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

London, 11 April 2003
EMEA/CVMP/369/03

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Meeting of 8 to 9 April 2003

The Committee welcomed Birgit Aasmäe (Estonia), Alfred Hera (Czech Republic), Tibor Soós (Hungary) and Milan Saljgalik (Slovak Republic) who attended the meeting as observers from the candidate countries under an arrangement which will continue until the expected date of accession in 2004.

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by majority a positive opinion on an initial marketing authorisation application for **Gonazon** (***azagly-nafarelin***) a synthetic analogue of gonadotrophin-releasing hormone, from Intervet intended to induce and synchronize ovulation for the production of eyed-eggs or fry in salmonid fish. The application procedure was initiated on 19 December 2001 and the opinion was adopted on 9 April 2003 with an active review time of 204 days.

For further details please see the summary opinion available on the EMEA web site: http://www.emea.eu.int

The Committee adopted by consensus three positive opinions for three type II variations for **Dexdomitor** for the inclusion of a new indication for cats, **Metacam 1.5 mg/ml oral suspension** for dogs and for **Metacam 5 mg/ml solution** for dogs and cats for a change in the summary of the products characteristics (SPCs) concerning the pharmacodynamic properties of the products.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the inclusion of **cypermethrin** in Annex I of Council Regulation (EEC) No. 2377/90 for cattle and sheep further to establishment of provisional MRLs. The application was submitted under the procedure for the so-called "old substances" ("old" Article 7 of Council Regulation (EEC) No 2377/90) and the current provisional MRLs will expire on 1 July 2003.

For further details please see the summary opinion available on the EMEA web site: http://www.emea.eu.int

The Committee noted the notification of an appeal against the negative opinion for **morantel** adopted by the Committee during the March 2003 meeting and appointed a new rapporteur for the appeal procedure. The decision on the appeal procedure is foreseen for the June 2003 meeting.

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Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Bayovac CSF E2, Pruban** and **Stronghold** and concluded that no further action or changes to the product literature of the products were required.

Post-Authorisation Issues

The Committee reviewed and accepted the Final Report to the EMEA on the 2002 post-authorisation sampling and testing programme, issued by the EDQM.

Guidelines, SOPs and Position Papers

The Committee adopted for release for a 6-month period of consultation, the **definitions for non-standard processes** prepared by the Joint CPMP/CVMP Quality Working Party intended to be included as an annex (Annex II) to the **note for guidance on process validation**. The publication of the document on the EMEA web site (http://www.emea.eu.int) will follow their final adoption by the CPMP at the April meeting (23-25 April 2003).

Availability of Medicines

The Committee initiated discussions on the "Points to Consider" document regarding **availability of products for minor species and minor indications** following the close of the consultation period and the Committee reaffirmed its commitment to examining further ways of facilitating availability by exploring further initiatives in consultation with the veterinarian professions and industry. The Committee welcomed the proposal from the Spanish members to host a meeting in Madrid on 26 June 2003 to consider future directions for this to important issue.

The Committee also proceeded with a discussion on further extrapolation of certain existing maximum residue limits to minor species and agreed the provisional criteria for such extrapolations. An initial proposal is to be finalised at one of the next meetings and a 3-month consultation period will be initiated with Interested Parties and inputs particularly from industry and veterinarian associations will be welcomed, before a formal recommendation for extrapolations under defined criteria are submitted to the European Commission.

International harmonisation

The Committee heard reports on progress made during the last VICH Expert Working Groups on Biologicals Quality Monitoring, Target Animal Safety Biologicals and Target Animal Safety Pharmaceuticals held in March 2003.

The Committee was informed on the preparation of the VICH Steering Committee meeting to be held in London on 7-8 May 2003.

The Committee was informed on the preparation of the PERF Workshop on Pharmacovigilance to be held in Lithuania, on 24-25 April 2003 and on the initial planning for the Veterinary Conference for users and producers to be held in Warsaw on 24-26 September 2003.

Organisational Issues

The Committee discussed the preparation of the Informal CVMP meeting to be held in Athens, 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 agreed that the meeting would focus on the future strategy on antimicrobial resistance and the implications of the enlargement of the European Union on the work of the Committee.

The Committee noted the following revised procedural announcement regarding mock-ups and specimens for new applications taking account of the implementation of the revised linguistic review process:

PROCEDURAL ANOUNCEMENT

MOCK-UP & SPECIMEN REQUIREMENTS FOR NEW APPLICATIONS

Further to the implementation of the "New product information linguistic review process" (http://www.emea.eu.int/pdfs/human/regaffair/554202en.pdf), the EMEA would like to clarify the mock-up and specimen requirements for new applications in the Centralised Procedure.
Applicants are reminded that mock-ups must be submitted in full size hard copy and in colour.

At submission (Day 0):
One English mock-up (preferably in colour) and one multi-lingual mock-up ("worst-case") of the outer and inner packaging for each pharmaceutical form, and target species (if applicable), in the smallest pack-size must be included in Part I of the application.

After adoption of the CVMP opinion (Day 210)
A reduced* mock-up package and package insert will have to be submitted by Day 260 for every country where marketing is proposed, within 6 months of the anticipated date of the Commission Decision. At this stage, the linguistic checking procedure will be finalised and the Applicant is expected to reflect the latest agreed translations, incorporating all comments made, into the mock-ups. The EMEA will perform the mock-up check in 30 days in parallel to the 28 day Standing Committee consultation.

Mock-ups for countries where marketing is not proposed within 6 months of the Commission Decision should be submitted on a country-by-country basis as soon as they are ready for the EMEA's check, well in advance of any proposed launch dates in those countries. The EMEA will perform the mock-up check within 30 days.

*Mock-ups must be submitted for the smallest pack-size of each strength and pharmaceutical form, for each container type (e.g. vial) for all relevant Member States, based on the latest version of the product information, together with a commitment that all other pack-sizes will be identical -except for pack-size specific information- and that EMEA comments will also be implemented in the other pack-sizes.

Before launch
Once the medicinal product is authorised and in all cases before the medicinal product is placed on the market, specimens of the final outer and inner packaging and the package leaflet must be submitted for review to the EMEA within a timeframe agreed between the EMEA and the Marketing Authorisation Holder.

The next meeting of the CVMP will be held on 13-15 May 2003

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This press release and other documents are available on the Internet at the following address:
http://www.emea.eu.int

Annex I to CVMP Press Release April 2003

Marketing Authorisations

	1995-2002	2003	Overall Total
Applications submitted	50	1	51
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	12	110
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	1	8
Renewal positive opinions	5	2	7
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	1	0	124
Withdrawals	5	4	9	0	0	0	9
Positive opinions*	36	79	115	0	1	0	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