

Public consultation paper
Review of commission regulation 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?

STALLERGENES: *Yes we agree.*

Consultation item no. 2:

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

STALLERGENES: *We prefer the b) option. Indeed harmonisation of dossiers (option a)) may require a lot of additional work and increase the timeline for their approval*

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?

STALLERGENES: *We need a precise definition of “public health considerations” in order to answer the question.*

Consultation item no. 4:

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

STALLERGENES: *Shorter deadlines for all categories of variations would be beneficial.*

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)?

STALLERGENES: *We agree.*

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?

STALLERGENES: *We need a precise definition of “public health standpoint”. If a deadline has to be introduced, it has to be realistic considering the constraints related to the implementation of changes to product information.*

Consultation item no. 7:**Do you agree with the above analysis?**

STALLERGENES: *We agree with the analysis but it is not always possible to make a grouping of changes concerning the summary of products characteristics. Enlarging the possibility for grouping may be a possible way to reach more stable SmPC.*

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?**

STALLERGENES: *We need a precise definition of “complex grouped applications”. This proposal is not interesting in term of delay for the MAH.*

Consultation item no. 9:**Do you think that changes to the procedure in Article 21 of the Variations Regulation are necessary?**

STALLERGENES: *We are not concerned by the item.*