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

PL comments

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?**

In our opinion the lack of harmonisation of the documentation between products should not cause any difficulties.
Harmonisation of the complete initial dossier or SmPC, PL and labelling is not a prerequisite for a worksharing procedure. In order to benefit from a worksharing procedure, it is expected that the same change(s) will apply to the different medicinal products concerned, with either no or limited need for assessment of a potential product-specific impact.

Consultation item no. 2: **Which option a) or b) mentioned above do you consider that should be adopted to allow worksharing ?**

To be consistent with the response to item 1, we think that there is no need of harmonisation in advance.
The procedure without harmonisation in advance (for several, different medicinal product) 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?**

We agree that the deadline for adoption of Commission Decisions must be driven by public health.

Consultation item no. 4: **Which category of variations do you consider that should be adopted within shorter deadlines?**

All safety variations, e.g. all changes to classification guideline categories C.I.1-C.I.3.

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)?

We agree to extent the current system to allow holders to implement certain variations prior to the adaptation of the Commission Decision. Safety-relevant changes could 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?

We consider that introduction of any new deadline is not necessary.
Article 24 (5) of the Commission Regulation (EC) 1234/2008 specifies a way of setting a deadline for implementation of changes.

Consultation item no. 7:

Do you agree with the above analysis?

We understand this issue, however in case of MRP/DCP procedures this problem is not so visible, from our point of view there is no such a proliferation of small changes in short period of time.

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 agree to extent the time limits for assessment of complex grouped applications.

Consultation item no. 9:

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

The changes to the procedure in Article 21 of the Variation Regulation is considered not necessary because the Variations Regulation provides for a flexible procedure to authorise exceptionally and temporarily variations to the terms of a marketing authorisation for a human

influenza vaccine where certain non-clinical or clinical trials are missing if a pandemic situation has been declared by the World Health Organisation or by the European Parliament and Council.