PUBLIC CONSULTATION PAPER - REVIEW OF THE VARIATIONS REGULATION
REVIEW OF COMMISSION REGULATION (EC) No 1234/2008
Mundipharma Research – Stakeholder Association

Deadline for Comments: 22 October 2011

Consultation item	Consultation Topics	Company Comment
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?	The company does not believe that worksharing difficulties could arise, as long as the aim of the changes is harmonised and no other parts of the dossier are affected.
2.	*a) Not to allow worksharing where the same product has several marketing authorisations in different member states which are not harmonised. A precondition to benefit from worksharing would be the harmonisation of dossiers.* *b) No additional restrictions to include variations to purely national marketing authorisations as long as the worksharing variations refer to a part of the dossiers that is considered not to need harmonisation.* Which option a) or b) mentioned above do you consider that should be adopted to allow worksharing?	Option b should be adopted. It would be considered useful to get clarification of the paragraph ".....as long as the worksharing variations refer to a part of the dossier that is considered not to need harmonisation"
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 company supports this principle.
4.	Which category of variations do you consider that should be adopted within shorter deadlines?	For critical changes a shorter period could be considered appropriate.
5.	Do you agree to extend 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)?	The company agrees with the proposal, however crucial changes should also be included. The product implemented should remain on the market even if the final decision differs, unless a serious risk to public health recommends at different approach.

6.	Do you consider appropriate to introduce a deadline for the implementation of changes to product information significant from a public health standpoint?	In principle the company considers the introduction of a deadline appropriate. However, the deadline has to be related to the severity of the change.
7.	*The current proliferation of variation procedures has led to frequent changes to the summary of products characteristics in some cases. The Commission services aim at ensuring that changes that are required to address a significant public health concern are reflected promptly. However, the proliferation of small changes in a short period of time is considered to be detrimental as it makes more difficult to practitioners to keep up with latest information and, more fundamentally, it makes more difficult to distinguish changes with serious implications for public health from other changes.* Do you agree with the above analysis?	The company is in agreement with the analysis. It would be appreciated if a simultaneous assessment of various not necessarily related/consequential changes of the SmPC results in a single outcome at the same time.
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?	The company does not believe that time limits should be extended. However, this may be welcomed if new grouping opportunities are offered in advance for the assessment.
9.	Do you think that changes to the procedure in Article 21 of the Variations Regulation are necessary?	No comment since specifically related to vaccines