

WRITTEN QUESTION P-1417/09
by Alessandro Foglietta (UEN)
to the Commission

Subject: Homeopathic medicines in Italy

The European Union has expressly recognised the importance and usefulness of homeopathic medicines and has regulated their placing on the market by means of a number of directives, the most recent of which is Directive 2004/27/EC¹, which amends the Community code relating to medicinal products for human use (Directive 2001/83/EC²).

Italy officially transposed that directive by means of Decree Law 219/2006, chapter 2 of which lays down special provisions applying to homeopathic medicines, including the option, as required under EU law, to use a simplified procedure to register some homeopathic medicines (for oral administration/external use/without therapeutic indications and with a given degree of dilution).

However, Article 17 of Decree Law 219/2006 required the publication in the Official Gazette, within three months of the decree law's entry into force, of a specimen registration application form drawn up by the AIFA (Italian Medicines Agency). Inexplicably, that form, the contents of which were specified in the transposing act, has, several years later, still to be published. This situation constitutes an inadmissible barrier to implementation of the provisions of Directive 2004/27/EC.

Some nine million Italians use homeopathic medicines, and the failure to publish the above form has, in practice, made it impossible to place new homeopathic medicines on the market, thus seriously damaging the interests of both producers and consumers.

Given the above, and with a view to ensuring that EU citizens are free to choose treatments and producers are able to develop new products, would the Commission state whether:

1. it is aware of the above issue;
2. it intends to take steps to put an end to this situation, which is hampering the establishment of a harmonised internal market and causing serious damage to European producers and consumers?

¹ OJ L 136, 30.4.2004, p. 34.

² OJ L 311, 28.11.2001, p. 67.