

Presidenza del Consiglio dei Ministri



**STATEMENT ON LABELLING HOMEOPATHIC
PRODUCTS AND INFORMATION TRANSPARENCY**

28 April 2017

In accordance with the regulations in force¹ homeopathic preparations in Italy do not bear specific therapeutic indications on the label or any information of any kind related to individual preparations.

The term "homeopathic medicinal product" is, in fact, followed by the phrase "without approved therapeutic indications".

However, the National Committee for Bioethics, does not believe this to be sufficient to ensure the necessary information transparency and rigour that are a prerequisite for the placing on the market of any drug.

The Committee therefore requests that in our country the labelling system for homeopathic preparations be modified in order to reduce potentially confusing effects and ensure the objective of providing correct, complete and truly understandable information.

In view of the need to renew the marketing authorisation² for all homeopathic medicinal products by 30 June 2017 in accordance with the 2015 Stability Law (Law No 190, article 1, paragraph 590 of the Law of 23 December 2014), The Committee hopes that the "scientific denomination of the strain or homeopathic strains" - as defined in paragraph 2, letter b, art. 85 of the Legislative Decree referred to in footnote (1) - is

¹ Legislative Decree no. 219 of 24 April 2006, *Implementation of Directive 2001/83 / EC (and subsequent amending Directives) on a Community Code on Medicinal Products for Human Use and Directive 2003/94 / EC*, G.U. General Series, no. 142 of June 21, 2006, goes to Art. 85, Specific requirements applicable to labelling and package leaflet of homeopathic medicinal products:

1. Without prejudice to the provisions of paragraph 2, homeopathic medicinal products shall be labelled in accordance with this title and marked by the indication of their homeopathic nature in clear and legible characters.

2. The labelling and, where appropriate, the package leaflet of the homeopathic medicinal products referred to in Articles 16 and 20 shall bear the following particulars and the following:

- a. Clear mention of the words 'homeopathic medicinal product', followed by the phrase 'without approved therapeutic indications';
- b. Scientific denomination of the strain or homeopathic strains or, failing this, the scientific designation of the materials or source materials for homeopathic preparations or any other name appearing in a pharmacopoeia accompanied by the name of the homeopathic tradition followed by the degree of dilution expressed with the symbols of the pharmacopoeia used in accordance with article 1, paragraph 1, letter (d); If the homeopathic medicine is composed of two or more homeopathic strains, on the label their scientific denomination may be supplemented by an invented name;
- c. the name and address of the holder of the registration and, if different, of the producer;
- d. the method of administration and, if necessary, the route of administration.
- e. month and year of expiry indicated in words or numbers;
- f. pharmaceutical form;
- g. *contents by weight, by volume or by number of doses* of the product;
- h. special storage precautions, if any;
- i. a special warning, if required by the medicinal product;
- j. production lot number;
- k. registration number;
- l. a warning to the user to consult a doctor if symptoms persist;
- m. the price of the medicinal product;
- n. the wording 'medicinal product not charged to the National Health Service.'

² From the website of the Italian Medicines Agency (AIFA): "AIC - Authorisation to place a drug on the market. It is granted by AIFA after a group of experts have evaluated its safety and efficacy. It is the 'identity card' of the medicinal product since it indicates the essential characteristics that identify it, www.agenziafarmaco.gov.it/glossary/term/1432.

accompanied by the Italian translation and requests that in the labelling and possibly in the leaflet of homeopathic preparations:

- the term "medicinal product" should be replaced by the term "preparation";
- the phrase "Homeopathic medicine without approved therapeutic indications" should be modified and supplemented in this way: "Homeopathic preparation not scientifically proven to be effective and without approved therapeutic indications".

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The text was drawn up by Prof. Cinzia Caporale.

The statement was voted in the plenary session on 28 April 2017 by Profs. Salvatore Amato, Stefano Canestrari, Cinzia Caporale, Carlo Casonato, Bruno Dallapiccola, Antonio Da Re, Lorenzo d'Avack, Mario de Curtis, Riccardo Di Segni, Carlo Flamigni, Paola Frati, Silvio Garattini, Marianna Gensabella, Assunta Morresi, Laura Palazzani, Monica Toraldo di Francia, Grazia Zuffa. Prof.ssa Luisella Battaglia voted against.

The advisory member, Dr. Carlo Petrini (ISS) also voted in favour, while Dr. Maurizio Benato (FNOMCeO) abstained.

Profs.: Carlo Caltagirone, Francesco D'Agostino, Rodolfo Proietti and the advisory members: Prof. Anna Teresa Palamara (CSS) and Prof. Tullio Pozzan (CNR) were absent from the plenary session and subsequently expressed their support for the Statement.