Metacam 5mg/ml cattle and pigs

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Steps taken for the assessment of the product

- The company Boehringer Ingelheim submitted an application to the EMEA on 10 June 1996 for the granting of a Community marketing authorisation for Metacam in accordance with Council Regulation (EEC) No 2309/93. This application was validated on 21 June 1996.
- The centralised procedure started on 24 June 1996.
- The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on 11 September 1996.
- The consolidated list of questions as agreed by the CVMP during its meeting held on 22-23 October 1996 was sent to the Applicant and the clock stopped.
- The Applicant circulated the responses to the CVMP list of questions on 17 March 1997 at which point 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 18 April 1997.
- The joint Rapporteur and Co-rapporteur assessment report, the overview of the scientific data and the overall conclusions were discussed during the meeting of the Committee held on 6-7 May 1997. The Committee considered that some of the answers provided did not address satisfactorily the points raised in the list of questions and therefore agreed that the Applicant should be invited to provide oral explanations. The clock was stopped on 7 May 1997.
- The Applicant provided oral explanations on three outstanding issues during the meeting of the Committee held on 10-12 June 1997 and the clock was restarted on 11 June 1997.
- 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 16 July 1997 a positive opinion for the granting of a Community marketing authorisation for Metacam.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. Manufacturing authorisations and inspection status

Manufacturer of the active substance :

Dr Karl Thomae GmbH
Germany
or
Bidachem S.p.A.
Italy

Manufacturer of the medicinal product responsible for batch release :

Labiana Life Sciences S.A.
Venus, 26
Can Parellada Industrial
08228 Terrassa
Spain

Manufacturing Authorisation no. 314, as granted by the national Ministerio de Agricultura, Pesca Y Alimentacion on 3 November 1981, has been presented. GMP status was confirmed by the same Ministry in May 1996.

2. Proposed conditions or restrictions of supply and use

Veterinary medicinal product subject to prescription.

- The company Boehringer Ingelheim Vetmedica submitted an application to the EMEA on 22 December 1998 for the granting of a Community marketing authorisation for Metacam 5 mg/ml Solution for Injection in accordance with Council Regulation (EEC) No 2309/93. This application was an extension to the authorisation for Metacam 5 mg/ml Solution for Injection for Cattle, granted on 7 January 1998 (OJ No C 32 of 30.01.98).

- The application was validated on 12 January 1999.

- The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on 23 March 1999 and 7 April 1999.

- The consolidated list of questions as agreed by the CVMP during its meeting held on 11-12 May 1999 was sent to the Applicant and the clock stopped.

- The Applicant circulated the responses to the CVMP list of questions for Metacam 5 mg/ml Solution for Injection by 13 August 1999 at which point 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 17 September 1999.

- The joint Rapporteur and Co-rapporteur assessment report, the overview of the scientific data and the overall conclusions were discussed during the meeting of the Committee held on 12 – 14 October.1999. The CVMP considered that the answers provided addressed the points raised in the list of questions satisfactorily.

- 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 10 November 1999 a positive opinion for the granting of a Community marketing authorisation for Metacam 5 mg/ml Solution for Injection.

GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. Manufacturing authorisations and inspection status

Manufacturer and assembler of the finished product:

Labiana Life Sciences S.A
Venus, 26
Can Parellada Industrial
08228 Terrassa
Spain

Manufacturer of the medicinal product responsible for batch release:

Labiana Life Sciences S.A
Can Parellada Industrial
08228 Terrassa
Spain

Manufacturing Authorisation no. 314, as granted by the national Ministerio de Agricultura, Pesca Y Alimentacion on 3 November 1981, has been presented.

2. Proposed conditions or restrictions of supply and use

Veterinary medicinal product subject to prescription.

3. Prohibition of sale, supply and/or use

Not applicable.

4. Statement of the MRLs

Not applicable.

Metacam 1.5mg/ml oral suspension dogs

- The company Boehringer Ingelheim Vetmedica submitted an application to the EMEA on 22 December 1998 for the granting of a Community marketing authorisation for Metacam 1.5 mg/ml Oral Suspension in accordance with Council Regulation (EEC) No 2309/93. This application is an extension to the authorisation for Metacam 5 mg/ml Solution for Injection for Cattle, granted on 7 January 1998 (OJ No C 32 of 30.01.98).

- The application was validated on 12 January 1999.

- The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on 23 March 1999 and 7 April 1999.

- The consolidated list of questions as agreed by the CVMP during its meeting held on 11-12 May 1999 was sent to the Applicant and the clock stopped.

- The Applicant circulated the responses to the CVMP list of questions for Metacam 1.5 mg/ml Oral Suspension by 13 August 1999 at which point 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 17 September 1999.

- The joint Rapporteur and Co-rapporteur assessment report, the overview of the scientific data and the overall conclusions were discussed during the meeting of the Committee held on 12 – 14 October.1999. The CVMP considered that the answers provided satisfactorily addressed the points raised in the list of questions.

- 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 10 November 1999 a positive opinion for the granting of a Community marketing authorisation for Metacam 1.5 mg/ml Oral Suspension.

GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

Manufacturing authorisations and inspection status

Manufacturer and assembler of the finished product:

Boehringer Ingelheim Vetmedica Inc.
15 & Oak, Elwood,
Kansas,
USA.

Manufacturer of the medicinal product responsible for batch release :

Boehringer Ingelheim Pharma KG,
Binger Str. 173,
55216 Ingelheim am Rhein,
Germany

Manufacturing Authorisation issued on 9 July 1999 by the Ministerium fur Arbeit, Soziales und Gesundheit (Rheinland Pfalz).

Further to a Type I variation, the batch release site was changed to

Boehringer Ingelheim Pharma GmbH & Co. KG
55216 Ingelheim/Rhein
Germany

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

Veterinary medicinal product subject to prescription.

C. PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

D. STATEMENT OF THE MRLs

Not applicable.

Metacam 15ml/mg horses

The company **Boehringer Ingelheim Vetmedica** submitted an application to the EMEA on 28 October 2002 for the granting of an extension to the Community Marketing Authorisation for **Metacam** to Horses in accordance with Council Regulation (EEC) No 2309/93 and Annex II of Commission Regulation (EC) No. 542/95 as amended.

- The application was validated on 12 November 2002 and the procedure started on 13 November 2002.

- The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on 21 January 2003 and 5 February 2003.

- The consolidated list of questions as agreed by the CVMP during its meeting held on 12 March 2003 was sent to the Applicant and the clock stopped.

- The Applicant circulated the responses to the CVMP list of questions by 21 March 2003 at which point 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 April 2003.

- The joint Rapporteur and Co-rapporteur assessment report, the overview of the scientific data and the overall conclusions were discussed during the meeting of the Committee held on 14 May 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 18 June 2003 a positive Opinion for the extension of the Community Marketing Authorisation to Metacam 15 mg/ml oral supension for horses.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

II.1. Manufacturing authorisation

Manufacturer responsible for batch release:

Boehringer Ingelheim Pharma GmbH & Co. KG
55216 Ingelheim/Rhein
Germany

II.2. Proposed conditions or restrictions of supply and use

Veterinary medicinal product subject to prescription.

II.3. Statement of the MRLs

The Committee for Veterinary Medicinal Products has recommended the inclusion of Meloxicam in Annex I of Council Regulation (EEC) No 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	**Marker residue**	**Animal species**	**MRLs**	**Target tissues**	**Other provisions**
Meloxicam	Meloxicam	Equidae	20 µg/kg 65 µg/kg 65 µg/kg	Muscle Liver Kidney	

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

Pharmacologically active substance	Animal Species	Other provisions
Sorbitol	Annex II (E420): All food producing species	
Glycerol	Annex II (E422): All food producing species	
Saccharin	Annex II (E954): All food producing species	
Xylitol	Annex II (E967): All food producing species	
Sodium dihydrogen phosphate dihydrate	Annex II (E339): All food producing species	
Silica, colloidal anhydrous	Annex II (E551): All food producing species	
Sodium benzoate	Annex II (E211): All food producing species	

Hydroxyethylcellulose and Water (purified) are not within the scope of Council Regulation (EC) 2377/90.

The applicant provided a statement regarding the nature-identical honey aroma used as a flavouring agent and this was considered acceptable.

Metacam 20mg/ml cattle and pigs

- The application was validated on 14 September 1999 and the procedure started on 15 September 1999.

- The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on 23 November 1999 and 8 December 1999.

- The consolidated list of questions as agreed by the CVMP during its meeting held on 11- 13 January 2000 was sent to the Applicant and the clock stopped.

- The Applicant circulated the responses to the CVMP list of questions for Metacam 20 mg/ml Solution for Injection by 7 September 2000 at which point 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 13 October 2000.

- The joint Rapporteur and Co-rapporteur assessment report, the overview of the scientific data and the overall conclusions were discussed during the meeting of the Committee held on 7 – 9 November 2000.

- The Committee considered that some of the answers provided did not address satisfactorily the points raised in the list of questions and therefore agreed that the Applicant should be invited to provide oral explanations. Written explanation of a number of issues was also requested by the Committee. The clock was stopped on 8 November 2000.

- The Applicant provided oral explanations on two outstanding issues during the meeting of the Committee held on 9 – 11 January 2001 and the clock was restarted on 9 January 2001.

- 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 10 January 2001 a positive Opinion for the extension of the Community Marketing Authorisation to Metacam 20 mg/ml solution for injection for Cattle.

GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. Manufacturing authorisations and inspection status

Manufacturer of the medicinal product responsible for batch release :

Labiana Life Sciences S.A.
Venus, 26
Can Parellada Industrial
08228 Terrassa
Spain

Manufacturing Authorisation no. 314, as granted by the national Ministerio de Agricultura, Pesca Y Alimentacion on 3 November 1981, has been presented.

2. Proposed conditions or restrictions of supply and use

Veterinary medicinal product subject to prescription.

3. Specific Obligations on the Marketing Authorisation Holder

None.

4. Statement of the Maximum Residue Limits (MRLs)

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Meloxicam	Meloxicam	Bovine	20 µg/kg 65 µg/kg 65 µg/kg 15 µg/kg	Muscle Liver Kidney Milk	
		Porcine	20 µg/kg 65 µg/kg 65 µg/kg	Muscle Liver Kidney	

STATEMENT OF THE MRLs WHICH ARE ACCEPTED IN ACCORDANCE WITH COUNCIL REGULATION (EEC) No 2377/90

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

Pharmacologically active substance(s)	Animal species	Other provisions
Ethanol[1]	All food producing species	
Poloxomer 188[2]	All food producing species	
Macrogol 300	All food producing species.	
Sodium Chloride[3]	All food producing species	
Glycine[4]	All food producing species	
Disodium edetate	All food producing species	
Sodium Hydroxide[5]	All food producing species	
Hydrochloric acid	All food producing species	
Water for injection[6]	All food producing species	
Nitrogen[7]	All food producing species	

N.B. Meglumine was not considered within the scope of Council Regulation 2377/90 at concentrations up to 1.5 mg/kg bw (concentrations up to 34.75 mg/ml).

[1] OJ No. L 143 of 27.06.95
[2] OJ No. L 290 of 5.12.95
[3] OJ No. L 290 of 5.12.95
[4] OJ No. L 272 of 25.10.96
[5] OJ No. L 272 of 25.10.96
[6] OJ No. L 143 of 27.06.95
[7] OJ No. L 272 of 25.10.96