MINISTRY OF HEALTH

ORDER
on approval of the Guidebook regarding "umbrella" brands

Taking into account provisions of Government Ordinance No. 152/1999 on medicinal products for human use, approved with changes and completions through Law No. 336/2002, with further changes and completions, and Government Ordinance No. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved with changes and completions through Law No. 594/2002, with further changes and completions,

on seeing The Approval Report of the General Pharmaceutical and Medical Devices Directorate No. E.N. 5.743/2005,

based on Government Decision No. 168/2005 on organisation and functioning of the Ministry of Health, with further changes and completions,

the minister of health hereby issues the following order:

Article 1. - Approval of the Guidebook regarding “umbrella” brands, provided in the annex which is an integral part of the order.

Article 2. - Guidebook regarding “umbrella” brands shall be applied to applications for marketing authorisation submitted to the National Medicines Agency after publication of the present order in the Official Gazette of Romania, Part I.

Article 3. - The National Medicines Agency shall carry out provisions of the present order.

Article 4. - The present order is to be published in the Official Gazette of Romania, Part I.

The minister of health,
Gheorghe Eugen Nicolăescu

Bucharest, 28 December 2005.

No. 1453.
(Published: the Official Gazette of Romania, Part I, No. 26 of 11 January 2006)

ANNEX

GUIDEBOOK
on "umbrella" brands

CHAPTER I
Introduction

Article 1 - (1) An "umbrella" brand is a single trade name for a group of medicinal products.

(2) Medicinal products in "umbrella" brands may be different with regard to their active substances and/or therapeutic indications.

(3) "Umbrella" brands may be set up by either applying for approval of such a trade name for a group of medicinal products from the very beginning or by subsequent application for inclusion of other medicinal products in the same "umbrella" brand.

CHAPTER II
Issues to be considered in proposing "umbrella" brands

Article 2. - In support of applications for approval of "umbrella" brands, applicants have to submit the following information:

a) the reason for the proposal;

b) description of other medicinal products belonging to the respective company or some other company, that are introduced in the same or similar "umbrella" brands (in phonetic or linguistic terms);

c) therapeutic indications ale each relevant medicinal product;

d) comments on any safety risk possible through use of the "umbrella" brand for the new application, in case confusion arises between the medicinal product and other medicinal products in the same or similar "umbrella" brands, based on the safety profile of the active substances;

e) special patient populations, whenever differences are present among medicinal products in the same "umbrella" brand as far as this aspect is concerned (for instance: children, pregnant women, elderly people, patients with renal or hepatic impairment);

f) differences regarding interactions with other medicinal products;

g) differences regarding indications, Contraindications, special warnings and special precautions for use, posology (dosage rate and different concentrations included) as well as other information in the summary of product characteristics/package leaflet;

h) differences regarding overdose effects and monitoring;

i) differences regarding action method and speed of effect among active substances in medicinal products using the same "umbrella" brands in their trade name;

j) use of different suffixes/prefixes and how they differentiate among medicinal products, taking into account their strength, populations, therapeutic area etc.;

k) details on packaging, including:

- packaging (immediate and outer) shape, design and colour;
- place and highlight of information on the active substance and use;
- the medicinal product form(s);
- pack size;
- the capacity to differentiate among medicinal products using the same "umbrella" brands in their trade name.

CHAPTER III
Instances when “umbrella” brands are possible

Article 3. - Instances when “umbrella” brands are possible are as follows:

a) The proposed medicinal product, whose name is to use an “umbrella” type segment, contains additional active substances and is intended for the same therapeutic areas as the existing medicinal product using the same “umbrella” type segment in the trade name;

b) The proposed medicinal product, whose name is to use an “umbrella” type segment, contains the same active substance or additional active substances is intended for different therapeutic areas than the existing medicinal product using the same “umbrella” type segment in the trade name;

c) The proposed medicinal product, whose name is to use an “umbrella” type segment, contains different active substances and is intended for the same therapeutic areas or different therapeutic areas then the existing medicinal product using the same “umbrella” type segment in the trade name.

Article 4. – The case under Article 3 (c) is the most difficult to prove and convincing proof is therefore needed that the use of the “umbrella” type segment will not give rise to safety or efficacy risks.

CHAPTER IV
Final provisions

Article 5. – The main concern of the National Medicines Agency (NMA) regarding trade names of medicinal products is that these should be in keeping with legal provisions, and, by way of consequence, to insure proper and safe administration.

Article 6. - (1) For reasons of avoiding safety risks, it is it is preferable for the NMA that marketing authorisation holders create new trade names for each medicinal product submitted to authorisation procedure without resort to “umbrella” brands.

(2) However, the NMA considers every application for approval of an “umbrella” brand and evaluates respective applications.

Article 7. - The NMA may reject any trade name should it consider, in accord with its own evaluations, that the information it conveys leads to confusion, is misleading or unsafe.

Article 8. - (1) Approval by the NMA of a trade name of a medicinal product defined within an “umbrella” brand does not exempt its marketing authorisation holder from responsibility in case effective or potential safety risks emerge after marketing of the medicinal product.

(2) Under such circumstances, the marketing authorisation holder is requested to inform the NMA, who takes all necessary measures.