DECISION

No. 14/07.06.2010

on approval of National Medicines Agency policy concerning resolution of proposed "umbrella" trade names and other trade names

The Scientific Council of the National Medicines Agency, set up based on Minister of Public Health Order no. 1027/22.05.2008, as amended, reunited on summons of the National Medicines Agency President in the ordinary meeting of 07.06.2010, in accordance with Article 10 of Government Ordinance no. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved as amended through Law no. 594/2002, as further amended, agrees on the following

DECISION

Single Article – The National Medicines Agency policy concerning resolution of proposed "umbrella" trade names and other trade names is approved, according to the Annex which is an integral part of this decision.

PRESIDENT
of the Scientific Council
of the National Medicines Agency

Acad. Prof. Dr. Victor Voicu

ANNEX

National Medicines Agency policy concerning resolution of proposed "umbrella" trade names and other trade names

Given the numerous applications submitted to the NMA of marketing authorisation holders (MAH) requiring approval of "umbrella" trade name and other trade names, as well as provisions of Scientific Council Decision no. 3/2005 on approval of the Guideline on "umbrella" trade names, approved by Order of the Ministry of Health no. 1453/2005 and Scientific Council Decision no. 2/2008 on approval of the Guidelines on the name of medicinal products for human use, the NMA hereby expresses the following views:

1) the trade name of an authorised medicinal product which has been switched from “non-prescription” to “on-prescription” classification may not be used as an "umbrella" trade name for a “non-prescription” medicinal product.

2) the same trade name may not be preserved following switch from “on prescription” to “non-prescription” classification for release of an authorized medicinal product, where the request for switch to the “non-prescription” status only concerns certain package sizes. In such cases, an application for authorisation with a different invented name will be submitted.

3) proposed "umbrella" trade names for “on-prescription” medicinal products are accepted only in cases where the proposed medicinal product whose name includes an “umbrella” type segment also contains additional active substances besides the same active substance, is intended for the same therapeutic area(s) and has the same classification for release as the already authorised medicinal using the same “umbrella” segment.

4) "umbrella" trade names proposals are accepted for “non-prescription” medicinal products only in cases where the proposed medicinal product whose name includes an "umbrella" segment has the same classification for release as the already authorised medicinal product using the same “umbrella” segment.

As far as MAH choice of trade names is concerned, the NMA recommends the use of certain terms in justified cases only, such as:

- "**Plus**" to be used only when, in addition to the already authorised medicinal product, the proposed product contains one or several active substances giving additional or synergistic therapeutic actions, for which the

applicant also provides clinical trials attesting the superiority of the respective product over the initially authorised formula;

- "**Rapid**" - a term indicating quick onset of action (e.g. action starting in less than 30 minutes after oral administration) may only be used when this assertion is supported by pharmacokinetic and pharmacodynamic data from SPC Product (SmPC) and is relevant for the indication(s) for which the drug is proposed for authorisation/authorised;

- "**Triple Action**" may only be used when the medicinal product has three obviously different therapeutic actions. This relates to either a medicinal product with a single active substance with three different actions, or a product with three active substances with three different action ways. When the application for authorisation refers to a qualified therapeutic action, e.g. "pain relief through triple action", the three different modes of action must be relevant to pain relief.

To the extent necessary, the NMA will initiate change of certain existing legal provisions in force on medicinal product trade names.