I. BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

Further to the submission of a letter of intent by Novartis Animal Health on 24 September 2004, the CVMP accepted on 9-11 November 2004 that Prac-Tic was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised system as provided for under Part B of the Annex to Council Regulation (EEC) 2309/93.

The Committee for Medicinal Products for Veterinary Use appointed Dr. Margarita Arboix from Spain (later replaced by Dr. Cristina Muñoz-Madero) as Rapporteur and Dr. Bruno Urbain from Belgium as Co-Rapporteur for the assessment of the application for Prac-Tic during its meeting of 9-11 November 2004.

The company Novartis Animal Sanidad S. L. submitted an application to the EMEA on 21 April 2005 for the granting of a Community marketing authorisation in accordance with Council Regulation (EEC) No 2309/93.

1.2. Steps taken for the assessment of the product

- The procedure started on 11 May 2005.
- The consolidated list of questions as agreed by the CVMP during its meeting held on 7 September 2005 was sent to the Applicant and the clock stopped.
- 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 11 October 2006 a positive Opinion for the granting of a Community marketing authorisation for Prac-Tic.

1.3 Commission Decision

The European Commission granted a marketing authorisation valid throughout the European Union for Prac-tic on 18.12.2006.

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

Name and address of the manufacturer responsible for batch release

Novartis Santé Animale S.A.S
Usine de Huningue
26 rue de Chapelle
F-68330
France

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

For animal treatment only – to be supplied only on veterinary prescription.
The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

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

Not applicable

V. STATEMENT OF THE MRLs

Not applicable

