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

London, 19 March 2004
EMEA/CVMP/317/04

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Meeting of 16 to 18 March 2004

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted a positive opinion by consensus for a type II variation for **SevoFlo** regarding a strengthened warning highlighting the risk of using sevoflurane if the CO_2 absorbent has become desiccated.

The Committee adopted a positive opinion by consensus for a type II variation for **Clomicalm** regarding changes to the quality of the product.

Maximum Residue Limits

The Committee adopted a positive opinion by consensus recommending the extension of provisional MRLs for **fenvalerate** for cattle until 1 July 2006.

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

The Committee agreed on comments on the Commission Reflection Paper on Residues in Foodstuffs of Animal Origin currently under consultation.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Oxyglobin** and **Ibaflin,** and concluded that no action or changes to the product literature of the product(s) were required.

The Committee adopted for release for a 6-month consultation period a major revision of the Guideline on pharmacovigilance of veterinary medicinal products - Guidance on procedures for Marketing Authorisation Holders (EMEA/CVMP/183/96-Rev.1-CONSULTATION).

The Committee adopted a revision of the Guideline on Data Elements for the electronic submission of ADRs to veterinary medicinal products authorised in the European Economic Area (EEA) (EMEA/CVMP/065/03-Rev.1) including message and transmission specifications, implementing requests for changes received from Member States and the Commission. Due to the mostly administrative nature of the changes no consultation period was considered necessary. Furthermore the Committee adopted a Guideline on EudraVigilance Veterinary XML Schema Definition (XSD) and Veterinary Acknowledgement XSD. This document is the technical version of the Guideline on Data Elements for the electronic submission of ADRs to veterinary medicinal products, transposing the guideline contents into XML format. It is mainly addressed to IT personnel in order to facilitate the mapping of existing pharmacovigilance database to the EudraVigilance Veterinary message model. It does not contain new information and therefore no consultation period was considered necessary (EMEA/CVMP/280/04).

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.eu.int http://www.emea.eu.int

Furthermore, the Committee adopted the EMEA public bulletin 2003 on veterinary pharmacovigilance (EMEA/CVMP/359/04). This is the first such bulletin, to be published annually, aiming to improve communication to the interested public.

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

Availability

Further to the end of the consultation period on the proposal for free scientific advice for veterinary medicinal products for minor uses and minor species, the Committee agreed to amend the document in light of comments received. The finalisation of the document and the start of the pilot phase are expected for 15 May 2004.

Quality issues

The Committee adopted a guidance document on the control of impurities of pharmacopoeial substances (EMEA/CVMP/059/04) prepared by the Joint CPMP/CVMP Quality Working Party:

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

Organisational issues

The Committee discussed the preparation of the Informal CVMP meeting to be held in Cork, on 24-25 May 2004, at the initiative of the Irish Authorities under the activities of the Irish Presidency of the European Union. The Committee agreed that the meeting would focus on the procedure for applications for veterinary medicinal products containing genetically modified organisms (GMOs), the organisation of the Committee activities in light of the new EU legislation on Pharmaceuticals, expected to be published in April 2004, and the enlargement of the European Union.

The next meeting of the CVMP will be held on 14-15 April 2004

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

***Revised* PROCEDURAL ANNOUNCEMENT**

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 multi-lingual mock-up ("worst-case") (preferably in colour) 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. Additionally, one English mock-up, if English is not one of the three languages in the trilingual mock-up, should also be submitted.

After adoption of the CVMP opinion (Day 210)
A reduced* mock-up package and package insert is recommended 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. When this recommendation is followed, the EMEA can 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.

PROCEDURAL ANNOUNCEMENT

REQUEST FOR APPLICANTS TO SUBMIT A COMPLETE SET OF ANNEXES FOR ALL FUTURE PROCEDURES

The EMEA is applying a new policy to facilitate the handling of product information submitted in connection with all centralised procedures.

The 'complete set of Annexes' includes Annex, I, II, IIIA and IIIB i.e. all SPC, labelling and Package Insert texts for all strengths and pharmaceutical forms of the product concerned, as well as Annex II (information on the manufacturers involved and the Maximum Residue Level status of all constituents). The complete set of Annexes should be presented sequentially (i.e. Annex I, II, IIIA, IIIB) as one document for each official EU language. Page numbering should start with "1" (bottom, centre) on the title page of Annex I.

Where there are a large number of presentations, the possibility of combining labelling for two or more presentations during the procedure should be discussed with the EMEA. For mock-ups, individual presentations (as they will be marketed) must be presented.

The electronic copy of all languages should be provided in Word format together with the application either on diskette or via Eudralink.

Icelandic and Norwegian language versions must be included when the Marketing Authorisation for the product concerned has been granted after 1 January 2000, or when the Marketing Authorisation has been renewed or voluntarily harmonised in Iceland or Norway.

Applicants are reminded that for variations affecting the product literature, the application must, in addition, be accompanied by the language versions for the new Member States (with the exception of full and extension applications where the English language version is the only version submitted at the start of the procedure and other languages are only submitted once an Opinion has been adopted).

Marketing Authorisations

	1995-2003	2004	Overall Total
Applications submitted	60	5	65
Withdrawals	9	1	10
Positive CVMP opinions	42	1	43
Negative CVMP opinions[1]	0	0	0

Variations

	1995-2003	2004	Overall Total
Variations type I	146	3	149
Variations type II	49	2	51
Transfers	4	1	5

Extensions

	1995-2003	2004	Overall Total
Extensions (Annex II applications) submitted	35	0	35
Withdrawals	1	0	1
Positive opinions	21	0	21
Negative opinions	0	0	0

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

Renewals of marketing authorisations

	1995-2003	2004	Overall Total
Renewal applications submitted	11	0	11
Renewal positive opinions	9	2	11
Renewal negative opinions	0	0	0

Scientific advice

	1995-2003	2004	Overall Total
Applications submitted	22	2	24

Establishment of maximum residue limits

	1995-2003			2004			Overall Total
	Full	**Extension/ Modification**	**Total**	**Full**	**Extension/ Modification**	**Total**	
Applications submitted	52	81	133	2	2	4	137
Withdrawals	5	4	9	0	0	0	9
Positive opinions*	37	86	123	3	1	4	127
Negative opinions**	5	5	10	1	0	1	11

*Including 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

	1995-2003	2004	Overall Total
Referrals	8	1	9