Public consultation paper – Review of the Variations Regulation
Review of Commission Regulation (EC) No. 1234/2008

Comments of the Spanish Agency of Medicines and Medical Devices

The Spanish Agency of Medicines and Medical Devices (AEMPS) agree that rules for the variation of purely National authorisations should be the same that those already included in the Commission Regulation (EC) No. 1234/2008 for centralised and MR/DC procedures provided they are maintained under the management of NCAs. However, national administrative procedures might sometimes be different than those proposed in the regulation (for example, in terms of notification procedure) and should be circumventing in order to achieve an identical procedure.

Consultation item no. 1.-

Answer.- Although non harmonised authorisations and dossiers could raise some difficulties, worksharing is already an ongoing procedure in products that are not harmonised in advance. Thus, we consider that it may be applied for purely national products in the same way than already used for MRP/DCP without problems that can not be solved satisfactorily.

Consultation item no. 2.-

Answer.- We consider that, as explained in previous answer, there is no need for any restriction to be included in the new variation regulation for applying the worksharing procedure. Of course, worksharing would be easier when variations refer to a part of the dossiers where harmonisation is considered unneeded or fully harmonised parts of the dossier. However, as already stated, worksharing without harmonisation in advance is already common practice for MRP/DCP without unsolved problems.

Consultation item no. 3.-

Answer.- Yes, we agree in principle but we need a clarification of what is understood as "public health considerations" and do not support longer deadlines than current timelines.

Consultation item no. 4.-

Answer.- Variations affecting the benefit/risk profile of the medicinal product as well as some urgent changes to Module 3 should have a shorter deadline. We consider that implementation of variation by the MAH prior to updating the marketing authorisation would be considered an option in some cases provided there is a need for urgent implementation, there is a decission taken by the competent authority and post-implementation inspection is allowed in order to simplify the procedure.

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Consultation item no. 5.-

Answer.- The proposal is not clear enough to provide a definite opinion. We are in favour of any simplification of the procedure without putting in risk safety issues or negative impact on public health (thus limiting implementation before the decision of competent authorities to those variations without impact in these issues). However, the same rules than for centralised authorised products should be applied to national products.

Consultation item no. 6.-

Answer.- We do not considered necessary new rules in cases where urgent safety restrictions and variations might be implemented as previous regulation (Article 24 (5) of the Commission Regulation (EC) 1234/2008) already considered it. We support the definition of deadlines for implementation of non-urgent variations and believe that we need a rule to oblige the companies to immediate implementation of safety (or benefit/risk) relevant changes keeping the system as simple as possible.

Consultation item no. 7.-

Answer.- This seems to be very specific to centralised authorised products and far from the way NCAs are dealing with these changes in product information of MRP/DCP products. We think that current barriers to an easier handling of product information changes are mostly related with IT systems, translations and lack of harmonisation. Any measure that does not take into consideration these barriers would create a more complex system that is not necessary.

Consultation item no. 8.-

Answer.- Yes, we would be in favour of extending the time limits for complex variations provided (a) there is a clear definition of "complex variation"; (b) the submission time point is agreed with the relevant competent authority before submission; (c) a proposal for time limit for complex variations of 90 days (as for procedures in Annex V) is included; and (d) a detailed description of the proposed changes (p.e. in the application form present/proposed) is provided.

Consultation item no. 9.-

Answer.- Yes, a high degree of flexibility is necessary with regard to the amount of data needed at submission and at authorisation depending upon the time between identification of a pandemic and its impact on the Community. However, as changes to the overall guidance for influenza vaccines are currently under consideration, there is no need to change Art. 21 now.

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