Dicural 100 mg/ml Oral Solution for Chickens and Turkeys

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

During its meeting of September 27-28, 1995, the Committee for Veterinary Medicinal Products appointed Dr. P. Hekman as Rapporteur and Dr. K. Woodward as Co-Rapporteur for the assessment of the application of Solvay Duphar. As Dr. K. Woodward resigned from the CVMP in July 1996, he was replaced, as Co-Rapporteur, by Mrs. J. Ashley-Smith for the assessment of the answers to the CVMP list of questions.

The company Solvay Duphar submitted an application to the EMEA on October 5, 1995 for the granting of a Community marketing authorisation for Dicural in accordance with Council Regulation (EEC) No 2309/93. The Drug Master File (DMF) supporting the above mentioned application was received from Profarmaco Nobel S.r.L. on November 3, 1995.

This application was validated on November 6, 1995.

2. Steps taken for the assessment of the product

- The consolidated list of questions as agreed by the CVMP during its meeting held on April 23-24, 1996, was sent to the applicant.

- The CVMP in the light of the current scientific standards issued on June 11, 1997 a positive opinion for the granting of a Community marketing authorisation for Dicural.

NB: During the evaluation of the application, Solvay's animal health business was sold to American Home Products. As a consequence, the applicant notified the EMEA on March 6, 1997, that, as of March 1, 1997, it would operate in Europe under the name Fort Dodge Animal Health Holland.

The European Commission granted a marketing authorisation valid throughout the European Union for Dicural on 16 January 1998.

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

Name and address of the manufacturers responsible for batch release:

Fort Dodge Animal Health Holland
C.J. van Houtenlaan 36
1381 CP Weesp
The Netherlands

Manufacturing Authorisation issued on 5 September 1996 by Ministerie van Landbouw, Natuurbeheer en Visserij, the Netherlands.

Fort Dodge Veterinaria S.A.
Ctra. Camprodón, s/n "La Riba"
17813 Vall de Bianya (Girona)
Spain

Manufacturing Authorisation issued on 4 March 1997 by Ministerio de Agricultura, Spain.

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

Veterinary medicinal product subject to prescription.

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

Not applicable.

D. STATEMENT OF THE MRLs

Annex I of Council Regulation (EEC) No 2377/90[1]

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Difloxacin	Difloxacin	Chicken, turkey	300 µg/kg 400 µg/kg 1900 µg/kg 600 µg/kg	Muscle Skin and fat Liver Kidney	

Annex II of Council Regulation (EEC) No 2377/90

Pharmacologically active substance	Animal Species	Other provisions
Edetic acid[2]	All food-producing species	
Potassium Hydroxide[3]		
Propylene glycol[4]		
Benzyl alcohol[5]		For use as excipient
Hydrochloric acid[6]		For use as excipient

[1] OJ No. L 110 of 26.04.97
[2] OJ No. L 290 of 5.12.95
[3] OJ No. L 272 of 25.10.96
[4] OJ No. L 45 of 15.02.97
[5] OJ No. L 143 of 27.06.95
[6] OJ No. L 143 of 27.06.95

Dicural 15 mg, 50 mg, 100 mg and 150 mg Coated Tablets for Dogs

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Fort Dodge Animal Health Holland submitted an application to the EMEA on 16 February 1998 for the granting of a Community marketing authorisation for Dicural Coated Tablets in accordance with Council Regulation (EEC) No 2309/93. The application was validated on 2 March 1998.

During its meeting of July 1997, the Committee for Veterinary Medicinal Products appointed P. Hekman from The Netherlands as Rapporteur and J. O'Brien from the United Kingdom as Co-Rapporteur for the assessment of the application. P. Hekman was replaced by H. Hoogland in October 1998.

The application was validated on 2 March 1998.

2. Steps taken for the assessment of the product

- The consolidated list of questions, as agreed by the CVMP during its meeting held on 9 – 11 June 1998, was sent to the Applicant and the clock was 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 14 July 1999 a positive opinion for the granting of a Community marketing authorisation for Dicural Coated Tablets.

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

Name and address of the manufacturer responsible for batch release:

Fort Dodge Animal Health Holland
C.J. van Houtenlaan 36
1381 CP Weesp
The Netherlands

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

Veterinary medicinal product subject to prescription.

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

Not applicable.

D. STATEMENT OF THE MRLs

Not applicable.

Dicural 50 mg/ml Solution for Injection for Cattle and Dogs

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The CVMP accepted on June 1998 that Dicural 50 mg/ml solution for injection for cattle and dogs was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised system as provided for under the last indent of Part B of the Annex to Council Regulation (EEC) No 2309/93. During that meeting, the Committee for Veterinary Medicinal Products appointed P. Hekman from The Netherlands as Rapporteur and J. O'Brien from the United Kingdom as Co-Rapporteur for the assessment of the application. P. Hekman was replaced subsequently by H. Hoogland.

The company Fort Dodge Animal Health Holland submitted an application to the EMEA on 1 December 1998 for the granting of a Community marketing authorisation for Dicural 50 mg/ml solution for injection for cattle and dogs in accordance with Council Regulation (EEC) No. 2309/93.

The application was validated on 15 December 1998.

2. Steps taken for the assessment of the product

- The consolidated list of questions as agreed by the CVMP during its meeting held on 13-15 April 1999 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 21 June 2000 a positive opinion for the granting of a Community marketing authorisation for Dicural 50 mg/ml solution for injection for cattle and dogs.

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

Name and address of the manufacturers responsible for batch release:

Fort Dodge Veterinaria S.A.
Ctra. Campródon, s/n, La Riba,
17813 Vall de Bianya (Girona)
Spain

Manufacturing Authorisation issued on 4 March 1997 by Ministerio de Agricultura, pesca y alimentacion, C/Velasquez, 147 28002 Madrid, Spain.

Fort Dodge Animal Health Holland
C.J. van Houtenlaan 36
1381 CP Weesp
The Netherlands

Manufacturing Authorisation issued on 5 September 1996 by Ministerie van Landbouw, Natuurbeheer en Visserij, The Netherlands

B. CONDITIONS OF THE MARKETING AUTHORISATION INCLUDING RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

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

Not applicable.

D. STATEMENT OF THE MRLs

Annex III of Council Regulation (EEC) No 2377/90

Pharmacologically active substance	Marker residue	Animal species	MRLs (*)	Target tissues
Difloxacin[7]	Difloxacin	Bovine	1400 µg/kg 800 µg/kg 400 µg/kg 100 µg/kg	Liver Kidney Muscle Fat Not for use in animals from which milk is produced for human consumption

(*) Provisional MRLs expire on 1.1.2001

Annex II of Council Regulation (EEC) No 2377/90

Pharmacologically active substance	Animal Species	Other provisions
Ethanol [8]	All food-producing species	For use as excipient
Propylene glycol [9]		
Benzyl alcohol [10]		
Arginine [11]		

[7] O.J. No L 122 of 12.05.99

[8] OJ No. L 143 of 26.06.95
[9] OJ No. L 45 of 15.02.97
[10] OJ No L 143 of 26.06.95
[11] OJ No. L 240 of 10.09.99

