19th October 2011
Prague, Czech Republic
State Institute for Drug Control
and Ministry of Health

# Contribution to Public consultation by the Czech Republic – Review of the Variations Regulation Review of Commission Regulation (EC) No. 1234/2008

**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?**

Yes, we are of the opinion that difficulties for worksharing could raise when accepting the assessment carried out by one member state by other member states in the course of national procedures. This would be the case especially where relevant inconsistencies exist in the marketing authorisations.
We though believe that worksharing is an excellent tool for lowering administrative burden. Measures other than harmonisation should be sought to overcome the possible difficulties.
In the simpliest possible terms, we think a case-by-case approach should be preferred in order to distinguish where the difficulties foreseen would prevent from effective use of the worksharing tool. At the first stage, it should be up to the MAH to consider appropriateness of submission of a worksharing application with regards to the existing marketing authorisations. On the side of the NCAs, changes requiring separate assessment should not be accepted for worksharing.

**Consultation item no. 2:**

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

As mentioned above, we suppose that prior harmonisation should not stand as a precondition for accepting worksharing procedure. We sense that none of the options reflect this standpoint. Where inconsistencies prevail worksharing should not be encouraged.

**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?**

It is not clear to us whether the proposed principle shall apply solely to centrally authorised products cases or whether its application is meant to cover MRP/DCP and national procedures, as well. It is crucial to determine which of the procedures is the case as the decisions are adopted by different subjects in courses of each of them (EC, NCAs) and it is not the rule for each of the procedure that implementation inevitably has to follow adoption of a decision.
If the subject question covers also other than centralized marketing authorisation we would oppose application of the principle in MRP/DCP procedures. Pursuant to current rules, MAHs are allowed to implement variations before the adoption of decision.
We would furthermore like to stress that while interpreting the term "public health considerations" it is inevitable not to restrict its meaning only to the changes to safety information. Though we are aware it will be difficult, the meaning of the term should be specified in a clear way.

**Consultation item no. 4:**

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

All safety-relevant changes should be adopted within shorter deadlines.

**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)?**

Again, it is not clear to us whether the proposed principle shall apply solely to centrally authorised products cases or whether its application is meant to cover MRP/DCP and national procedures, as well.
We would welcome the possibility to implement changes in centrally authorised products before the adoption of the Commission Decision. We do agree that changes with relevant impact on public health should be left out of the scope of this institute. Such changes should be clearly specified and should include safety-relevant changes.

**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?**

The provision of the Sec. 5 in the Article 24 of the Commission Regulation (EC) 1234/2008 set forth a time frame for safety-relevant changes.
Nevertheless, we are aware of possibility of a failure of reaching an agreement among MAH and NCAs within a time frame necessary for a given case. We are open to discuss possible measures to guarantee that the implementation of safety-relevant changes is done on time (e.g. to set a deadline for reaching an agreement among MAH and NCAs with the right of NCAs to determine the deadline if no agreement is reached within the time set).

**Consultation item no. 7:**

**Do you agree with the above analysis?**

We do experience the practice of frequent changes to SPC and PIL of individual products. Though this practice represents a significant administrative burden to us, we currently do not dispose of any effective tool to moderate the burden and would welcome measures aimed thereat.
We are in favour of the concept of cumulative assessment of changes. Such assessment should take place on a regular basis with a frequency not longer than 6 months. No safety-relevant changes could be included in the cumulative assessment. This category of changes should be treated separately on an ad-hoc basis.

**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?**

In principle, we are in favour of extending the time limits for assessment of complex variations. However, this would require a legislative definition of “complex variations”.

**Consultation item no. 9:**

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

We would welcome changes aimed at simplification of the procedure under the subject Article 21. The changes to be proposed must in no way lower the guarantee of the level of safety, effectiveness and quality.