Better Regulation – Belgian Comments

The AFMPS welcomes the Commission initiative which aims to simplify the Variations Regulation. We also would like to thank the Commission for giving us the opportunity to comment on the proposal.
As a general comment, we would like to stress that the revision should not increase the administrative workload at the level of NCA's.

Article 2: Scope

The AFMPS fully agrees with the application of this new regulation to purely nationally authorized medicinal products.

Article 3: Definitions

Together with other colleagues, we are of the opinion that the word "negative" should be deleted in the definition of minor variation type IA and major variation of type II.

Article 4: Classification of variation

In our opinion, it is essential that the list of variations published in the guideline will be as complete as possible. Incompleteness clearly includes the risk that a major change which should be a type II variation shall be treated as a type IB variation. Therefore we recommend that any variation not defined in the guideline would be subject to a regulatory advice given by the member state(s) (or EMEA) and that the guideline would be updated accordingly.

We cannot endorse the new definition of an extension of a marketing authorization. In Belgium, for this kind of submission, a new marketing authorization is granted at the end of the procedure. As a consequence, it is considered to be a new marketing authorization procedure.

We fully support the concept of design space which gives undoubtedly more flexibility for the MAH to make changes without variation application.

Article 7: Grouping

We can accept the grouping of variations within the following well defined scope:

- One variation for different medicinal products
- Different variations for one medicinal product
- Different variations for different medicinal products under the condition that all variations are relevant for all the products included.

It will be extremely difficult for us to handle a group-submission of different variations for different medicinal products if all the products are not affected by the variations.
We would also propose that the whole application is refused as soon as one variation of the group applied for is refused.
Nevertheless we still have one pending question on how this grouping should be handled within an e-CTD submission and the life cycle management.

Article 8 and 12: Do and tell procedure for type IA variations

The annual report should not contain any variation that is essential information for the marketing authorization. All changes to the information mentioned on the Marketing Authorization Document should follow a type IA $_{IN}$ variation.

Article 24: Worksharing

Worksharing is a very good concept but can involve practical problems when the content of the initial dossier is not harmonized over the member states concerned by the variation (eg purely national medicinal products with differences in module 3).

Regarding the final outcome of the worksharing exercise and its national implementation, we would be more in favour of a national procedure without any reference to the variations as defined in the regulation.