

APREFAR

Consultation 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?

Agree

Consultation item #2:

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

Our opinion is that worksharing can be a real challenge for dossiers not harmonized, from a point of view of the Authorities and Companies. However, we also think that for some issues it is important to have worksharing procedures, therefore we think that the most adequate option is b).

Consultation 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

Consultation item #4:

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

Administrative variations, such as address changes of the MAH or manufacturers; quality variations with low impact on the quality of the product (minor changes).

Consultation 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)?

Administrative variations, such as address changes of the MAH or manufacturers; quality variations with low impact on the quality of the product (minor changes).

Consultation item #6:

Do you consider appropriate to introduce a deadline for the implementation of changes to product information significant from a public health standpoint?

In our perspective it will depend on the definition of implementation, but in our opinion 2 months is a short period of time to coordinate the implementation with the manufacturers.

Consultation item #7:

Do you agree with the above analysis?

The most important here is to define “serious implications for public health”. For example if the definition applies to different sections of the SPC so it should be possible to submit different changes in the some variation (even if they are not related).

Consultation 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?

We think that in these cases it should be analyzed case by case and it should be agreed between the Competent Authority and the Company.