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?

Agreed.

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

Both options a) and b) could be adopted so that:

1. where worksharing variations refer to a part of the dossiers that is considered not to need harmonisation, variations can be submitted without undue delay
2. where the same product has several marketing authorisations in different member states which are not harmonised, then the dossiers should be harmonised prior to variation submission

Above all, a pragmatic approach must be adopted which will allow some room for manoeuvre for those occasions where situations arise whereby they do not fall into category 1 or 2 above.

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?

Agreed

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

Any variation which involves changes to the medical sections of the SPC should be adopted with a shorter deadline. The same consideration should also be applied for changes to the pharmaceutical sections of the SPC particularly in those instances where there is an impact on e.g storage conditions, shelf-life or changes to instructions for use of the product.

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)?

Agreed.

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?

Absolutely. This is perhaps the most crucial point under consideration. All important changes to the must be conveyed to the end users, both prescribers and patients in a timely manner. It seems somewhat pointless to approve changes via variations if the product information then remains unchanged for many months thereafter.

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

It is a requirement for MA holders to maintain the currency of their Marketing Authorisations . On this basis, it is not unreasonable that the SPC for a product might change many times if this is indeed required and as such, this cannot be considered to be detrimental. It is in fact a clear sign that MA holders are fulfilling their obligations. What might be detrimental is if an MA holder failed in their obligation to maintain the currency of the SPCs for their products.
Neither practitioners nor patients are informed individually about all SPC changes on an ongoing basis and as such, there is no cause for confusion.. MA holders normally inform the requisite audience about crucial SPC changes through the appropriate communication channels when there is the need to do so.

What might benefit from being reviewed is whether all of the individual steps leading to the approval of variations and their adoption by the commission (including the internal steps carried out by the commission) includes any redundant steps which might be removed to facilitate the timely approval of variations and their adoption by the commission so that the product information can be updated in a timely manner and conveyed to the end users.

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?

Agreed in principal, as it might benefit both MA holders and regulatory authorities by reducing the overall number of variations submitted. However, further deliberation of the issue is required in order to establish how the process would work in practice. If it results in substantially increased timelines and delays in variations getting assessed and approved, then it might not be worth progressing this idea.

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

No comment