Apotex Europe B.V. input dd. 20 October 2011 to EC Public consultation paper 'Review of Commission regulation (EC) No.1234/2008'

Apotex Europe B.V., Darwinweg 20, 2333 CR Leiden, The Netherlands

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?

Apotex response:
Yes, for the situations where there is a potential for product-specific impact due to different medicinal products.

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

Apotex response:
Option b) as long as the worksharing variations refer to a part of the dossiers that doesn't need harmonization.

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?

Apotex response:
Yes, a faster response should be envisioned where there is a potential for a significant impact on public health.

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

Apotex response:
Safety updates to the Product Information in order to comply with a preset text could be assessed and approved faster.
Validation issues (always administrative) should not be blocking the start of a procedure.

Consultation item no. 5:
Do you agree to extend 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)?

Apotex response:
Yes, as proposed, based on the favourable opinion from the relevant committee of EMA.

Apotex Europe B.V. input dd. 20 October 2011 to EC Public consultation paper 'Review of Commission regulation (EC) No.1234/2008'

Apotex Europe B.V., Darwinweg 20, 2333 CR Leiden, The Netherlands

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?

Apotex response:
Yes, based on

- the favourable opinion from the relevant committee of EMA even prior to a Commission Decision and
- the internal assessment that the variation needs urgent implementation.

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

Apotex response:
Yes, since multiple changes in a short time span could make it difficult to distinguish the critical SmPC' updates.

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?

Apotex response:
Yes, if it will simplify the grouping procedure, increase the grouping options and acceptability and lead to an overall lower review timelines.
In this regard we would like to indicate our wish it should still be possible to submit larger updates to DMF or updates of the complete module 3 as type II changes without having to submit all the type IA/type IB variations that the complete update consists of.

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

Apotex response:
No comments since we are not manufacturing these types of medicinal products.