DECISION

No. 4/07.03.2012

on approval of Regulations for handling of proposed “umbrella” trade names and other trade names for medicinal products for human use, as related to food supplements, cosmetic products and medical devices

In accordance with Article 12(5) of Government Decision No. 734/2010 on establishment, organisation and operation of the National Agency for Medicines and Medical Devices, as amended, the Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 1123/18.08.2010, as amended through Order of the Minister of Health No. 1601/28.11.2011, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 07.03.2012, adopts the following

Decision

Article 1. - The Regulations for handling of proposed “umbrella” trade names and other trade names for medicinal products for human use, as related to food supplements, cosmetic products and medical devices are approved according to the annex which is integral part of this decision.

Article 2. - On the date of this decision coming into force, the Regulations for handling of proposed “umbrella” trade names and other trade names for medicinal products for human use, as related to food supplements and cosmetic products shall be repealed.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

ANNEX
(SCD no. 4/07.03.2012)

Regulations for handling of proposed "umbrella" trade names and other trade names for medicinal products for human use, as related to food supplements, cosmetic products and medical devices

Art. 1. – Considering the late issues on the market of medicinal products for human use, in relation to food supplements and cosmetics, related to "umbrella" trade names or even to the same trade names of medicinal products for human use and food supplements/cosmetics, the National Agency for Medicines and Medical Devices hereby issues the following regulations, based on the legal provisions differentiating between medicinal products for human use and products of the aforementioned types:

- Law No. 95/2006, Title XVII – The medicinal product, transposing Directive 2001/83/EC as amended;
- Order of the Minister of Health no. 1069 of 19 June 2007 for approval of Regulations on food supplements;
- Law No. 178/2000 on cosmetic products, as amended;
- Regulation EC no. 1223/2009 on cosmetic products;
- Law No. 176/2000 on medical devices, as amended;
- Order of the Minister of Health no. 1453/2005 on approval of the Guidelines for "umbrella" trade names;
- Scientific Council Decision No. 2/2008 on approval of the Guideline on the trade name of medicinal products for human use;
- Scientific Council Decision No. 14/2010 on approval of National Medicines Agency policy concerning resolution of proposed "umbrella" trade names and other trade names.

Art. 2. – The following shall not be accepted as regards medicinal products for human use:

1) The proposal of an "umbrella" trade name, in case the respective "umbrella" segment can also be found in the trade name of a food supplement, cosmetic product or medical device marketed by the same legal entity.

2) The maintaining of an approved "umbrella" trade name as of its placement on the market, performed by the same legal entity, of a food supplement, cosmetic product or medical device containing the respective "umbrella" segment in its trade name.

In such cases, the Marketing Authorisation Holder is required to submit, within 30 days as of the commencement of the marketing of the food product, cosmetic product or medical device, the applications for variation

to the terms of the marketing authorisations of the respective medicinal products, related to the change of their trade name.
Otherwise, sanctions mentioned under Art. 836 1(i) of Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product, as amended, shall be applied.
3) The proposal of the same trade name as owned by a food supplement, cosmetic product or medical device, placed on the market by the same legal entity.
4) The maintaining of the same approved trade name as of placement on the market, performed by the same legal entity, of a food supplement, cosmetic product or medical device with the same trade name.
In such cases, the Marketing Authorisation Holder is required to submit, within 30 days as of placement on the market of the food supplement, cosmetic product or medical device, an application for variation to the terms of the marketing authorisations of the respective medicinal product, concerning the change of its trade name.
Otherwise, sanctions mentioned under Art. 836 1 (i) of Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product, as amended, shall be applied.