

**PUBLIC CONSULTATION PAPER
REVIEW OF THE VARIATIONS REGULATION
REVIEW OF COMMISSION REGULATION (EC) No 1234/2008**

REPLY OF THE REPUBLIC OF HUNGARY

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, we do agree.

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

a) Not to allow worksharing where the same product has several marketing authorisations in different member states which are not harmonised. A precondition to benefit from worksharing would be the harmonisation of dossiers.

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, we do agree.

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

All safety variations.

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)?

Yes, we do agree, with the exclusion of changes with public health concerns.

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.

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

Yes, we do agree.

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, we do support the extension, since it may help process complicated applications.

Do you think that changes to the procedure in Article 21 of the Variations Regulation are necessary?

No, the current procedure is proved to be appropriate in pandemic situation.