Eye-Care Industries
European Economic Interest Grouping
Registered number: GE167
www.eci-eeig.org

General comments from the Eye-Care Industries European Economic Interest Grouping (ECI-EEIG) on the Public Consultation Paper 'Better Regulation of Pharmaceuticals - Towards a Simpler, Clearer and More Flexible Framework on Variations' and the corresponding draft Commission Regulation (versions 24 October 2007).

ICH

The ECI welcomes the inclusion of ICH principles related to the new Q8, Q9 and Q10 guidelines into the legislative framework and looks forward to further references in the detailed guidelines. To ensure a consistent interpretation across the EU, we believe that the provisions for 'design space', outlined in the Consultation Paper, should be included in the final text of the Regulation. However 'design space' should not be considered to be mandatory for all manufacturers, but only for those who choose to apply it.

Scientific recommendation by EMEA

The ECI welcomes the possibility to seek a scientific recommendation on the classification of a variation from the Agency according to Article 5. The timeline to deliver such recommendation should be no more than 30 days to avoid unnecessary delay of the subsequent procedure. There should be no fees charged for this service, as there will be a fee for the variation that will follow the advice.

Validation timelines

The ECI recommends that maximum validation timelines be included in the Regulation to enhance the predictability of the process by ensuring that any procedure will start without delay.

Type IB by default

The ECI supports the principle that unclassified variations by default be categorised as Type IB and the 'safeguard clause' to leave regulators the option for a more extensive assessment for such variations.

There is a need for a provision that a clear justification is given in such cases, that the proposed variation has an impact on the quality, safety or efficacy of the product concerned and that the applicant has the possibility to discuss the decision with the competent authority. This should ensure that only in exceptional circumstances member states would invoke this clause. Moreover, if a switch is triggered based on this mechanism, this should not affect the overall timeline of a Type II variation. Finally, a switch of an unclassified Type IB to Type II should not require the resubmission of documentation.

Line extensions

New strengths, new pharmaceutical forms and/or new routes of administration, requiring an extension procedure, could well be evaluated within a 90 days timeframe, as is the case for a Type II submission. We suggest therefore reducing the timeline in Article 23 for the assessment

of extension applications to allow speedy patient access.

In addition the possibility to submit an application for a 'stand alone' marketing authorisation, as in the current legislation, needs to be maintained. It should be clarified that sponsors have the choice to file an application for a new marketing authorization in circumstances where such changes can also be made by way of variations or extensions.

These new provisions should not result in greater requirements or cost for a particular variation compared to the current requirements.

Work sharing

The ECI fully embraces the concept of a work sharing model facilitated by EMEA or alternatively CMD(h), to be applied to variations that would otherwise require assessment by more than one member state. However, we wish to recommend that the corresponding update of any national marketing authorisation(s) in the second step, as resulting from the binding Agency opinion, should be made through a purely administrative Type IA procedure.

The time taken in the work sharing model should be no longer than that allowed for a national or centralised variation procedure.

Grouping of variations

The ECI welcomes and supports the various options under the new draft proposals for grouping of variations for one or more products. In addition, we would be happy to also have a grouping option for different Marketing Authorisation Holders, where it can be demonstrated that a licensing agreement is in place and/or that the Marketing Authorisation Holders belong to the same company (or family of companies).

Further input

The ECI would be pleased to receive for comment the draft detailed guidance that will result from this initiative and would be please to participate in any future interested parties meetings on this and related topics.

B R Matthews
Secretary
Eye-Care Industries European Economic Interest Grouping