Document **Comments on European Commission Consultation on Review of Commission Regulation (EC) No 1234/2008**

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1. Introduction

Today, homeopathic medicinal products are marketed in the member states of the EU based on national authorisation procedures. They might be based on simplified registrations according to art. 14 of DIR 2001/83/EC or marketing authorisation based on article 16.2 of the Directive. Or the marketing is based on a national registration according to art. 13th of the Directive.

Due to the strongly individualised character of the therapeutic approaches homeopathy and anthroposophic medicine need a large range of starting materials (in the range of thousands) and of specific medicinal products. This large number of products during the product life cycle means a large number of variations regarding production, quality control of starting material as well as of the finished products. Many of these products have a very low turnover. To handle this amount of variations it is extremely important to install a suitable pragmatic system for the industry as well as for the authorities.
This was already acknowledged in the considerations of Commission Regulation (EC) No 1234/2008 (consideration 2): …."For reasons of proportionality, homeopathic and traditional herbal medicinal products which have not been granted a marketing authorisation but are subject to a simplified registration procedures should remain excluded from the scope of the Regulation."
Therefore at the moment there is no European harmonised variation system for homeopathic and traditional herbal medicinal products even not for the homeopathic medicinal products holding a marketing authorisation according to art. 16.2.
The lack of an adequate variation system for art. 16.2. products should lead to specific amendments in the variation guideline.

2. Answers on the consultation questions

Consultation item1:
Yes, we agree with this statement.

Consultation item 2:
Option number b should be adopted

Consultation items 3-6 not relevant for our products.

Consultation item 7:
We agree with this analysis.

Consultation item 8:
We consider it appropriate to extent the time limits for these cases.

Consultation item 9:
N.A.

3. Further comment regarding consultation item 2 - worksharing

We appreciate the possibility offered by the regulation about grouping of variations. We therefore strongly support this item and are considering appropriate to extend time limits for assessment of complex grouped applications. Indeed, this would be a very pragmatic and practical approach for homeopathic products. However we think that the existing possibilities for grouping of variations have to be amended and adapted to the particularities of homeopathic medicinal products.
In this context we want to raise attention to the fact that due to the large number of homeopathic medicinal products a single modification may refer to more than 1000 dossiers per applicant in one Member State (MS). Even variations with comparatively low risk for public health (e. g. the methods for testing pesticides) could be cited in up to more than 500 dossiers (amount of different homeopathic stocks) of one applicant in one MS. Hence leading to high costs in fees and also huge work amount for the applicant and the national authority.