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ACOM 11-016

Les Ulis, le 21octobre 2010

Public consultation on paper on the extension of Regulation (EC) 1234/2008 to the handling of variations to purely national marketing authorisations

Responses from *Laboratoire du Fractionnement et des Biotechnologies* (LFB)

Questions	Responses
Item 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
Item 2 Which option a) or b) mentioned above do you consider that should be adopted to allow worksharing ?	b) MAH will ask for WS when parts of the MAs are harmonised
Item 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?	Yes, in case of public health concern, deadlines should be shorter
Item 4 Which category of variations do you consider that should be adopted within shorter deadlines?	- Variations with an impact on the safety - Administrative variations
Item 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)?	Yes, to be encouraged
Item 6 Do you consider appropriate to introduce a deadline for the implementation of changes to product information significant from a public health standpoint?	Yes
Item 7	Partially, MAH should be encouraged to group

Do you agree with the above analysis?	minor changes whenever possible but Authorities have also to respect deadlines in assessing SPC proposed changes. To date AFSSAPS (France) take more than 2 years to assess a renewal which makes it particularly difficult for the MAH to have an up to date SPC (variations approved in an order different than that of submission) and globally detrimental for practitioners and patients (they do not have access to an up to date SPC) Couldn't we think of a system (exchange zone) that could enable MAH and Authorities to have a permanent access to the current SPC with a quicker assessment for minor changes?
Item 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, if authorities could ensure that the grouping will reduce deadline in comparison with assessment of separate variations and in the case where variations are complex
Item 9 Do you think that changes to the procedure in Article 21 of the Variations Regulation are necessary?	Not concerned