

NECESSARY AMENDMENTS ON THE HOMEOPATHY PARAGRAPHS REVIEW OF DIRECTIVE 2001/83/EC

Art. 14.1/Indent 3

The phrasing of the Commission proposal remains ambiguous. The **article lacks any scientific basis** making the contents arbitrary. It discriminates without justification within the category of single homeopathic medicinal products. After eleven years this Article has never contributed to the free movement of goods and works contra productive to the objectives of the Directive 2001/83.

The 1:10.000 rule

Proposed Wording:

"... there is sufficient degree of dilution to guarantee the safety of the medicinal product. In particular, with regard to active principles whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription, the medicinal product shall not contain more than one part per 10.000 of the homeopathic stock or more than 1/100th of the smallest dose customarily used in allopathy."

Art. 14.1/Indent 1

The **scope** of simplified registration should be **widened** to all pharmaceutical forms mentioned in a pharmacopoeia, including injections. The limitation to oral and external use discriminates without having any scientific basis. It limits free movement of goods within the EU. Hence, it conflicts with the objective of the Directive 2001/83.

All pharmaceutical forms under simplified rule

Proposed Wording (see proposal of the European Parliament, Amendment 45 - first reading, 22nd October 2002):

"- they are administered by a route of administration described in the European Pharmacopoeia or in absence thereof in a Pharmacopoeia currently used in a Member State,"

Art. 68 and 69

Reference to anthroposophic nature should be made possible as regards the bibliography and on the labelling. Present legislation deprives hundreds of thousands of people of the medicine of their choice. This would be made possible by just **allowing appropriate references** to be made.

Reference to anthroposophic nature

Proposed wording:

insert after homeopathic resp. homeopathic medicinal product the words "or anthroposophic" resp. "or anthroposophic medicinal product"

Art. 69.1/Indent 11

The disclaimer "without approved therapeutic indications" on a package of a homeopathic medicinal product is **confusing and discriminating**. The simplified registration does not allow a therapeutic indication. The proposal is based on emotional arguments rather than logic and science.

Disclaimer on the packaging

Proposed wording:

"homeopathic medicinal product registered without indications"

Art. 16

The marketing authorisation of homeopathic medicinal products must be made possible with specific rules in **all Member States**, aiming at a later framework of mutual recognition.

Marketing authorisations for homeopathic medicinal products

Proposed Wording (see proposal of the European Parliament, Amendment 179 - first reading, 22nd October 2002):

"- Member States shall introduce or retain in their territory specific rules for the proof of quality, safety and efficacy of homeopathic medicinal products other than those referred to in Article 14(1), taking into account the provisions of paragraph 1 and in accordance with the criteria laid down for homeopathic medicinal products in Annex 1.

Member States shall notify the Commission of the specific rules in force."