(2) (a) of Regulation (EC) No 726/2004, since the active substance robenacoxib was not authorised by any Member State for use in animals on the date of entry into force of the Regulation.

The Committee for Medicinal Products for Veterinary Use appointed Dr Hans Hoogland, (later replaced by Johan Schefferlie) from Netherlands as Rapporteur and Dr Anja Holm from Denmark as Co-Rapporteur for the assessment of the application for Onsior during its meeting of 14-16 March 2006.

The company Novartis Animal Health UK Ltd submitted an application to the EMEA on 27 February 2007 for the granting of a Community marketing authorisation in accordance with Article 31 of Regulation (EC) No 726/2004 of 21 March 2004.

The application was validated on 13 March 2007.

2. STEPS TAKEN FOR THE ASSESSMENT OF THE PRODUCT

- The Rapporteur and Co-Rapporteur's assessment reports were circulated to all CVMP Members on 28 May 2007 and 6 June 2007 respectively.
- The consolidated list of questions as agreed by the CVMP during its meeting held in July 2007 was sent to the Applicant and the clock stopped.
- The Applicant circulated the responses to the CVMP list of questions on 17 April 2008 and the clock was restarted.
- The joint Rapporteur and Co-Rapporteur assessment report on the responses to the consolidated list of questions, the overview of the scientific data and the overall conclusions were circulated to all CVMP Members on 28 May 2008.
- An oral explanation was held on 17 September 2008.
- The CVMP, in the light of the agreed scientific standards and methods for evaluating veterinary medicinal products at the time of submission of the dossier, issued on 15 October 2008, a positive Opinion for the granting of a Community Marketing Authorisation for Onsior.