We appreciate very much the Better Regulation initiative and simplification of the process of variations. We support DG Enterprise and Industry of the European Commission in a continuation of the task in hand.

After the revision of the draft Commission Regulation concerning the examination of amendments to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products we have some comments below.

General remarks for the draft document

We would like to revise grouping principle. We agree that variation can be applied for some authorised products, however documentation has to be prepared for every product separately because every paper goes to appropriate dossier. We also do not do duplication as that can be easier done by company.

In case when a variation which is classified in this guideline but which does not fulfil all the necessary conditions laid down in the relevant subcategory, company and competent authority should discuss on type of variation. Then company could present application for variation.

In many cases revision of fee distribution has to follow, especially in case of work sharing and groups of products. According to our legislation it is obligatory to take fee for variation. It seems that in case of work sharing company will pay fee for the institution which assessed the variation. So, it should be stated in the regulation, when fee can not be required.

Remarks for the concrete text parts

3. Article, Definition 4. Probably it would be better to use type IC variation instead of variation IA_{IN}. Variation IC could be assigned to the variation requiring immediate notification. Moreover it is simpler to write.

Names of articles in Chapter III should be corrected with addition at the end of name with “/DCP”.

Text about extensions in the second subparagraph of 1.(c) in Annex I. “Extensions of marketing authorisations” (page 23) is similar to the text in page 47 explanation New.4. Extensions can not be categorised as variations of type I or II, however variation described in the page 47 is of type II.

Deletion of conditions for classification 9 (page 29) makes confusion. Does it mean that conditions will be not applied? If yes, please leave the appropriate text.

There are too many conditions for classification 13.b (page 31), for 20.a (page 34), for 38.a (page 42) as condition 5 is withdrawn.

We would like to suggest to withdraw two lines in page 35 for classification 21.b: 1. and 2. as they are the same now. Then it is necessary to write conditions for 21.b: “Conditions: 1, 2, 3”.