

Ladies and Gentlemen

We are pleased to send our electronic comment with special reference to the regulations in all European Union (EU) countries.

Omeoimprese is the Association of the Italian Homeopathic Companies. We are the reference institute of AIFA (the Italian drugs agency) on matters concerning the regulation of homeopathic medicinal products (HMP) and we also represent our associates in any issue of general interest involving our companies.

We appreciate the opportunity to provide comments about the present status of homeopathy in the United States. Given the international market for homeopathic medicines, the decisions we make affect homeopathic companies in our nations as well as the rest of the world.

We would like to offer our contribution of knowledge and experience based on our extensive history with the European laws and regulations related to homeopathy.

As you may know, homeopathic medicines are governed in all European Union (EU) countries by the European Directive 2001/83 that concerns pharmaceutical products, and specifically includes homeopathic medicinal products (HMP).

Certain EU Directive regulations differ from the USA rules and we believe it may be beneficial for the FDA and FTC to consider adopting some of the approaches taken by the EU.

In Europe, HMP are authorized only by approval of the respective national agencies after evaluation of a registration dossier or “CTD”.

There are two manners for registration: a “simplified” registration procedure and a registration procedure very similar to the conventional medicine registration procedure. Both the procedures (simplified and normal) require the evaluation of that nation’s relevant agency for the release of the Marketing Authorisation.

The simplified procedure is somewhat similar to the FDA procedure for registration of homeopathic medicines, but with a few important differences.

The EU simplified procedure requirements are:

(1) *External or oral use;*

(2) *No therapeutic indications;*

(3) Sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product may not contain either more than one part per 10 000 of the mother

tincture and / or

(4) More than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription.

SAFETY

Safety is mainly ensured by degree of dilution and the absence of the claims so that patients are driven towards the advice of a health professional

Essentially, these HMPs are not “over the counter”, but rather are delivered under license per practitioner advice and their efficacy is only under medical practitioner’s evaluation of the individual patient.

EFFICACY

Only HMPs registered pursuant to the normal procedure may claim indications based on proof of efficacy with similar standard parameters as those of the conventional medicine.

As you know, in the United States, HMPs can be marketed without FDA approval under the enforcement policies set forth CPG 400.400. In this case, the responsibility for appropriate manufacturing, marketing and labelling is delegated to the homeopathic companies themselves, all of which must follow the guidelines of CPG 400.400.

HOMEOPATHIC QUALITY

In the United States, any substance may be considered a homeopathic medicine if it has known "homeopathic provings" and/or known effects which mimic the symptoms, syndromes or conditions which it is administered to treat, and is manufactured according to the specifications of the Homeopathic Pharmacopoeia of the United States (HPUS). Official homeopathic drugs are those that have been monographed and accepted for inclusion in the HPUS.

These requirements are quite strict as they are based on the inclusion of the manufacturing process and monographs only in the HPUS. The EU definition of Homeopathic medicine is similar, but significantly, it takes into consideration as homeopathic products other official pharmacopoeias, relevant literature and a well-established use (beyond a single official pharmacopoeia).

In particular, in EU countries, the relevant Pharmacopoeias are Eu. Ph, HAB, French PH. In the United States, however, the only official pharmacopoeia is the HPUS, which is produced by a non-governmental organization.

Observations and Recommendations:

1. In the United States, the lack of official limits to guarantee the safety of the products may be a danger for the consumers. For example, a manufacturer might use a non-tested or unconventional concentration of a starting material. In this respect we have noted the high number of reported poison exposure in 2012 by the American Association of Poison Control Center. In Europe the number of reported side effects for this category of products are much inferior, probably due to the compulsory minimal dilution requested, as above mentioned.
2. The exclusive reliance on HPUS monographs regarding the starting material to be considered as homeopathic is a limitation for the industry and the consumer, as it tends to exclude a certain number of homeopathic medicines. Further, conflicts of interest could arise due to the fact that members of HPUS are also officials of homeopathic manufacturers. That is, the single source material for approval of homeopathics is governed by certain competitors in the homeopathic market.
3. We suggest considering a more simplified authorization procedure with similar criteria as the European Directive. This would enable the FDA to accept the homeopathic medicaments already in the market on the condition they are safe (degree of dilution and the absence of the claims).
4. We also suggest defining a procedure for the evaluation of new homeopathic products, taking into consideration the new and expanding developments of the homeopathic remedies in the last years. In fact, in the last decades many new proving and studies in the field of homeopathy have allowed the production of innovative homeopathic remedies coming from new sources. Many of these new sources included in new HMPs are not listed in the HPUS and we believe that this is inhibiting the therapeutic freedom and opportunities of the American citizens.

We again appreciate the opportunity to submit our comments and welcome the chance for further dialogue.

With best regards.

Omeoimprese
The President
Giovanni Gorga

A handwritten signature in black ink, appearing to read 'G. Gorga', is written over a faint, light-colored signature line.

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