Sanofi-Aventis GmbH Österreich

Comments to the Consultation items raised in the Consultation Paper to include purely national Marketing Authorizations under the provisions of 1234/2008/EC:

Ad Consultation item No. 1:
Do you agree that were dossiers are not harmonized difficulties could raise for worksharing when accepting the assessment carried out by one member state by other member states?

Comment: Yes; based on the regionally different medicinal approaches to certain disease catagories and also based on the often divergent historical decisions of national authorties concerning the section 4 of the SmPCs, difficulties will most probably arise during work-sharing if a prior text harmonization has not been achieved (i.e. current CSP-Updates seem to be no proper approach as still purely national aspects have to be kept in the texts). This may lead to the fact that well known pharmaceutical products may suddenly lose indications (with the threat of having no local alternatives) or have to implement additional contra-indications (sometimes without satisfying scientific rationale), resulting in regular off-label prescriptions. This often has an impact on the affected medicinal community and also on the reimbursement status of a product.

Also Modules 3 would easily be affected as the practical experience shows that national decisions even for recently registered products differ from each other. Consequently, Modules 3 of purely national products still may have significant differences which contradict a target oriented worksharing. As long as no common approach has been defined and achieved on this topic any such worksharing may easily lead to time/resource consuming discussions and probably even to withdrawals.

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

Comment: Based on the above statement option a) is still the more target oriented solution to variations of purely national marketing authorisations.

Ad 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?

Comment: Under the strict provision that the term "significant public health implications" is clearly and precisely defined, I agree to the proposal. If such a binding definition cannot be achieved at EMA-level any amendment to sections 4.1 - 4.9 could be defined as "significant" which would give raise to overestimate the importance of some amendments and consequently lead to unrealistic requirements for implementation time lines requirering continuous repackaging of products.

Ad Consultation item No. 4:
Whch category of variations do you consider that should be adopted within shorter deadlines?

Comment: Only amendments with proven life-threatening potential (additional contraindications, additional warnings and precautions, additional interactions, additional side effects) should be adopted with shorter timelines.

Ad Consultation item No. 5:
Do you agree to extent the curent system that allows holders to implement certain variations prior to the adoption of the Commission Decision?

Comment: Yes.

Ad 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?

Comment: No. This responsibility should remain with the marketing authorisation holder, who is fully responsible for the concerned product, including product liability. The marketing authorisation holder can best track the implementation timelines in cooperation with manufacturing, packaging and product release. Nevertheless, to reach a product specific agreement between the MAH and EMA beforehand is fully supported.

Ad Consultation item No. 7:
Do you agrre with the above analysis (more stable SmPC)?

Comment: Yes. Nevertheless, the experience with the provision of annual submissions of certain variations has alraedy shown that the tracking of minor variations is very complex and requires signifiicant resources. It is therefore not well accepted by the industry. If the same system should be adopted with the aim to achieve more stable SmPCs, I do expect that this would not work better. Both options (e.g. annual submissions of minor changes vs. immediate submissions should be allowed). In addition, local authorities must be encouraged to publish updated SmPCs quickly on their websites. This would allow interested parties to have a single and reliable source of data providing the latest product information.

Ad Consultation item No. 8:
Do you consider appropriate to extend the time limits for assessment of complex grouped applications to enale a larger amount of cases where grouping under one single application could be agreed by the competent authority?

Comment: Yes.

Ad Consultation item No. 9: no personal experience.