18 October 2011

EGGVP's contribution to the Public Consultation Paper (DG SANCO)

REVIEW OF COMMISSION REGULATION (EC) No 1234/2008

Comments from: EGGVP – European Group for Generic Veterinary Products

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. It is also important that the assessment performed by one Member State is accepted by other Member States.

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

Option b)

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?

No.

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

All categories. In any case, deadlines no longer than 60 days should be considered.

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.

EGGVP – European Group for Generic Veterinary Products
Espace Meeûs - De Meeûs Square 38/40 - B-1000 Brussels - T. +32 (0)2 401 87 95 - F. +32 (0)2 401 68 68
info@eggvp.org - www.eggvp.org

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.

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, providing that the length of the extension is fixed in advance, it is proportionate and never longer than 6 months. Additionally, any grouping accepted by a RMS should be automatically accepted by any other CMS.

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

No comments.