CMDv
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

London, 21st October 2011
EMA/CMDv/815611/2011

European Commission
DG Health and Consumers, Unit D3 'Pharmaceuticals
45, Avenue d'Auderghem, Office 10/130
B-1049 Bruxelles, Belgium

Attn.: **Mrs. Maria Figuerola**

Subject: **PUBLIC CONSULTATION PAPER - REVIEW OF THE VARIATIONS REGULATION (EC) No 1234/2008**

Dear Maria,

On behalf of CMDv, I would like to thank you and the Commission for the work you have undertaken in the review of the Variations Regulation (EC) No 1234/2008. This work is very much appreciated by CMDv. We welcome the inclusive approach the Commission has shown during the development of these proposals and CMDv is grateful for the opportunity to comment.

The following comments reflect the consolidated views of the CMDv members who attended the October meeting held on 13th and 14th October 2011. I should point out that separate views of the National Competent Authorities may also be submitted. I shall address each point as it is raised within the consultation paper.

Please do not hesitate to contact me should you require any further clarification or wish to explore any of the CMDv comments in greater detail.

Yours sincerely,

Esther Werner

Chair CMDv

c.c. Truus Janse-de Hoog (CMDh Chairperson), Martinus Nagtzaam (EC), Sonia Ribeiro EMA), Emily Drury (CMDv secretariat), CMDv members

Annex: CMDv RESPONSE TO THE PUBLIC CONSULTATION PAPER ON THE REVIEW OF THE VARIATIONS REGULATION (EC) No 1234/2008

CMDv Secretariat:
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@ema.europa.eu http://www.ema.europa.eu

Annex: CMDv RESPONSE TO THE PUBLIC CONSULTATION PAPER ON THE REVIEW OF THE VARIATIONS REGULATION (EC) No 1234/2008

CONSULTATION TOPICS:

2.1 Extension to purely national marketing authorisations

CMDv welcomes the extension of Commission Regulation (EC) No. 1234/2008 to include authorisations granted on a purely national basis. Furthermore, CMDv supports the proposal:

i. to change the scope of Article 1 of the current regulation to reflect the inclusion of nationals marketing authorisations;

ii. to extend Article 7 of the current regulation to allow grouping of several applications to purely national marketing authorisations;

iii. to include a new Chapter IV which is based on the chapter for handling European variations but adapted to reflect the requirements for national marketing authorisations.

iv) Work Sharing Procedures – consultation items no. 1 and 2

CMDv discussed that there might potentially be difficulties with worksharing procedures of purely national authorised products where the dossiers are not harmonised in different Member States. These risks, however, could be mitigated or prevented if the change(s) will be the same for each veterinary medicinal product involved in the worksharing procedure and will be supported by the same data set. There should be either no or limited need for a product-specific assessment. The result of these worksharing procedures would be a harmonisation of that particular part of the dossier and subsequent update of the SPC if appropriate.

The CMDv has been successfully operating the so-called 'informal' worksharing procedure for nearly two years, which has included purely national authorisations. This success was confirmed to CMDv by industry in its recent interested parties meeting with IFAH-Europe and EGGVP. Therefore CMDv prefers option b with the added caveat as detailed above and sees no need to introduce additional restrictions for inclusion of purely national marketing authorisations in worksharing procedures.

2.2 Focussing Public resources on the Procedures with Most Impact to Public Health – consultation items no. 3 to 7

Whilst the CMDv appreciates the points raised by the Commission, its members have not experienced the same issues within their respective National Competent Authorities. According to Member States experience the current procedures, timelines and processes as currently set out in Commission Regulation (EC) No. 1234/2008 are suitable and meet the needs for those authorisations issued following MRP or DCP.

CMDv also recognises the point raised regarding the publication of a stable SPC. However, as previously mentioned, CMDv members do not consider this as a difficulty experienced by Member States in relation to MRP/DCP authorisations. Therefore regarding to consultation items 3, 4, 5, 6 and 7 CMDv would prefer no change to the current wording of the regulation.

Should a change be implemented, it should be made clear that this only applies to centrally authorised products which can only be amended following the publication of an official

commission decision. MRP, DCP and hopefully in the near future national variations should continue to follow the existing processes which are working well.

Furthermore, it should be recognised that the economic drivers and market forces on the veterinary sector are different to those experienced by the human sector. The ability for holders of marketing authorisations to amend the SPC of veterinary medicinal products should not be compromised in an environment where financial margins are crucial to the continued marketing of a product or its expansion to other markets.

2.3 Addressing some workability concerns – consultation item no. 8

CMDv has only limited experience in handling and assessing complex grouped variation applications as described within the consultation paper. This is likely to be more of an issue for the human sector given the numbers of human products authorised and applications received. However, CMDv can see the merit in introducing an extended timeline for processing 'complex' groupings. The possibility to extend the timeline for a type II variation is already included in the existing regulation and consideration should be given if the applicability of this possibility could be extended.

2.4 Procedure for the authorisation of human influenza vaccines in a pandemic setting – consultation item no. 9

Finally, for completeness, the CMDv has no comments concerning consultation item 9, since this relates solely to the human sector.

CMDv Secretariat:
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@ema.europa.eu http://www.ema.europa.eu