RESPONSE TO THE PUBLIC CONSULTATION PAPER ON THE COMMISSION REVIEW OF THE VARIATIONS REGULATION 1234/2008

FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS - BELGIUM

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.

The FAMHP agrees that there might be difficulties with work sharing for purely national procedures where the dossiers are not harmonised.

Consultation item no. 2:
Which option a) or b) mentioned above do you consider that should be adopted to allow worksharing ?

b)

There are no additional restrictions to include as long as the change is the same for each product involved in the procedure and that this is supported by the same data set.

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?

Yes.

Of course we consider that the deadline must be driven by public health considerations. But in our experience the current timelines as currently set out in regulation 1234/2008 are suitable and meet the needs of public health.

We do not see why this question only refers to the centralized procedure.

Consultation item no. 4:
Which category of variations do you consider that should be adopted within shorter deadlines?

The FAMHP is not aware of categories of variations that need to 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)?

No.

The FAMHP does not see the need to extend the current system.

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?

Yes.

For certain variations (change in withdrawal periods for VMP's, addition of contra-indications,..) it 's appropriate from a public health standpoint to introduce a deadline for the implementation of the changes. A specific article is already foreseen in the Belgian Medicines law to impose a short deadline for implementation in case of public health concerns

We still wants to mention that the national implementation of safety changes following Pharmacovigilance Recommendations or Recommendation following Art45 from paediatric regulation is difficult to reach, due to the fact that those recommendations are not binding.

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

Yes.

The FAMHP agrees with the analysis that the proliferation of small changes in a short period of time is detrimental. Moreover it creates an administrative burden for NAC and industry.

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?

Yes.

The FAMHP can see the merit in introducing an extended timeline for processing ‘complex’ groupings.

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

No.

The FAMHP doesn’t see a need to adapt the article 21.