DECISION

No. 2/29.02.2008

on approval of the Guideline on the trade name of medicinal products for human use

The Scientific Council of the National Medicines Agency, set up based on Minister of Public Health Order No. 485/09.05.2005, reunited on summons of the National Medicines Agency President in the orderary meeting of 29.02.2008 in accord with Art. 10 of 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, as amended, agrees on the following

DECISION

Art. 1. - Approval of the Guideline on the trade name of medicinal products for human use, according to the Annex which is an integral part of this Decision.

Art. 2. - On the date of the coming into force of this Decision, SCD No. 2/02.06.2005 on approval of the Guideline on the trade name of medicinal products for human use, approved through Minister of Public Health Order No. 1452/28.12.2005, published in the Official Gazette of Romania, Part 1, No. 26/11.01.2006.

Art. 3. - The Guideline on the trade name of medicinal products for human use shall enter into force on the date of its publication in the Official Gazette of Romania, Part I of Minister of Public Health Order No. 1452/28.12.2005.

Art. 4. - The Guideline on the trade name of medicinal products for human use is meant for applications for authorisation/variation submitted to the National Medicines Agency after the date of its coming into force.

PRESIDENT
of the Scientific Council
of the National Medicines Agency

Acad. Prof. Dr. Victor Voicu

ANNEX

GUIDELINE
on the trade name of medicinal products for human use

CHAPTER I
Introduction

Art. 1. - (1) Medicinal products authorised for marketing should have a trade name.

(2) In accordance with Art. 695 (20) of Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product, the name of the medicinal product "may be an invented name which does not lead to confusion with the common name or scientific name, accompanied by the trademark or name of the marketing authorisation holder".

(3) In accordance with Art. 695 (21) of Law No. 95/2006 on healthcare reform, Title XVII - , the common name is the International Non-proprietary name (INN) recommended by the World Health Organisation (WHO), or in case such a name does not exist, it is the common standard name.

(4) In accordance with provisions of Art. 4 of amended Regulation (EC) 40/94, a trade mark may consist of "any signs capable of being represented graphically, particularly words, including personal names, designs, letters, numerals, the shape of goods or of their packaging, provided that such signs are capable of distinguishing the goods or services of one undertaking from those of other undertakings".

Art. 2. - Each application for marketing authorisation of a medicinal product should only refer to a single invented name for the medicinal product in view of authorisation.

Art. 3. - The invented name of the medicinal product is integral part of that medicinal product.

Art. 4. - (1) In case the proposed trademark for the invented name of a medicinal product is canceled, disputed or contested in accordance with the law concerning commercial trademarks, the Marketing Authorisation Holder (MAH) shall take all appropriate measures for the modification of the initially proposed name.

(2) For medicinal products undergoing an authorisation procedure, the MAH shall submit to the National Medicines Agency (NMA) a notice concerning the need for the modification of the initially proposed name in the application for authorisation.

(3) For already authorised medicinal products or products undergoing a renewal procedure for the marketing authorisation, the MAH shall submit an application for variation for the change of the current name, so as the patients are not disadvantaged and the access to the respective medicinal products is allowed.

Art. 5. - (1) The NMA role in the assessment of medicinal products safety within the authorisation procedure, as well as within the variation for change of medicinal products names, includes the obligation to assess whether the proposed invented name for a medicinal product may cause health problems or determine potential safety risks.

(2) This assessment should be undertaken based on the most relevant data and research.

(3) Even in those cases when Romania or other EU Member States register a certain invented name for a product, only safety-related considerations may decide whether the proposed invented name may be used for the respective medicinal product.

(4) The NMA should mainly ensure that a medicinal product does not have an invented name, which may cause confusion with another medicinal product's invented name, given the fact that such confusion may give rise to safety issues concerning the use of such medicinal products.

(5) The issue of a potential violation of the intellectual property right on a certain invented name done to a medicinal product by another product is not taken into consideration during the assessment step of the proposed invented name acceptability.

(6) Moreover, trademark examination is not done by the NMA, the respective procedure belongs to other delegated authorities at both national and European level.

(7) In view of a trademark's registration, the MAH should directly address to the authorities responsible for this activity.

(8) All information forwarded by the MAH relating to the invented names are confidential and all parties involved in the assessment of the invented names within the national procedure must maintain the confidentiality.

CHAPTER II
Criteria applied for evaluation of the proposed invented names acceptability

Art. 6. - (1) During the assessment process of the proposed invented names acceptability, the NMA enforces criteria based on public health aspects, especially safety-related criteria, shown under Art. 9-28 in this Guideline.

Art. 7. Prior to the application for approval of an invented name, the MAH should assess the proposed invented name, by applying the specific criteria shown in the present Guideline.

Art. 8. Where required, during assessment of the invented name acceptability, the MAH shall provide detailed information concerning support of the proposal.

Art. 9. - (1) The invented name of a medicinal product should not be liable to cause confusion in print, handwriting or speech with the invented name of another medicinal product.

(2) When assessing the potential for such confusion, the following aspects are considered systematically:

- the indication(s)
- patient population(s)
- pharmaceutical form(s)
- route(s) of administration
- strength(s)
- the settings for dispensing and use
- the legal status/ classification for supply
- orphan (designation) status
- (potential) new pharmaceutical forms and/or routes of administration for the medicinal product concerned, as appropriate.
- assessment of potential for harm to the patient in case of a mix-up.

Art. 10. - The invented name of a medicinal product should not convey misleading therapeutic and/or pharmaceutical connotations.

Art. 11. - The invented name of a medicinal product should not be misleading with respect to the composition of the product.

Art. 12. - (1) An invented name shall not be liable to confusion with the common name.

Art. 13. – Furthermore, when proposing an invented name, the MAH(s) is/are advised to take into consideration the WHO World Health Assembly resolution (WHA46.19), mentioning that it would be appreciated if invented names were not derived from international non-proprietary names (INNs) and if INN stems were not used in invented names.

Art. 14. - Two types of INN concerns could be considered, namely a potential similarity with an existing INN or the inclusion of an INN stem into the proposed invented name(s).

Art. 15. - Where a similarity between a proposed invented name and an existing INN is identified, the following criteria should be taken into consideration:

- The closeness either in speech or in writing to its own or a different INN;
- The similarity in medicinal setting, general use (indication) of concerned medicinal products;
- The similarity in classification for supply of the concerned medicinal products e.g. restricted to hospital setting;
- The route(s) of administration and, where possible, the concerned pharmaceutical forms.

Art. 16. - Where a proposed invented name includes an identified INN stem, the following criteria should be taken into consideration:

- The similarity in therapeutic class between the 'INN stem' and the medicinal product;
- The location of the 'INN stem' within the proposed invented name is *as per* WHO INN Stem location recommendations;
- The similarity in medical setting, general use (indication) of concerned medicinal products;
- The similarity in classification for supply of the concerned medicinal products e.g. restricted to hospital
- The route(s) of administration and, where possible the concerned pharmaceutical forms.

Art. 17. – The decision taken by the NMA concerning acceptability of the proposed invented name respects provisions of Annex 1 relating to the decision tree.

Art. 18. - (1) The use of qualifiers/abbreviations by letters as part of the invented name should in principle be acceptable. The use of numbers may also in certain cases be acceptable, e.g. vaccines (see also Art. 23).

(2) When assessing the acceptability of a proposed invented name from a risk to public health point of view, the EMEA „invented Name Review Group" (NRG) will take into consideration:

- Whether the qualifier/abbreviation provides further information on characteristics of the medicinal product (e.g. duration of action, devices, route of administration, composition, patient population) or provides for a differentiation, which may help healthcare professionals and/or patients to prescribe/select the appropriate medicinal product.
- The balance between the potential risk to public health in case of medication error potentially related to the qualifier/abbreviation versus the potential risk resulting from more complex names, adversely affecting in its turn their capacity to be remembered, pronounced and/or prescribed.

(3) The NRG recommends MAHs not to propose qualifiers consisting of a single letter or number (Arabic and Roman), because they may be confused with the strength and/or posology of the medicinal product;

Art. 19. - The invented name should not convey any promotional message with respect to the therapeutic and/or pharmaceutical characteristics and/or the composition of the medicinal product.

Art. 20. - (1) The invented name should not appear offensive or have a "bad" connotation.

(2) On a case-by-case basis, the NMA may decide to inform the company about an identified concern without it automatically resulting in rejection of the proposed invented name.

Art. 21. - (1) The invented name of a fixed combination medicinal product should be sufficiently different from those of the individual active substances and/or those of other fixed combinations containing the same active substance(s).

(2) The MAH is recommended not to insert the whole invented name of the individual active substance(s) in the proposed invented name for the fixed combination.

Art. 22. - For a medicinal product containing a prodrug, a different invented name from the invented name of the medicinal product containing the related active substance is required.

Art. 23. - (1) For vaccines composed of several serotypes, the original invented name may be kept when adding a new serotype; the name is then followed by the number of present serotypes and the pharmaceutical form. The description of present serotypes is then listed in the qualitative and quantitative composition.

(2) The same applies when different types of antigens are added. This is of particular importance in situations where both vaccines are simultaneously available on the market in order to allow differentiation of the products.

Art. 24. - For biological medicinal products in the case of manufacturing changes (for example leading to line extension etc.) the same invented name should be maintained, on a case-by-case basis. When the characteristics of the medicinal product are altered (for example such as by the addition of a new adjuvant etc.), then a new invented name may be necessary.

Art. 25. - (1) For non-prescription medicinal products, due account should be given to the specific legal status of these medicinal products.

(2) The use of qualifiers/abbreviations within the invented name should aid selection/identification/differentiation of the medicinal product by the patient and should minimise the risk of inappropriate use; in view of the above considerations, the specific restrictive criteria described under Art. 18 and 21 may not apply here.

(3) In order to help self-selection and compliance by patient/consumers, it is acceptable that invented names have a positive connotation and/or be informative.

Art. 26. - (1) In case of a switch from "prescription" to "non-prescription" status of an already authorised medicinal product it is up to the MAH to choose whether to vary/extend the existing marketing authorisation and consequently retain the same invented name or to submit a separate application for marketing authorisation under a different invented name (see section 3).

(2) In exceptional cases, depending on the therapeutic context, the acceptability of the maintenance of the existing invented name may be further considered by the NMA during the evaluation of the new application.

Art. 27. - For generic/hybrid/similar biological medicinal products the same criteria apply as for any other medicinal products in respect to the invented name.

Art. 28. - Where the MAH wishes to use instead of the invented name the common name, together with a trademark or the name of the Marketing Authorisation Holder, they should take into account the following rules:

- If an INN recommended by the World Health Organisation exists for the active moiety, it should be used within the name of the medicinal product exactly as published without omissions or abbreviations. All the linguistic versions of the INN, including translations officially recognised at the national level, shall be considered to be the same name. If one does not exist, the usual common name should be used.

- If a Modified INN (INNM) recommended by the World Health Organisation exists for the active moiety, it should be used within the name of the medicinal product exactly as published without omissions or abbreviations.

- Where the active moiety is an unpublished INNM the name of the medicinal product should be that as agreed by users of INNs (pharmacopoeia, regulatory bodies, stakeholders), in accordance with the WHO INNM working document 05.167/3.

- The 'name of the MAH' within the name of the medicinal product should correspond to all or part of the official name of the MAH as presented in the proof of establishment of the MAH.

CHAPTER III

Regulatory aspects related to the acceptability of proposed invented names and invented names during the post-authorisation period

Art. 29. - (1) Within the marketing authorisation procedure, the NMA decides upon the acceptability of the proposed invented names made by the MAH, following the assessment of all relevant factors in accordance with the provisions mentioned in this Guideline.

(2) In case the NMA decides that the proposed invented name cannot be accepted, the MAH is informed about this decision.

(3) The MAH shall submit new proposals for invented names which are about to undergo a new assessment.

(4) In case of the possibility of accepting a proposed invented name, the common or scientific name accompanied by the MAH's name shall be used.

Art. 30. - (1) When soliciting a variation/line extension, invented names should be identical with those of existing medicinal products.

(2) In case the MAH wants to submit a separate application for marketing authorisation for e.g. a new indication, a different invented name shall be used.

Art. 31. - (1) The name of a medicinal product may be changed after a marketing authorisation is granted through a Type IB (No.2) variation procedure.

(2) Such application for variation should be submitted in accordance with Minister of Public Health Order No. 874/2006 – on approval of the Norms concerning the NMA administrative procedure for management of variations.

(3) The NMA decides upon the acceptability of the application proposed following the assessment of all relevant factors, in accordance with the provisions mentioned in this Guideline.

(4) Within the term established in accordance with the regulations in force, concerning the variation to the marketing authorisation, the MAH shall be informed about the proposed application.

(5) In case the NMA decides that the proposed (invented) name cannot be accepted, the MAH shall submit a new proposal for an invented name, within the same application for variation, which shall be the object of a new assessment or shall justify the maintenance of the primarily proposed name, while specifically adopting each objection formulated by the NMA.

(6) Rejection of the application, following examination of supplementations, implies the proposal for submission of a new IB/2 variation, aiming to propose a new invented name.

Art. 32. - (1) In case the prescription errors/medication caused by invented names of medicinal products (e.g. mix-up with another medicinal product) result in an adverse drug reaction (ADR), such ADRs should be reported within the pharmacovigilance systems established at the site of the MAHs, i.e. expedited or periodic reporting of adverse drug reactions should be done in accordance with the legislation in force.

(2) Where names convey misleading therapeutic connotations, there may be a risk for misuse or abuse of the product.

(3) Such single updated periodic report concerning safety, a summary report concerning medication errors occurred in the respective medicinal product should be submitted, including those determined by the confusion with another product's name.

(4) When deemed necessary, the NMA shall take regulatory actions in order to change the invented name and/or the transmission of patients and healthcare professionals report.

Art. 33. - The principles of this Guideline also appear in the EMEA Guideline CHMP/328/98 Rev 5 on the acceptability of names for human medicinal products processed through the centralised procedure.

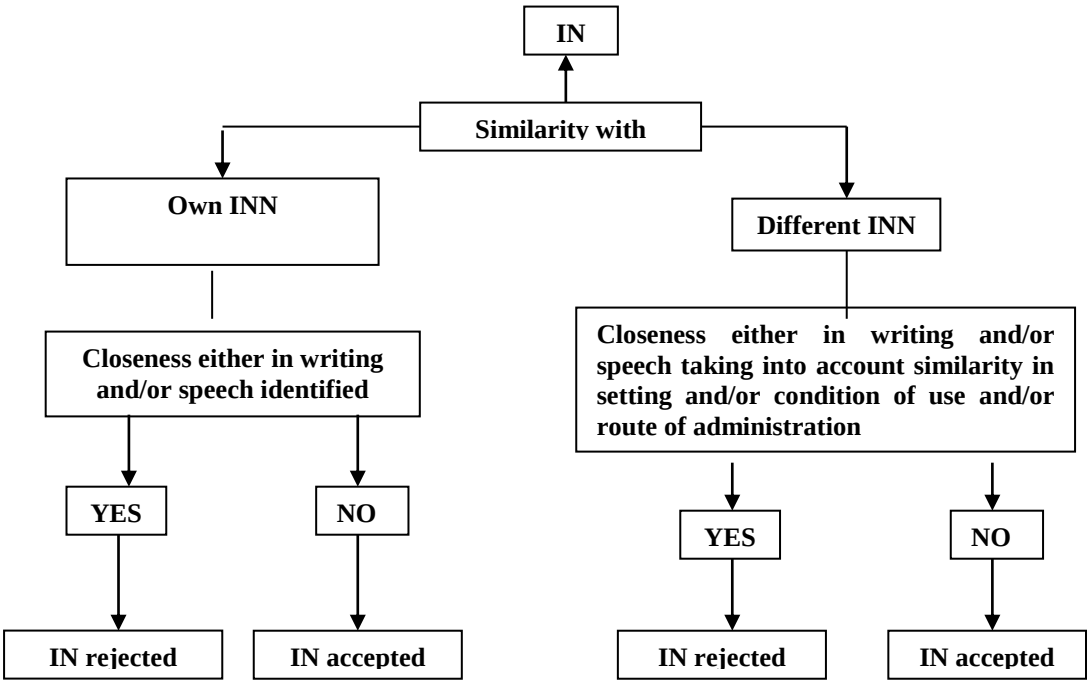
Abbreviations:
CHMP - Committee for Human Medicinal Products
EMEA – European Medicines Agency

ANNEX No. 1

Addressing International Non-proprietary Names (INNs) concerns in proposed invented names (IN)

1) Addressing similarity between an invented name and an INN (of the concerned medicinal product or a different one), the closeness either in writing and/or speech taking into account the medical setting and/or condition of use and/or route of administration of the concerned medicinal products should be considered as follows:

PROPOSED DECISION TREE



2) Addressing the inclusion of an INN stem in an invented name (of the same medicinal product therapeutic class or a different one), the location of the INNs and the medical setting and/or condition of use and/route of administration of the concerned medicinal products should be considered as follows:

PROPOSED DECISION TREE