



Internationale Vereinigung Anthroposophischer Ärztgesellschaften
International Federation of Anthroposophic Medical Associations
Fédération Internationale des Associations Médicales Anthroposophiques

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Heads of Medicines Agencies Homeopathic Medicinal Products Working Group

Re: IVAA Position on the draft HMPWG document "Points to Consider on Stability Testing of Homeopathic Medicinal Products"

Dear Madam, dear Sir,

The IVAA (International Federation of Anthroposophic Medical Associations) represents national anthroposophic medical associations in 18 EU member states as well as Norway and Switzerland, and in a further 11 countries worldwide.

The IVAA has taken notice of the draft document *"Points to Consider on Stability Testing of Homeopathic Medicinal Products"* and is very pleased, that the HMPWG is dedicated to high-quality standards for homeopathic medicinal products, which is valid also for anthroposophic medicinal products manufactured according to homeopathic procedures.

However, IVAA has serious concerns as to section 3.1 of the document (*homeopathic stock*), especially the following two phrases:

- Indent a, 2nd paragraph

"According to Annex I of Directive 2001/83/EC stability data from the homeopathic stock are generally transferable to dilutions / trituration obtained thereof. The expiry date of the dilutions / triturations obtained thereof may not exceed that of the homeopathic stock. The absence of an assay should be justified."

- Indent b, 1st paragraph

"If the homeopathic stock respectively the first preparation is tested for compliance with the monograph immediately before further processing to the finished product no stability tests on the homeopathic stock are required."

Up to now the availability of stored intermediate potencies made it possible for manufacturers to deliver a broad range of homeopathic medicinal products and anthroposophic medicinal products that are produced according to homeopathic procedures at a rather short notice and in a relatively easy way, even if they are less frequently prescribed. This possibility for the storage

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of even less frequently prescribed homeopathic and anthroposophic medicinal products is essential in anthroposophic medicine, as this medical approach aims to highly individualized treatment schemes according to the individual situation of the patient and his or her disorder. Therefore, if the possibility of storing these pre-potencies would be abandoned, the production of this category of anthroposophic medicinal products would entail prohibitive costs and manpower, which means that they are very likely to become unavailable. This would be a serious threat to the quality the treatment that anthroposophic doctors want to provide to their patients.

For this reason the IVAA would like to suggest deeply, that the HMPWG makes the decision on the matter of "Stability testing of homeopathic medicinal products" in close consultation with the manufacturers of anthroposophic medicinal products to find out the most pragmatic solutions at the highest appropriate level of safety, which allows the appropriate and adequate storage of intermediate potencies. The approach should guarantee that the patients will get the most suitable set of medical treatments for their disorders also in the future.

Yours faithfully,

On behalf of the IVAA Council,



Dr Peter Zimmermann

President