I BACKGROUND INFORMATION ON THE PROCEDURE

1. Steps taken for the assessment of the product

The company Intervet International B.V. submitted an application to the EMEA on 4 December 2001 for the granting of a Community marketing authorisation for GONAZON in accordance with Council Regulation (EEC) No 2309/93.

The Committee for Veterinary Medicinal Products appointed Mr. Rory Breathnach from Ireland as Rapporteur and Dr. Hanne Bergendahl from Norway as Co-Rapporteur for the assessment of the application for Gonazon during its meeting of 9-11 October 2001.

The application was validated on 18 December 2001.

2. Steps taken for the assessment of the product

- The company Intervet Innovation submitted an application to the EMEA on 4 December 2001 for the granting of a Community marketing authorisation in accordance with Council Regulation (EEC) No 2309/93.
- The application was validated on 18 December 2001.
- The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on 26 February 2002 and 13 March 2002.
- The consolidated list of questions as agreed by the CVMP during its meeting held on 16-18 April 2002 was sent to the Applicant and the clock stopped.
- The applicant circulated the responses to the CVMP list of questions on 17 October 2002 and the clock was restarted on 18 October 2002.
- 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 26 November 2002.
- Additional answers to the questions related to the restricted part of the EDMF were sent by Diosynth (the EDMF holder) on 2 December 2002.
- A list of outstanding issues, to be addressed at an oral explanation, were agreed by written procedure on 11 December 2002 and the clock was stopped.
- Written answers to the outstanding issues were provided by Intervet International B.V. and Diosynth on 20 February 2003 and on 5 March 2003.
- The Rapporteur provided an assessment report of the answers to the outstanding issues on 11 March 2003.
- An oral explanation was held on 12 March 2003 and the clock was restarted.
- A report on additional metabolism data presented at the oral explanation was provided on 26 March 2003.
- Further quality data related to the sterile container were provided on 7 April 2003.

- 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 9 April 2003, a positive opinion for the granting of a Community marketing authorisation for GONAZON.

- The CVMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 22 July 2003.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance(s)

Diosynth B.V.
P.O. Box 20
5340 BH OSS
The Netherlands

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

Gonazon for fish:
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Gonazon for dogs:
Intervet GesmbH
Siemensstrasse 107
A-1210 Wien
Austria

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

Veterinary medicinal product subject to prescription.

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

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

Substance	MRL status	Comments
Azagly-nafarelin	Annex II for Salmonidae[1]	Not for use in fish from which eggs are produced for human consumption
Sodium acetate (tri-hydrate)	Annex II for all food producing species	Approved food additive (E 262), CR No 2034/96
Acetic acid (glacial)	Annex II for all food producing species	Approved food additive (E 260), CR No 2034/96
Benzyl alcohol	Annex II for all food producing species. For use as excipient	CR No 1442/95
Sodium chloride	Annex II for all food producing species	CR No 2796/95
Sodium hydroxide	Included in Annex II for all food producing species	Approved food additive (E 524), CR No 2034/96
Hydrochloric acid	Annex II for all food producing species, for use as excipient.	CR No 1442/95
Water for injections	Not within the scope of Council Regulation 2377/90	

[1] Regulation 1530/02 / OJL230 of 28 August 2002