DECISION

No. 11/07.06.2010

on approval of the Guideline on the expression of strength in the name of centrally authorised medicinal products for human use

The Scientific Council of the National Medicines Agency,
set up based on Order of the Minister of Public Health 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 accord with Article 10 of Government Ordinance No. 125/1998 related to the set up, organisation and operation of the National Medicines Agency, approved as amended through Law No. 594/2002, as further amended, agrees on the following

DECISION

Sole article. – The Guideline on the expression of strength in the name of centrally authorised medicinal products for human use is approved, in accordance with the Annexes which are integral part of this decision.

PRESIDENT
of the Scientific Council
of the National Medicines Agency,

Acad. Prof. Dr. Victor Voicu

ANNEX

GUIDELINE
on the expression of strength in the name of centrally authorised medicinal products for human use

CHAPTER I
Introduction and legal basis

Art. 1. – (1) This Guideline is a translation into Romanian and an adaptation of the "QRD Recommendations on the expression of strength in the name of centrally authorised medicinal products for human use", issued by the Quality Review of Documents Group (QRD) of the European Medicines Agency (EMA);

(2) The Guideline provides recommendations on the concise expression of strength in the marketing authorisation, under the heading "Authorisation name", as well as in the context of its Annexes:

- Annex 1, Leaflet, in the title;
- Annex 2, the Summary of Product Characteristics, under point 1 "Medicinal product trade name";
- Annex 3, information on the labelling, under point 1 "Medicinal product trade name".

Art. 2. – In accordance with Art. 769 (1) (a) of Law No. 95/2006 (hereinafter Law on healthcare reform, as amended, transposing Art. 54 (a) of Directive 2001/83/EC transposing Art. 59 (1) (a), in the leaflet, the name, strength and pharmaceutical form shall be specified in view of identifying the medicinal product.

Art. 3. – In accordance with Art. 708 of the Law, transposing Art. 11 of Directive 2001/83/EC, the name, followed by strength and pharmaceutical form of the medicinal product should be stated under point 1 "Trade name of the medicinal product" of the Summary of Product Characteristics (hereinafter SPC).

Art. 4. – (1) In accordance with Art. 763. (a) of the Law, transposing Art. 54 (a) of Directive 2001/83/EC, information such as the name, followed by the strength and pharmaceutical form of the medicinal product (representing the trade name) should appear on the outer packaging of the medicinal product or on the inner packaging, if there isn't any outer packaging.

(2) The active substance(s) shall be stated right after the trade name.

Art. 5. – In accordance with Art. 17 (1) of the Guideline on Summary of Product Characteristics, strength represents the relevant quantity needed in view of the identification and use of the respective medicinal product and should be compliant with the quantity stated under 2.

Art. 6. – (1) The Purpose of this Guideline is to provide the most relevant information related to the composition of the medicinal product in view of using it appropriately, identifying and distinguishing it more easily from other formulations in view of medical prescription; moreover, other aspects of the therapeutic approach shall also be taken into consideration.

(2) Under points 2 of the SPC, 6 of the leaflet and 2 of the Information related to the labelling, full data is provided, related to the qualitative and quantitative composition of the medicinal product in terms of its active substance(s).

(3) Consequently, the inclusion of certain "redundant" information in the strength, which may be found under other points of the Summary of Product Characteristics, of the leaflet and of labelling information may not be deemed necessary.

CHAPTER II
Scope

Art. 7. – (1) This Guideline is meant for marketing authorisation applications for medicinal products through national procedure, as of September 2010.

(2) In case of medicinal products authorised prior to this date, this Guideline shall be enforced during the renewal of the authorisation.

CHAPTER III
Recommendations on the expression of strength in the name of medicinal products for human use

Art. 8. – (1) The expression of strength shall be done according to the pharmaceutical form and considering whether the medicinal product is single dose/multi-dose.

(2) The expression of strength as a percentage should not be used.

Art. 9. – (1) In case the strength mentioned in the trade name of the medicinal product solely refers to the total amount of the active substance on the packaging, the other points of the Summary of Product Characteristics, leaflet and information related to the labelling must contain an accurate statement concerning the total volume, as well as the strength per unit volume.

(2) Similarly, if the strength mentioned in the medicinal product's name is expressed per unit volume, other points of the Summary of Product Characteristics should clearly specify the total amount of active substance, as well as the total volume of the medicinal product.

Art. 10. – The recommendations on the expression of strength in the name of medicinal products for human use are exposed in Annex 1 which is integral part of this Guideline.

ANNEX 1

Pharmaceutical form	**Formulation/ Inner packaging[1]**	**Preferred strength in the trade name[2]**	**Format**
Oral preparations			
Solid-unit dose preparations (e. g. tablets, capsules)	Single dose	Amount per unit dose	X mg[5]
Solid preparations (e. g granules)	Multi-dose	Amount per unit weight	X mg/g
Semi-solid preparations (e. g. oral paste, gel)	Single dose	Total amount in the container	X mg
Semi-solid preparations (e. g. oral paste, gel)	Multi-dose	Amount per unit weight	X mg/g
Liquid preparations (e. g. ampoules, sachets)	Single dose	Total amount in the container	X mg
Liquid preparations (e. g. oral solutions)	Multi-dose	Amount per unit volume or quantity per unit volume of the measuring device	X mg/ml[6] or X mg/Y ml, if there is an adequate measuring device available
Powders/granules for liquid preparations	Single dose	Total amount in the container	X mg
Powders/granules for liquid preparations	Multi-dose	Total amount per unit volume after reconstitution or amount per unit volume of the measuring device	X mg/ml or X mg/Y ml, if there is an adequate measuring device available
Parenteral preparations			
Liquid preparations	Single dose (in cases of 'total' use[3])	Total amount in the container	X mg
Liquid preparations	Single dose (in cases of 'partial' use[4])	Amount per unit volume	X mg/ml
Liquid preparations	Multi-dose	Amount per unit volume	X mg/ml

Powder for liquid preparations, with or without solvents	Single dose	Total amount in the container	X mg
Powder for liquid preparations, with or without solvents	Multi-dose	Amount per unit volume after reconstitution[7]	X mg/ml
Concentrate	Single dose (in cases of 'total' use)	Total amount in the container	X mg
Concentrate	Single dose (in cases of 'partial' use)	Amount per unit volume before dilution	X mg/ml
Concentrate	Multi-dose	Amount per unit volume before dilution	X mg/ml
Implants			
Implants		Total amount in implant	X mg
Cutaneous, transdermal, rectal, vaginal, oromucosal and gingival preparations			
Solid preparations (e.g. suppositories, tablets, capsules)	Single dose	Amount per unit dose	X mg
Solid preparations (e.g. powder)	Multi-dose	Amount per unit weight	X mg/g
Transdermal preparations for systemic use (e.g. transdermal patch)	Single dose	Nominal amount released per unit time	X micrograms/Y o re
Transdermal preparations for systemic use (e.g. transdermal patch)	Single dose	Total amount in the patch	X mg
Semi-solid preparations (gel, cream, ointment)	Single dose/ Multi-dose	Amount per unit weight	X mg/g
Liquid preparations	Single dose	Total amount in the container	X mg
Liquid preparations	Multi-dose	Amount per unit volume	X mg/ml
Preparations for inhalation			
Preparations for inhalation (e.g. capsules, pressurized emulsion, pressurized solution, pressurized suspension, gas)	Single dose/ Multi-dose	Amount per released dose	X micrograms/dos e or X mg/dose
Nebuliser solution/ suspension/emulsion	Single dose	Total amount in the container	X mg
Nebuliser solution / suspension/emulsion	Multi-dose	Amount per unit	X mg/ml volume

Ophthalmic, auricular and nasal preparations			
Liquid forms	Single dose/ Multi-dose	Amount per unit volume	X mg/ml
Semi-solid preparations (e.g. ointment)	Single dose/ Multi-dose	Amount per unit weight	X mg/g

[1]A single dose packaging contains a quantity of medicinal products meant for 'total' or partial use by a single administration. A multi-dose packaging contains a quantity of medicinal products meant for the administration of two or several doses [the European Pharmacopoeia – the 6th edition, 2009 (6.4)]

[2]The quantity of active substance/entity, if needed. Moreover, the recommendations apply to nay other unit.

[3]'Total' use: the quantity inside the inner packaging is given in total as a single administration.

[4]'Partial' use: when the dose to be administered is calculated in mg/kg or mg/m^2 and any unused portion of the preparation is to be discarded.

[5]Where the total quantity of active substance in the container is included as the 'strength' in the name of the medicinal product, the total volume or total content per total volume and concentration

[6]Where the strength is expressed as active substance per millilitre, total quantity per total volume must also be displayed on the packaging.

[7]Where a unique recommendation exists regarding the volume of the solvent for reconstitution, the strength may alternatively be expressed as total amount per total volume after reconstitution "z mg/y ml".