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Stuttgart, 02.10.2013

No Braille format for registered homeopathic medicinal products

Dear Mr. Mol,

I come back to the question whether it is legally possible for Member States to require that the name of the medicinal product shall also be expressed in braille format on the packaging of homeopathic medicinal products which are registered according to Art. 14 (1) Directive 2001/83/EC.

From the notice to applicants (Rev. 4) Vol. 2A ("procedures for marketing authorisation", chapter 1 marketing authorisation) from June 2013 we learn that the European Commission opines that:

> "... there is no waiver from the braille requirements laid down by Art. 56a of the Directive with regard to homeopathic medicinal products registered through the simplified procedure, these requirements apply also to homeopathic medicinal products. However, this requirement has to be read in conjunction with Art. 69 (1) of Directive 2001/83/EC, which provides that the labelling and, where appropriate, the package leaflet for the homeopathic medicinal products registered through the simplified procedure, must bear only the information provided by that Article. Accordingly, the scientific name of the stock or stocks followed by the degree of dilution should be put in braille format on the packaging of the product. If the scientific names of the stocks on the labelling are supplemented by an invented name, this should also be put in braille format."
>
> cf. Point 3.3, Notice to Applicants Vol. 2A.

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Contrary to this opinion, we come to the result that no expression of the name of a registered homeopathic medicinal product in braille format on the packaging is requested. This is based on the following:

1. Art. 69 (1) of Directive 2001/83/EC governs which information the labelling and (if used) the package insert of a registered homeopathic medicinal product shall bear. Pursuant to the 1st indent the labelling shall bear the scientific name of the stock or stocks followed by the degree of dilution making use of the symbols of the pharmacopeia used in accordance with Art. 1 (5) of this Directive; if the homeopathic medicinal product is composed of two or more stocks, the scientific names of the stocks on the labelling may be supplemented by an invented name.

   Art. 56a of Directive 2001/83/EC provides that the name of the medicinal product, as referred to in Art. 54 point (a) must also be expressed in Braille format on the packaging. The marketing authorisation holder shall ensure that the package information leaflet is made available on request from patients' organisations in formats appropriate for the blind and partially-sighted.

   Art. 56a is not relevant for registered homeopathic medicinal products because this Article refers to Art. 54 point (a) of Directive 2001/83/EC only and not to Art. 69 (1) 1st indent of this Directive. The reference to the indication of the name of a registered medicinal product as given in Art. 54 and also Art. 56a of Directive 2001/83/EC is not a suitable legal basis for requirements that exceed the information pertaining to the name of such product as comprehensively stipulated in Art. 69 (1), 1st indent of this Directive. Furthermore, from Art. 68 of this Directive it follows that only for homeopathic medicinal products which are marketed on the basis of a marketing authorisation according to Art. 16 (1) or Art. 16 (2) Directive 2001/83/EC Art. 54 point (a), and Art. 56a are applicable.

   Consequently, the Homeopathic Medicinal Products Working Group realised in its 15th meeting held in Copenhagen on 5th and 6th of June 2012, that Art. 54 of Directive 2001/83/EC is not adapted to the name of the homeopathic medicinal product which is registered according to Art. 14.

2. From the exceptions as contained in Art. 69 (2), Art. 60 and Art. 57 of Directive 2001/83/EC one can take that the requirements of Title V of this Directive pertaining to the labelling and package leaflet of medicinal products provide for a complete harmonisation in that field, since this Title lists expressly the cases in which Member States are authorised to adopt provisions departing from the rules laid down by that Directive,

cf. with regard to Titles VIII and VIIIa, ECJ, judgement of 8th November 2007, C-374/05, marg. no. 20.

Therefore, there is no legal basis for the requirement of braille for the name of the registered medicinal product to be indicated on the packaging in braille format The Notice to Applicants (Rev.4) Vol.2A should be revised accordingly.

Kind regards,

Dr. Arnd Pannenbecker
Rechtsanwalt