Response: DG SANCO - Public consultation on variations

Consultation item no. 1:
Do you agree that where dossiers are not harmonised difficulties could raise for Work-sharing when accepting the assessment carried out by one member state by other member states?

Yes, we agree that where dossiers are not harmonised that there could be difficulties. Different NCAs will take a different approach depending on the issues that are of important concern to them. Some NCAs are quite strict on additional requirements needed for specific markets so the NCAs would need to agree in full with each other with respect to work-sharing.

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

We think option (b) is appropriate as each company can use their own discretion on when to apply for work-sharing and it is very clear that this can only be achieved if the section of the dossiers are harmonised. Option (a) would involve a lot of additional resources to harmonise dossiers. This harmonisation can be performed now by companies on a piece-meal basis as issues arise thus giving greater flexibility.

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, issues that concern public health must take priority.

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

Administrative changes such as name changes, updated revisions of CEPs, tightening of specs, reduction in storage/re-test period for API or reduction in shelf life for finished product, essentially all Type IA variations could be filed annually as part of the annual report as currently performed in the US. Perhaps, a template could be provided based on that used by the FDA for annual reports. This would decrease the work load for both the applicant & the assessor. The current application form does not have a category for filing annual submissions, perhaps if the form was updated to include "Annual submissions" as an application type in addition to the Type IA, IB & II categories it would make it easier for applicants to file annual reports.

(It should also be noted that the current situation regarding the lack of use of the annual reporting of Type1A variations is due to the fact that the annual reporting is not an option for national licenses.)

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, where there is no risk to quality, safety & efficacy of the product and it is appropriately justified.

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, in general, issues impacting on public health the change need to be addressed ASAP, so a deadline for implementation of changes would seem appropriate.

However, for example, the implementation of changes to withdrawal periods of products resulting from harmonisation across member states, should be phased in. In such a scenario, although the decision has an effect on public health, products have already been safely marketed under differing withdrawal periods, in some cases for many years, before a harmonised withdrawal period has been determined.

It would seem appropriate that imposed deadlines for implementation need to take into account differing scenarios and the impact of products already in the market place.

Consultation item no. 7:

ii) More stable "Summary of Product Characteristics".
The current proliferation of variation procedures has led to frequent changes to the summary of products characteristics in some cases. The Commission services aim at ensuring that changes that are required to address a significant public health concern are reflected promptly. However, the proliferation of small changes in a short period of time is considered to be detrimental as it makes more difficult to practitioners to keep up with latest information and, more fundamentally, it makes more difficult to distinguish changes with serious implications for public health from other changes.

Do you agree with the above analysis?

Yes, significant changes which may impact on public/animal health or the environment should be made promptly. Perhaps small changes could be filed annually as part of the annual report. Again a template would be of great benefit as there would be no grey areas or doubt over what changes can be filed annually. This would be of great benefit to the authorities as it reduces their work load and all these changes would be captured under one annual revision of the SPC. Then any significant changes impacting on public/animal health & the environment can be addressed as and when they arise.

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, as grouping ultimately saves time for both applicant (only one form) and CA extension of the time line for assessment of complex grouped applications could be agreed, however an extension of timelines should be realistic so that it doesn't discourage industry/ applicants from using this grouping category.

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

Not applicable to our company.