The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines and Inspections

London, 15 May 2003
EMEA/CVMP/484/03

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Meeting of 13 to 14 May 2003

Availability of Medicines

The Committee agreed the document entitled Points to Consider regarding availability of veterinary medicinal products – Extrapolation of MRLs, latest paper on defining the criteria for further extrapolation of maximum residue limits and proposing 8 more substances for extrapolation, for release for a 4-month period of consultation (EMEA/CVMP/457/03-CONSULTATION).

The document is available on the EMEA web site: http://www.emea.eu.int

The Committee also considered the CVMP paper entitled "Points to Consider regarding availability of products for minor species and minor indications". This paper has evolved from an earlier draft policy paper for efficacy testing for medicinal products intended for minor uses and minor species. The document has completed the consultation period and is now being developed as the basis of the CVMP Strategic Plan for further facilitating the provision of medicines for these specific types of use. The Strategic Plan and revised document will be further discussed at the Informal meeting of CVMP to be held in Greece on 20-21 May 2003 as a preclude to a meeting with the Interested Parties on this topic after the June CVMP meeting.

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Nobilis IB 4-91**. The Committee concluded that the quality, safety and efficacy of the product continued to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation.

Maximum Residue Limits

The Committee endorsed the updated list of substances considered as not falling within the scope of Council Regulation (EEC) No. 2377/90, to include **diethanolamine** (at doses up to 0.3 mg/kg bw/day) (EMEA/CVMP/046/00-Rev.5).

The document is available on the EMEA web site: http://www.emea.eu.int

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Post-authorisation issues

The Committee was informed on the preparation of the Joint EMEA/EDQM Seminar on Sampling and Testing of Centrally Authorised Products, to be held on 18-19 September 2003, in London. The aim of the seminar is to bring together the parties involved in the sampling and testing programmes and to discuss experience to date and proposals for future programmes. Therefore, representatives from CPMP, CVMP, Biotech Working Party, Immunologicals Working Party, Quality Working Party, ad hoc group on GMP and OMCL will be invited to attend the meeting.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Nobivac Bb** and **Metacam,** and concluded that no further action or changes to the product literature of the products were required.

International harmonisation

The Committee adopted the following VICH guidelines for release for a 6-month period of consultation:

- VICH GL36: Safety of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI (CVMP/VICH/467/03-CONSULTATION)
- VICH GL37: Safety of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing (CVMP/VICH/468/03-CONSULTATION)

The documents are available on the EMEA web site: http://www.emea.eu.int

The Committee was informed on the Efficacy and the Safety Workshops to take place in the context of the PERF III activities. The Workshops will be held on 11-12 June 2003 in Riga (Latvia) and 23-24 June 2003 in London, respectively.

Organisational issues

The Committee finalised the agenda of the Informal CVMP meeting to be held in Greece on 20-21 May 2003 at the initiative of the Greek Authorities under the activities of the Greek Presidency of the European Union. The Committee will discuss the future strategy on antimicrobial resistance, the mechanisms to improve quality of assessment reports and consequently European Public Assessment Reports (EPARs) for centrally authorised veterinary medicinal products, CVMP input into VICH procedures, the minor species and minor uses policy as well as implications for CVMP organisation resulting from the European Union enlargement and the means to facilitate integration of the new members.

The Committee noted the attached announcement regarding practical guidelines for delivery of a Marketing Authorisation Application.

The next meeting of the CVMP will be held on 17-19 June 2003

Peter G.H. Jones
Head, Veterinary Medicines Evaluation Unit
This press release and other documents are available on the Internet at the following address:
http://www.emea.eu.int

PROCEDURAL ANNOUNCEMENT

Practical guidelines for delivery of a Marketing Authorisation Application (MAA)

(1) For health and safety reasons and in accordance with recognised safe lifting limits, an application dossier should be packed in boxes weighing no more than 15kgs each

(2) All boxes should be numbered by an indication of the dossier part or module inside with the box containing the cover letter and diskettes/CD-ROMs clearly identified

(3) Very large dossiers of 10-15 boxes or more should be packed on pallets and delivered by truck with a tail lift unloading facility

(4) All dossiers are to be delivered to the following address:

EMEA Loading Dock
Ontario Way
(located at the rear of EMEA premises)
Canary Wharf
UK-London E14 4HB
(9:00 – 17:30 hours Monday to Friday)

We would be grateful if you could complete the information below for return by fax to +44 20 7418 8660 before shipment of your dossier to the EMEA.

Company name: ……..

MAA/dossier name: ……....

No. of boxes: ……...

Estimated date of arrival: ……

In the event of queries, the EMEA mail/archive team will be pleased to assist:

Fergal Cooney - Tel: + 44 20 7418 8487 **fergal.cooney@emea.eu.int**
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Annex I to CVMP Press Release May 2003

Marketing Authorisations

	1995-2002	2003	Overall Total
Applications submitted	50	2	52
Withdrawals	8	1	9
Positive CVMP opinions	38	1	39
Negative CVMP opinions[1]	0	0	0

Variations

	1995-2002	2003	Overall Total
Variations type I	98	16	114
Variations type II	37	3	40

Extensions

	1995-2002	2003	Overall Total
Extensions (Annex II applications) submitted	33	1	34
Withdrawals	1	0	1
Positive opinions	15	2	17
Negative opinions	0	0	0

[1] In case of appeal the opinion will not be counted twice

Renewals of marketing authorisations

	1995-2002	2003	Overall Total
Renewal applications submitted	7	2	9
Renewal positive opinions	5	3	8
Renewal negative opinions	0	0	0

Scientific advice

	1995-2002	2003	Overall Total
Applications submitted	20	1	21

Establishment of maximum residue limits

	1995-2002			2003			Overall Total
	Full	Extension/ Modification	Total	Full	Extension/ Modification	Total	
Applications submitted	50	73	123	0	4	4	127
Withdrawals	5	4	9	0	0	0	9
Positive opinions*	36	79	115	0	1	1	116
Negative opinions**	5	5	10	0	0	0	10

*Including 16 opinions recommending definitive MRLs for substances with previously provisional maximum residue limits

**Including 2 opinions (1 full, 1 extension) concluding that final maximum residue limits could not be established for substances with provisional maximum residue limits previously established

Referrals

	1995-2002	2003	Overall Total
Referrals	8	0	8