MINISTRY
OF HEALTH

Slotsholmsgade 10-12
DK-1216 Copenhagen K

P +45 7226 9000
F +45 7226 9001
M sum@sum.dk
W sum.dk

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European Commission
DG Health and Consumers, Unit D 3 "Pharmaceuticals"
45 Avenue d'Auderghem
B-1049 Brussels-Belgium

E-mail: maria-angeles.FIGUEROLA-SANTOS@ec.europa.eu

Contribution to public consultation paper

Comments on review of Commission Regulation (EC) No 1234/2008 – review of the variations regulation

The Danish Ministry of Health has the following comments to the consultation items:

General comments
The current regulation and guidance for applying variations in type IA, IA(IN), IB and II are complex and an adminstrative burden for both industry and authorities although the general downgrading of variations and the "Do and Tell" concept of type IA are regarded as beneficial for the industry.

We welcome the inclusion of purely national procedures in the regulation. However, we have some concerns about the increasing administrative burden, which will not decrease by the inclusion of purely national procedures. The regulation as it is, results in difficulties in interpretation and classification of changes and this leads to a large number of invalid applications and high amount of administrative work. Therefore, we have some proposals for improvements of the regulation.

The previously accepted concept of an umbrella type II variation should be allowed to be used more frequently. It has recently been accepted for major updates of ASMFs, an area where the current regulation resulted in major problems in validation of these grouped variations. The problems include classifying the changes consistently in order to ensure uniform case assessment and also the same amount of variations in the groupings. Other major changes should be allowed to be applied for in the same manner in stead of being applied for and validated as grouped variations containing many variations. It is a waste of valuable time for both authorities and industry. A way to define umbrella type II variations could be to reintroduce the concept of consequenses in the regulation; all changes that are consequenses of a type II variation are included in the same type II variation.

Another way to reduce the number of procedures could be by deciding that certain minor changes should not be applied for but only handled internally by

the company. Assessment should only be upon request by the authority. An example could be some of the type IA variations. These changes should be independent from other variations which have to be applied for. However, this proposal would have to be considered further and cannot be introduced during this consultation.

An increased use of annual reports would reduce the number of procedures. However, it seems to be a logistic challenge for the companies to keep track of when it is time for applying for an annual report. Therefore, it is more convient for companies with few variations to apply for the changes immediately. For the authorities the annual reports will not necessarily reduce the administrative burden as all reports have to somehow be handled logistically.

It should be mentioned that applying the same time limits for pure national variations as for MRP will be a challenge and an extra burden for the authorities and will make the current rules even more difficult to follow.

As for time limits, if any at all, it is important to stress, that these should not differ from the ones used for the products all ready covered by the regulation. Also, it is important to stress that the introduction of such time limits for purely national products would implicate a significant reduction in time limits which are in place at the moment. This reduction in the time available for the processing of variation applications would again implicate a major increase in resources needed to keep the time limits and a reorganization of the administrative structures in place. It should further be noted that the number of variations for purely national products by far exceeds the number of variations for centralized and MRP/DCP products (80% vs. 20%). Hence, there is a need for a substantial transition period which should be no shorter than 12 months.

Consultation item nr. 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.

Answer
We agree.

Consultation item nr. 2. Which option a) og b) mentiones above do you consider that should be adopted to allow worksharing?

Answer
Option b – can be considered when more experience has been gained with worksharing – including worksharing with pure national MA.

Comments
Bearing in mind that there were only 32 finalized variation work sharing procedures under Mutual Recognition by September 2011, it is difficult to reach a solid conclusion at this point of time. However, there are some indications that it is mainly the applicants that benefit from using this procedure.

It is proposed only to use worksharing for dossiers that are harmonised (option a). The nationally authorised products are more diverse than MRP/DCP products. Although some worksharing procedures have been finalized for marketing authorisations issued in the EU procedures, it is foreseen that many

more worksharing procedures will be initiated when a purely national MA can be included and the consequence will be a substantiel increase in more complex variation procedures. From the perspective of the authorities it will be even more difficult to be in control of the purely national MA granted in each member state.

Consultation item nr. 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?

Answer
We agree.

Consultation item nr. 4. Which category of variations do you consider that should be adopted within shorter deadlines?

Answer
Minor variations and crucial changes for reasons and importance of public health.

Consultation item nr. 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)?

Answer
We agree. On certain conditions – e.g. conditional upon a favourable opinion from the relevant committee of the European medicines Agency.

Consultation item nr. 6. Do you consider appropriate to introduce a deadline for the implementation of changes to product information significant from a public health standpoint?

Answer
Yes we do.

Consultation item nr. 7. Do you agree with the above analysis?

Answer
We agree that it is required with more stable "Summary of Product Characteristics".

Consultation item nr. 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?

Answer
We agree.

Comments
It is agreed that a b-grouped variation including only type IA and IB variations may be too complex to follow a type IB procedure. We therefore agree with the statement.

This is also an example where the concept of the an umbrella type II variation could be beneficial to use.

Consultation item nr. 9. Do you think that changes to the procedure in Article 21 of the Variations Regulation are necessary?

Answer
The attitude of the Ministry in this matter wait for the current analysis of the European Medicines Agency.

Yours sincerely,

Dorthe Eberhardt Søndergaard
Chief of section

C.C:
Danish Medicines Agency