ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES

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Dear Maria,

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

Firstly on behalf of the Veterinary Medicines Directorate (VMD) 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 the VMD is grateful for the opportunity to comment.

The following comments reflect the views of the VMD who, as you know, is the National Competent Authority in the United Kingdom with responsibility for Veterinary Medicines. I shall address each point as it is raised within the consultation paper.

Extension to Purely National Marketing Authorisations

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

- to change the scope of Article 1 of the current regulation to reflect the inclusion of national marketing authorisations;
- to extend Article 7 of the current regulation to allow grouping of several applications to purely national marketing authorisations; and
- 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 VMD agrees that there might potentially be difficulties with work sharing purely national procedures where the dossiers are not harmonised. These risks, however, would 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 the harmonisation of the corresponding element of the Summary of Product Characteristics (SPC) if appropriate. It should be noted that 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 VMD considers that:

Option a) is unnecessarily restrictive.
Option b) is not appropriate as there is not a common understanding of " part of the dossiers that is not considered not to need harmonisation" and this is also likely to be unnecessarily restrictive

The VMD therefore proposes that work sharing is permitted when the conditions set out above are met i.e. the change is the same for each product involved in the procedure and that this is supported by the same data set.

The UK is of the opinion that there should be no compulsion for companies to use work sharing and that this should remain optional.

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

Whilst the VMD appreciates the points raised by the Commission, we have not experienced the same issues within our Competent Authority. 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. The VMD also recognises the point raised regarding the publication of a stable SPC, however, as previously mentioned this is not a difficulty experienced by the UK in relation to MRP / DCP or authorisations issued on a national only basis. In response therefore to consultation items 3, 4, 5, 6 and 7 the UK would prefer no change to the current wording of the regulation. Furthermore, with particular regard to consultation point 7 it is likely that the proliferation of changes referred to in the consultation paper concerns human medicines rather than being directly related to veterinary medicines.

You seek information as to the types of variation which might be considered to relate directly to public health. On the veterinary side you would also need to factor in animal health and welfare and protection of the environment. Nevertheless, it is the UK view that it is very difficult to be specific and categorise variations in this

way. Multi-factorial considerations would need to be taken into account which would effectively result in a case by case approach.

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 from 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 VMD 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 the numbers of variation applications received. That said, however, the VMD can see the merit in introducing an extended timeline for processing 'complex' groupings and can offer cautious support to the proposal under consultation point 8.

Perhaps there might be scope to define a complex variation and to include this within the classification guideline as one which should be processed within the same timelines as an extension.

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

Once again, we would like to 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 these comments in greater detail.

Yours sincerely,

Gavin Hall

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