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

Input from APIC:

General comment:

APIC, the Active Pharmaceutical Ingredient Committee, represents producers of APIs (Active Pharmaceutical Ingredients) and API intermediates in Europe. APIC contributed to the revised EU Variations Regulations and is generally in favour of supporting harmonisation in the regulatory affairs fields. The variation regulation applies to marketing authorisations granted and is therefore also indirectly related to dedicated API submissions. Because of this APIC would like to comment above all on procedural aspects rather than in detail. However, part of the APIC member companies are also involved in marketing authorisation procedures, being next to an Active Pharmaceutical Ingredient Producer also a Final Medicinal Product Producer. Therefore please find our comments below.

One additional comment:
We assume that extension of the applicability of Variation Regulation 1234/2008 will also imply that in National Procedures exactly the same time lines will be mandatory.

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 agree that difficulties may arise.
However, we would like to note that the applicant must inform the Coordination group about an upcoming work sharing procedure three months in advance of the planned submission. A Letter of Intent template is available in which pre submission information is requested, e.g. justification for work sharing procedure. The template could be extended with details about not harmonised dossier sections, if applicable. This process could be used by the Coordination Group to assess if difficulties are expected in case of a work sharing procedure including one or more national marketing authorisations.

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

Option b is the best approach, in our opinion.

Harmonisation of a dossier is a joint effort of marketing authorisation holder and competent authority. Depending on the workload of the competent authority, national variations (which are required in a harmonisation procedure) have normally less priority than MRP variations, with as consequence long lead times. In addition, it's not guaranteed that a complete harmonised dossier will be the end result.

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 agree.

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

We support the general principle of shortening deadlines whenever possible but would rather not point at all specific variations.
In particular we would welcome a two months deadline for all Type 1B 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 agree.

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. A deadline for implementation of safety information, requested by the Pharmacovigilance Working Group is already applicable. Therefore, we think this is appropriate. However, it should be clarified who will assess that the change is significant from a public health standpoint.

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

Yes, we 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, for such specific cases we would agree, but we would propose that the competent authority will inform the applicant in advance about the time required for the assessment of complex grouped variation applications. This could be done by providing an amended timetable.

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

We have no comments (the subject area is outside the scope of our members' activities)