Consultation item no. 1:
Do you agree that where dossiers are not harmonized difficulties could be raised for worksharing when accepting the assessment carried out by one member state by other member states?

Yes we agree.

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

Option (a) should be adopted prior to allow worksharing.

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.

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

1) B.I.a.3
2) B.I.b.1.h
3) B.II.c.1.f
4) B.II.d.1.g
5) B.II.e.4.b
6) B.II.f.1.d
7) B.V.a.1.c
8) B.V.a.2.b
9) C.I.2.a
10) C.I.3.a
11) C.I.4
12) C.I.6

Consultation item no. 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)?

Not completely. At times it is observed that the MAH implements a minor change to a product assuming that a variation would be filed at a later date, but the variation for the same is never filed. Hence, there should be a system where the Agency has information on which minor changes have been implemented even though the actual variation submission is yet to be submitted by the MAH.

By doing this, the MAH and Agency will have a complete list of all minor variations that have been implemented. The Agency can thus highlight the same to the MAH in case the MAH fails to file the variation.

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. However, the timelines should be optimized taking into consideration,

a) the time required by the MAH to dissolve the existing stocks and

b) extent of risk and urgency for its implementation

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

Yes.

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.

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