I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Janssen Animal Health BVBA on 29 July 2004, the Committee for Medicinal Products for Veterinary Use (CVMP) accepted during its meeting from 6-7 September 2004 that Yarvitan was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised system. This was reconfirmed by CVMP during its meeting from 6-8 December 2005 following the entry into force of Regulation (EC) No 726/2004 in November 2005. The Committee confirmed that the product was eligible for the centralised procedure under Article 3(2)(a) of Regulation (EC) No 726/2004, since the active substance mitratapide was not authorised by any Member State for use in animals on the data of entry into force of the Regulation.

The CVMP appointed Mr Breathnach from Ireland as Rapporteur and Dr JP Hoogland from The Netherlands as Co-Rapporteur for the assessment of the application for Yarvitan during its meeting of 6 – 7 September 2004.

The company Janssen Animal Health BVBA submitted an application to the EMEA on 7 December 2005 for the granting of a Community marketing authorisation.

The procedure started on 22 December 2005.

2. Steps taken for the assessment of the product

- The Rapporteur's and Co-Rapporteur's assessment reports were circulated to all CVMP Members on 1 March 2006 and 16 March 2006 respectively.
- The consolidated list of questions as agreed by the CVMP during its meeting held in April 2006 was sent to the Applicant and the clock stopped.
- The Applicant circulated the responses to the CVMP list of questions on 16 June 2006 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 25 July 2006.
- 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 13 September 2006, a positive Opinion for the granting of a Community Marketing Authorisation for Yarvitan.
- The corresponding Commission Decision was issued on 14 November 2006.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) responsible for batch release

Janssen Pharmaceutica N.V.
Turnhoutseweg 30
B-2340 Beerse
Belgium

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

To be supplied only on veterinary prescription.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE PRODUCT

Not applicable.

D. STATEMENT OF THE MRLs

Not applicable.