Purpose

This position paper addresses the Notice to Applicants, Volume 2A - procedures for marketing authorisation, Chapter 1, Rev. 4 from June 2013. In concrete it refers to the obligation to provide the name of the medicinal product in Braille format on the packaging of simplified registered homeopathic products as explained in section "3.3 Procedure for homeopathic medicinal products" which here is introduced for the first time.

The paper intents to demonstrate, that this new requirement is in contradiction to the Directive. In addition it will point to the enormous burden this revision presents to availability of registered homeopathic medicinal products in the EU because of their special situation.

As a result, we are going to ask for correction of the relevant part of section 3.3.

Legal context

Article 56a of Directive 2001/83/EC (Directive 2004/27/EC) requires the name of the medicinal product as referred to in Article 54(a) to be expressed in Braille format on the packaging. The deadline for implementation into national law of the Member States was October 30, 2005.

For products labeled according to Article 54(a) exceptions from this obligation are given by the Guideline on the Readability of the Labeling and Package Leaflet of Medicinal Products for Human Use, Chapter 2, Specific recommendations for blind and partially-sighted patients. It interprets the requirements for Braille with a certain waiver: "There is no need to put the name in Braille on the packaging of products which are only intended for administration by health care professionals, for example it is not required to put the name in Braille for vaccines." (Rev. 1, dated 12 January 2009).

In the Notice to Applicants, Volume 2A - procedures for marketing authorization, Chapter 1 Rev. 4 from June 2013, the European Commission defines for the first time "as there is no waiver from the Braille requirements laid down by Article 56a of the Directive with regard to homeopathic medicinal products registered through the simplified procedure," that "these requirements apply also to homeopathic medicinal products."

We consider this interpretation in contradiction to the Directive as Article 56a exclusively refers to products labeled according to Article 54a. And Article 56a does *precisely not* refer to products labeled according to Article 69, section 1, first indent which defines and limits the labeling of homeopathic medicinal products referred to in Art 14(1). This view is substantiated by a legal statement which we attach to this paper (see Annex).

Special characteristics of homeopathic medicinal products

Homeopathic medicinal products have a long-standing, traditional, safe and effective use in Europe. Today a great variety of homeopathic medicinal products according to Article 14 without special indications are available in series of potencies and diverse dosage forms. For the therapeutic approach of homeopathy the following characteristics are typical:

1. Small presentation units are offered without package leaflet or card box.
2. The homeopathic names (scientific names) may be long and difficult to abbreviate in an understandable way, for example Antimonium sulfuratum aurantiacum, Arnica montana e planta tota, Calcium carbonicum Hahnemanni etc. And the scientific name still is to be followed by the degree of dilution.
3. A huge number of finished products with low to very low sales per product are produced by one manufacturer. We refer to the figure of one of our member companies offering 400.000 finished products where 350.000 products are sold with each less than 50 packages a year.

Thus, the technical realisation of labelling the name in Braille would lead to specific problems:

1. Medicinal products sold in small packages

   The space on the label/box is limited and not sufficient for Braille. The names are difficult to clearly abbreviate.

2. Homeopathic medicinal products produced in huge numbers but very small batches:

   The labelling of presentations composed of primary packaging, package leaflet and outer packaging is technically realised by the fact that pre-folded universal boxes carrying pre-printed common labelling elements independent of the specific medicinal product are used. The medicinal product specific information is labelled in-line during the production process via adhesive labels.

   The name in Braille (which is individual information) could be realised in two ways: (a) There is no possibility to press pre-folded boxes. So the manufacturers would have to change to ordering individually pre-printed boxes (before punching and folding the box), this never would be economoic for the small remedies.
   (b) By adding the information to the adhesive labels. However, there is no technology for in-line-impressing in appropriate quality. The quality of labels produced by manual punching tools is sufficient for private use, but does not at all grant pharmaceutical demands on quality of labelling medicinal products (easily legible, indelible).

Overview on actual situation in the Member States:

The EU Member States considered several practical limitations when they introduced the requirement to indicate the name of the medicinal products on the label in Braille. Various countries exempt or specifically address those products to which patients have no direct access, such as clinical packages, and packages of small formats (up to 10-20 g/ml), and homeopathic medicinal products according to Article 14.

Country	Exemptions and alternative solutions
Austria	Braille is not foreseen for homeopathic medicinal products registered acc. to Article14.
Finland	Small size homeopathic medicinal products up to 10 ml and Article 14 products are exempted from Braille obligations.
France	Packages for hospitals; medicinal gases; small size homeopathic medicinal products, homeopathic medicinal products registered according to Article 14. Long names on small packages ≤ 10 g or 10 ml: abbreviations are possible; additional Braille label or oversize format via web can be provided.
Germany	Presentations ≤ 20 g or 20 ml; batches ≤ 7.000 units/year; homeopathic medicinal products according to Art.14; packages administered through healthcare professionals. In some cases Braille abbreviations are allowed.
Italy	Packages for hospitals and products used by specialists only. There is no exemption for homeopathic medicinal products but it is allowed to provide an Braille version on individual demand of the consumer within 24 hours. This label is produced in an isolated way and added to the product after release.
Netherlands	Packages for hospitals and homeopathic medicinal products according to Article 14. Small formats ≤ 10 g or 10 ml: abbreviations allowed; additional Braille label to be provided in web of national association for blind people.
Portugal	Medicinal products for hospital use or to be used by a health professional only. Small-size packages of homeopathic medicinal products. Braille is not foreseen for homeopathic medicinal products registered according to Article 14.
Spain	Medicinal products which patients cannot access directly. Currently homeopathic medicinal products are notified and marketed without Braille. Within a mutual recognition procedure Spain regarded Braille as mandatory for Article 14 products.
Sweden	Braille is not foreseen for homeopathic medicinal products registered according to Article14.
UK	Packages for hospitals and homeopathic medicinal products according to Article 14; for presentations ≤ 10 g or 10 ml additional label, abbreviations are allowed. Special provisions for eye drops. Health Agency UK & national organization for blind people provide oversized Braille via web.

In summary, up to date Austria, Finland, France, Germany, Netherlands, Portugal, Sweden, UK explicitly exempt homeopathic medicinal products according to Article 14 from Braille obligation. Italy offers a specific solution and Spain allows marketing of notified homeopathic medicinal products without Braille as well.

Conclusion

A medicinal product name given in Braille format on the outer packaging doubtlessly is an advantage for those blind patients who are able to use this reading and writing system. However, due to the handling of other technology there is even a decreasing use of Braille by blind people.

The obligation to indicate the name in Braille format on the label would be exceedingly difficult for simplified registered homeopathic medicinal products. Due to existing labeling practices (universal pre-folded card boxes with product specific adhesive labels) and the huge number of individual finished products (several hundreds homeopathic stocks in several potencies in several dosage forms) with often very low sales it would mean an enormous organizational and financial burden whenever it would be introduced.

Under such an economic pressure, availability and therapeutic variety of homeopathic medicinal products will be at severe risk.

Therefore, to ensure that prescribers and patients can be supplied furthermore with a broad range of different homeopathic products, the specific regulation situation of simplified registered homeopathic medicinal products according to the Articles 14 and 69 of the Directive have to be taken into consideration and correctly implemented.

We therefore ask to correct the Notice to Applicants, Volume 2A - procedures for marketing authorisation, Chapter 1, according to the provisions given in the Directive and to withdraw the Braille obligation for homoeopathic medicinal products registered through the simplified procedure according to Article 14 in section 3.3.

Annex

- Legal statement