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

Joint Statement of the Federal Institute for Drugs and Medical Devices (BfArM), the Paul-Ehrlich-Institut (PEI) and the Federal Office of Consumer Protection and Food Safety (BVL)

Consultation item no. 1:

Do you agree that where dossiers are not harmonised difficulties could raise for worksharing when accepting the assessment carried out by one member state by other member states?

No, the worksharing procedure is already practised successfully for MRP/DCP products that are not harmonised in advance. It may be extended for purely national products in the same way without any problems to be expected. This procedure is regarded as one of the main advantages of the extension of the Variation Regulation to purely nationally licenced products for the applicants as well as for the NCAs.

Consultation item no. 2:

Which option a) or b) mentioned above do you consider that should be adopted to allow worksharing ?

Neither a) nor b) are supported. There should be no restrictions for the worksharing procedure for purely national products but full allowance as for MRP/DCP without any restrictions. The procedure without harmonisation in advance is already common practice for MRP/DCP products and no problems have occurred

Consultation item no. 3:

Do you agree with the principle that the deadline for adoption of Commission Decisions amending marketing authorisations must be driven by public health considerations?

The problems described are restricted to centrally authorised products. Generally it is agreed that the deadline for adoption of Commission Decisions must be driven by public health considerations but these deadlines may not be longer than the current timelines. A definition for such changes with impact on public health has not been given so far and is probably difficult to determine, e.g. warnings etc.

Consultation item no. 4:

Which category of variations do you consider that should be adopted within shorter deadlines?

All safety-relevant changes, e.g. all changes to classification guideline categores C.I.1-C.I.3 should be adopted within short timelines as these categories of type IB have been introduced in order to make the rapid implementation of safety-relevant changes possible.

Consultation item no. 5:

Do you agree to extent the current system that allows holders to implement certain variations prior to the adoption of the Commission Decision (to the exclusion of those changes with most impact for public health)?

If it is in agreement with the legal framework of the Union to implement changes in centrally authorised products before the adoption of the Commission Decision the extension of the current system would be highly appreciated. Safety-relevant changes should then be implemented after the Opinion.

Consultation item no. 6:

Do you consider appropriate to introduce a deadline for the implementation of changes to product information significant from a public health standpoint?

According to Article 24 (5) of the Commission Regulation (EC) 1234/2008 the implementation dates for safety-relevant changes are already considered:

5. Urgent safety restrictions and variations which are related to safety issues shall be implemented within a time frame agreed by the holder and the relevant authority and, in the case of a centralised marketing authorisation, the Commission.

A new discussion is therefore not regarded necessary.

Consultation item no. 7:

Do you agree with the above analysis?

No, this seems to be a specific administrative problem for centrally authorised products. The NCAs are handling changes in the product information of MRP/DCP in a completely different way then the Commission does for CP.

Consultation item no. 8:

Do you consider appropriate to extend the time limits for assessment of complex grouped applications to enable a larger amount of cases where grouping under one single application could be agreed by the competent authority?

Yes, we would be in favour of extending the time limits for complex variations and to allow them to be submitted as single change applications. However, this would require a strict definition in the legislation and/or the classification guideline, comparable to Annex V of the Regulation. We propose to introduce such changes as single type II complex variations in order to reduce the administrative burden for NCAs and the pharmaceutical industry.

Consultation item no. 9:

Do you think that changes to the procedure in Article 21 of the Variations Regulation are necessary?

Following the "lessons learnt" concerning the pandemic vaccines there are currently several general discussions ongoing to revise the whole concept of Influenza vaccines. A concept paper for the overall revision of the influenza guidelines has been adopted by CHMP in September 2011 for public consultation (http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500115612&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc) to pull together all the available evidence and to re-consider the minimum quality, non-clinical and clinical data requirements to support initial approval of all types of influenza vaccines.
There has been agreed on a worksharing between EMA and the working parties to update the quality aspects, the non-clinical and clinical aspects, pharmacovigilance and risk management as well as the evaluation whether new concepts identified to further facilitate pandemic preparation do fit into the existing legal provisions or will require extensions/modifications.