CMDv RESPONSE TO THE PUBLIC CONSULTATION PAPER ON THE COMMISSION REVIEW OF THE VARIATIONS REGULATION 1234/2008

Dear Maria,

Firstly on behalf of CMDv, please let me thank you and the Commission for the work you have undertaken in the review of the variations regulation. This is very much appreciated. We also 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. 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.

Extension to Purely National Marketing Authorisations

CMDv welcomes the extension of regulation 1234/2008 to include authorisations granted on a purely national basis. Furthermore, CMDv supports the proposal:

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

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

- 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.

Work Sharing Procedures

Regarding consultation item 1, the CMDv agrees that there might potentially be difficulties with work sharing purely national procedures where the dossiers are not harmonised. These risks, however, could be mitigated by clearly stating that work sharing may include national procedures authorised in different Member States provided that the change is the same for each product involved in the procedure and that this is supported by the same data set. The result 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 an informal work sharing procedure for nearly two years, which has included purely national authorisations. This success was confirmed to CMDv by the industry in its recent interested parties meeting with IFAH-Europe and EGGVP. Therefore in response to consultation item 2, the CMDv prefers option b with the added caveat as detailed above.

Focussing Public resources on the Procedures with Most Impact to Public Health

Whilst the CMDv appreciates the points raised by the Commission, its members have not experienced the same issues within their respective National Competent Authorities. In our experience the current procedures, timelines and processes as currently set out in regulation 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 this is not a difficulty experienced by Member States in relation to MRP / DCP authorisations. In response therefore 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. The MRP, DCP and soon to be national variations, should be allowed to continue to follow the existing processes which work 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. Whatever is decided, the ability for holders of 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.

Addressing some Workability Concerns

The CMDv has little experience of receiving large multiple grouped variations 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. That said, however, CMDv can see the merit in introducing an extended timeline for processing ‘complex’ groupings and can support the proposal under consultation point 8.

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

Once again, thank you for the opportunity to comment. 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

CMDv Chair