DECISION

No. 10/27.11.2009
on the approval of the consolidated version of the Romanian Standard Terms refering to formulations, primary packages, closure systems and administration systems, in accordance with the European Standard Terms approved by the European Pharmacopoeia Commission

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 27.11.2009, in accord with Article 10 of Government Ordinance no. 125/1998 related to the setup, 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 consolidated version of the Romanian Standard Terms referring to formulations, primary packages, closure systems and administration systems is approved, in accordance with the European Standard Terms approved by the European Pharmacopoeia Commission, according to the Annex which is integral part of this Decision.

PRESIDENT
of the Scientific Council
of the National Medicines Agency

Acad. Prof. Dr. Victor Voicu

ANNEX

ROMANIAN STANDARD TERMS

for

PHARMACEUTICAL FORMS
ADMINISTRATION SYSTEMS
PRIMARY PACKAGES,
CLOSURE SYSTEMS
ADMINISTRATION DEVICES

in accordance with the **European Standard Terms** approved by the

European Pharmacopoeia Commission,
European Directorate for the Quality of Medicines (EDQM),
European Council, Strasbourg

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EUROPEAN STANDARD TERMS

INTRODUCTION AND GUIDELINE FOR USE

General principles and instructions for the use of these lists

The lists of Standard Terms were drawn up by the European Pharmacopoeia Commission further to the request of the EU Commission for the use in the marketing authorisation application, Summary of product Characteristics (SPC), labelling and electronic communications.
Standard terms have the double purpose of bringing information to the patient/user/prescriber and distinguishing medicinal products having the same trade name. Because of the SPC, leaflet and labelling purposes it is imperative that any Standard Term and combination of Standard Terms is constructed with a view to the patient.
Standard terms should convey essential information on the properties and uses of the particular medicinal products. However, information on the container and the route of administration need not always be included in the Standard Terms but may appear elsewhere in the labelling, package leaflet and SPC.

1. Pharmaceutical forms

1.1. The essential information to be conveyed for all products is the "pharmaceutical form" defined as follows:

The pharmaceutical form is the combination of the form in which a medicinal product is presented by the manufacturer (*form of presentation*) and the form in which it is administered including the physical form (*form of administration*).

1.2. The list of Standard Terms for pharmaceutical forms presents the basic terms needed to characterise the pharmaceutical form. The Standard Terms for pharmaceutical forms may be used for medicinal products intended for human as well as veterinary use.

1.3. The List of Standard Terms for pharmaceutical forms has been set up and revised according to the following principles:

- Terminology is to be used consistently throughout the list;

- Each term should be as short as possible, commensurate with providing the necessary information to inform the patient or the user;

- Each term needs to convey several "elements" of information; the number of elements will vary from one medicinal product type to another.

- Two elements of a pharmaceutical form are linked by "and" e.g. "Powder and solvent" or "Emulsion and suspension for emulsion for injection".

- If the same pharmaceutical form may be used by alternative ways, these ways are mentioned separated by "/", e.g. "Gargle/mouth wash", "Chewable/dispersible tablet".
In both cases ("and", "/"), the terms are placed in alphabetical order (English language). For combinations created before June 2009, this rule may not have been followed. Future uses of these combinations will use the same order (e.g. "Oromucosal/laryngopharyngeal suspension").
Where several routes of administration are intended for the same product, the focus should be placed on the primary use for the creation of a standard term or a combination of standard terms, for example "oral solution" is sufficient as the primary use for a request of "oral /gastric /gastroenteral solution".
- Terms in singular may also be used in plural when the same pharmaceutical form is presented in two or more containers prior to preparation of the finished product, e.g. 'solutions for sealant', 'powders for implantation suspension'.
The creation of unnecessary terms or combinations is discouraged.
1.4. In certain cases, a complete characterisation of the pharmaceutical form requires additional information about the immediate container. This applies in any case to pre-filled syringes, pressurised preparations or single-dose eye preparations; it also applies in cases where the administration of the same physical form differs due to different design of the container/administration device. For example, the term pharmaceutical form "oral suspension" is acceptable as such if only one form is licensed. If it is supplied in a sachet as well as a preparation in a bottle, this represents two pharmaceutical forms: "oral suspension" and "oral suspension in sachet".
1.5. The same principle applies to the construction, when needed, of a product-specific term by combination of a Standard Term for the pharmaceutical form and a Standard Term for the route of administration, e.g. "Powder for intravesical solution".
The common parenteral routes, for "intravenous use" and "intramuscular use" need not be added to a Standard Term unless they are needed to distinguish medicinal products having the same trade name.
1.6. If the physical form in which the medicinal product is supplied by the manufacturer is different from that in which it is to be administered to/used by the patient that is, if transformation of the medicinal product is required before it can be administered/used, both these elements of information need to be conveyed within the term.
In case of a powder that is dissolved in a small amount of solvent before it is diluted in a larger volume to be infused and this dilution is mandatory for safety reasons, the term « concentrate » should appear in the pharmaceutical form (e.g. "Powder for concentrate for solution for infusion").

If the powder that is dissolved in a small amount of solvent can either be administered as such or be further diluted before administration (i.e. no safety issue), the use of the term "concentrate" is not mandatory (e.g. "Powder for solution for infusion").

1.7. If the medicinal product has certain special characteristics that are relevant to its use, these need to be included in the term.

1.8. In some cases, the level of information required for the purpose of the marketing authorisation dossier (and leaflets) may be higher than required for inclusion on the medicinal product label. Therefore, in addition to the Standard Terms given in the Pharmaceutical Dosage forms section, patient-friendly terms (short terms), which may be used for labelling only. These short Standard Terms are not agreed by all Member States.

1.9. Definitions of Standard Terms and requirements applicable to the different categories are given in the general monographs of the latest Edition of the European Pharmacopoeia.

1.10. In some cases, established usage allows one word within a term to convey more than one element of information. For example, the term "Tablet", unless otherwise qualified, denotes a product for oral use, i.e. to be swallowed.

1.11. The term "modified release" is not sufficiently precise for describing a particular medicinal product. More specific terms such as "prolonged release", "delayed release" or "gastroresistant" should be used, wherever applicable.

2. Routes of administration

2.1. The route of administration indicates the part of the body on which, through which or into which the medicinal product is to be introduced.

Where several routes of administration are intended for a product, the focus should be placed on the primary use for the creation of a standard term or a combination of standard terms, for example, "oral use" is sufficient as the primary use for a request of "oral/gastric/gastroenteral use".

The creation of unnecessary terms or combinations is discouraged.

3. Primary packages, closure systems and administration devices

3.1. The pharmaceutical form is supplied in an *immediate packaging* which is the *container* or other form of packaging immediately in contact with the medicinal product. A *closure system* is a means to close an immediate container for the purpose of the correct storage and use of the medicinal product. In some cases a special *administration device* is needed for the correct administration of the product. The administration device may be an integral part of the immediate container or closure.

3.2. Definitions, requirements and recommendations for containers are provided in Part 3.2 of the latest Edition of the European Pharmacopoeia.

4. New Standard Terms

A request for a new Standard Term will only be made to the European Directorate for the Quality of Medicines (EDQM) when the nature of the product is such that

no existing Standard Term or combination of Standard Terms accurately describes it. Such requests will be made in accordance with the procedure described hereafter.

5. Combinations of existing Standard Terms

5.1 In the case of a novel product, the member state or the European Medicines Agency (EMA) may consider that a suitable product-specific term can be constructed by a combination of existing Standard Terms or elements thereof. The member state or the EMA is requested to notify the EDQM of such cases so that the suitability of the proposed combination of terms is confirmed by the EDQM. Where appropriate, the combination will be included in the list of combinations of existing Standard Terms Combined terms.

The list of all standard terms is only available electronically by subscription on the EDQM website (www.edqm.eu).

5.2 Combination of existing Standard Terms, e.g. combination of the pharmaceutical form and the immediate container (c.f. item 1.4) and combination of the pharmaceutical form and the route of administration (c.f. item 1.5) may be necessary for safety reasons or to distinguish marketed products.

5.3 In some cases, a medicinal product may be intended for more than one route and/or method of administration. In these cases, the two (or more) terms may be included, for example "chewable/dispersible tablet".

5.4 In other cases, where no existing Standard Term applies, characterisation of the pharmaceutical form may be obtained by combination of elements of Standard Terms for pharmaceutical forms, or combination of such elements with Standard Terms, or elements thereof, for the route of administration. For example, when the form of presentation (e.g. solution/suspension/emulsion or ointment/cream/gel) differs from that of the existing Standard Term, replace the form in the Standard Term.

PROCEDURE FOR THE ADDITION, DELETION OR MODIFICATION OF TERMS IN THE LIST OF STANDARD TERMS

Before submitting any request for the addition, deletion or modification of a Standard Term, please read the "Introduction" to Standard Terms publication which provides information on the general principles on which Standard Terms are established. Particular attention should be given to the expectation that a request for a new Standard Term will only be made when the nature of the medicinal product is such that no existing Standard Term or combination of Standard Terms accurately describes it.

1. The member state, the European Commission or the EMA send the request form, filled in accordingly, to the EDQM.
2. The EDQM sends immediately (within one week) the proposal to the Working Party on Standard Terms of the European Pharmacopoeia Commission.

3. The Working Party examines the proposal by correspondence or in a meeting, if required, and if necessary designates a rapporteur.

4. Within 6 weeks, if necessary for a new term, unless a meeting is required, the Working Party gives an opinion along with a proposal for a provisional definition.

The European Commission, the member states' competent authorities and the EMA are informed about this opinion and are asked to comment within 1 month. Any disagreement should be justified.

The opinion is submitted to Group of Experts No.12 of the European Pharmacopoeia Commission so that, where necessary, it can make a proposal on the revision of the corresponding monograph or on elaboration of a new monograph.

5. Taking into account any comment received and the advice of the Working Party for Standard Terms, the European Pharmacopoeia adopts (by correspondence) the new Standard Term(s) or the deletion or modification of a Standard Term so that the change can be introduced in the list of the European Standard Terms. It authorises, if necessary, the revision of the corresponding monograph or elaboration of a new monograph.

A new or modified Standard Term is introduced in the updated list of Standard Terms and is then translated into the various languages by the national authorities, each authority translating it into its own language.

6. In case the request for a new Standard Term is made for a marketing authorisation application, the request mentions the date of the receipt of the valid application so that an approved Standard Term is provided within 120 days. The EDQM is duly informed of the result of the assessment of the license application before publishing the new Standard Term.

Part 1: Pharmaceutical forms

Part 2: Routes of administration

Căi de administrare ***Routes of administration***		
Romanian	**English**	**Observations**
Auriculară	*Auricular use*	Administration of a medicinal product inside the ear.
Bucofaringiană	*Oromucosal use*	Administration of a medicinal product in the oral cavity, in view of obtaining a local/systemic effect; oral route included; the term "oromucosal" is only used when specific terms (i.e. gingival, sublingual…) are not applicable; oral route excluded.
Cutanată	*Cutaneous use*	Administration of a medicinal product on the skin and/or cutaneous plaques and/or nails and/or hair, in view of obtaining a local effect.
Dentară	*Dental use*	Administration of a medicinal product on and inside the teeth/on and around the dental nerves.
Endocervicală	*Endocervical use*	Administration of a medicinal product in the uterine cervix.
Endosinusală	*Endosinusial use*	Administration of a medicinal product in the facial sinuses, in view of obtaining a local effect.
Endotraheo-pulmonară	*Endotracheo-pulmonary use*	Administration of a medicinal product via bronchial or tracheal instillation (inhalation preparations excluded; see inhalation route).
Epidurală	*Epidural use*	Injection of a medicinal product in the epidural space.
Epilezională	*Epilesional use*	Administration of a medicinal product on a wound.
Extra-amniotică	*Extraamniotic use*	Injection of a medicinal product between the chorion and amnion.
Gastrică	*Gastric use*	Administration of a medicinal product in the stomach, using an adequate device.

Gastroenterală	*Gastroenteral use*	Administration of a medicinal product in the gastroenteral tract, using an adequate device; to be used only when terms for the route of administration ,,gastric" or ,,intestinal" cannot be applied.
Gingivală	*Gingival use*	Administration of a medicinal product on the gingiva.
Hemodializă	*Haemodialysis*	Blood purification using a semipermeable membrane.
Inhalatorie	*Inhalation use*	Administration of a medicinal product at the level of the respiratory tract by inhalation, in view of obtaining a systemic or local effect in the lower respiratory tract; nasal and endotracheopulmonary routes excluded.
Intestinală	*Intestinal use*	Administration of a medicinal product in the bowel by using an adequate device. Gastroenteral route excluded.
Intraamniotică	*Intraamniotic use*	Injection of a medicinal product in the amniotic cavity.
Intraarterială	*Intra-arterial use*	Injection of a medicinal product in the artery.
Intraarticulară	*Intraarticular use*	Injection of a medicinal product in the articular cavity.
Intrabursală	*Intrabursal use*	Injection of a medicinal product in the synovial bursa or synovial sheaths.
Intracardiacă	*Intracardiac use*	Injection of a medicinal product in the cardiac muscle and/or cardiac cavity.
Intracavernoasă	*Intracavernous use*	Injection of a medicinal product in the cavernous bodies.
Intracerebrală	*Intracerebral use*	Administration of a medicinal product directly in the cerebral tissue.
Intracervicală	*Intracervical use*	Injection of a medicinal product in the uterine cervix.

Intracoronariană	*Intracoronary use*	Injection of a medicinal product in a coronary artery.
Intradermică	*Intradermal use*	Injection of a medicinal product in the derma.
Intraepidermică	*Intraepidermal use*	Administration of a medicinal product in the epidermis.
Intradiscală	*Intradiscal use*	Injection of a medicinal product inside the intervertebral disk.
Intralesională	*Intralesional use*	Administration of a medicinal product directly on the wound, via injection or any other way.
Intralimfatică	*Intralymphatic use*	Injection of a medicinal product in a lymphatic vessel.
Intramusculară	*Intramuscular use*	Injection of a medicinal product in the muscular tissue.
Intraoculară	*Intraocular use*	Administration of a medicinal product in the eye; the term "intraocular" is only used when the specific term (e.g. intravitreous) cannot be used; ocular and subjonctival routes excluded.
Intraosoasă	*Intraosseous use*	Administration of a medicinal product in the bone marrow. Intrasternal route excluded.
Intrapericardială	*Intrapericardial use*	Injection of a medicinal product in the pericardial cavity.
Intraperitoneală	*Intraperitoneal use*	Injection of a medicinal product in the peritoneal cavity.
Intrapleurală	*Intrapleural use*	Injection of a medicinal product in the pleural cavity.
Intrasternală	*Intrasternal use*	Injection of a medicinal product in the sternal bone marrow.
Intratecală	*Intrathecal use*	Injection of a medicinal product through the dura mater in the subarachnoid cavity.
Intratumorală	*Intratumoral use*	-

Intrauterină	*Intrauterine use*	Administration of a medicinal product in the uterine cavity.
Intravenoasă	*Intravenous use*	Injection of a medicinal product in the vein.
Intravezicală	*Intravesical use*	Administration of a medicinal product in the bladder.
Intravitroasă	*Intravitreal use*	Administration of a medicinal product in the vitreous body.
Juxtascleralăposterioară	*Posterior juxtascleral use*	Administration of a medicinal product in the episcleral space, adjacent to the macula.
Laringofarin-giană	*Laryngopha-ryngeal use*	Administration of a medicinal product in the laryngopharynx, in view of obtaining a local (anaesthetic) effect.
Nazală	*Nasal use*	Administration of a medicinal product in the nasal cavity, in view of obtaining a local/systemic effect; treatment via inhalation for the lower respiratory tract is excluded; see inhalation route.
Oftalmică	*Ocular use*	Administration of a medicinal product on the ocular globe and/or the conjunctiva.
Orală	*Oral use*	Administration of a medicinal product by swallowing.
Orofaringiană	*Oropharyngeal use*	Administration of a medicinal product in the oropharynx (throat), in view of obtaining a local effect.
Periarticulară	*Periarticular use*	Injection of a medicinal product around a joint.
Periodontală	*Periodontal use*	Administration in the dental alveolus between the tooth and gum.
Perineurală	*Perineural use*	Injection of a medicinal product directly in the proximity of one or several nerves.
Rectală	*Rectal use*	Administration of a medicinal product in the rectum, in view of obtaining a local/systemic effect.
Scarificarea pielii	*Skin scarification*	Administration of a medicinal product via skin scarification.

Subconjuctivală	*Subconjunctival use*	Injection of a medicinal product under the conjunctiva.
Subcutanată	*Subcutaneous use*	Injection of a medicinal product directly under the skin.
Sublinguală	*Sublingual use*	Administration of a medicinal product under the tongue, in view of obtaining a systemic effect.
Transdermică	*Transdermal use*	Administration of a medicinal product on the skin, in view of obtaining a local/systemic effect, after surpassing the cutaneous barrier.
Uretrală	*Urethral use*	Administration of a medicinal product in the urethra.
Vaginală	*Vaginal use*	Administration of a medicinal product in the vagina.
Cale de administrare nespecificată	*Route of administration not applicable*	Applies to medicinal products which do not come in direct contact with the patient's body or are administered to various/unspecified anatomical parts.

Part 3: Containers

Ambalaje primare, sisteme de închidere şi de administrare ***Containers***		
Romanian	**English**	**Observations**
Ac pentru injecţie	*Injection needle*	Void needle, with a fixing device, for the administration of liquid pharmaceutical forms.
Aplicator	*Applicator*	Administration device used when applying a medicinal product on/in a particular anatomical part.
Aplicator bucal	*Mouthpiece*	Auxiliary device for the administration/inhalation of a medicinal product via oral route.
Aplicator cu ac	*Needle applicator*	Needle closure system.

Aplicator multipuncţio-nal	*Multipuncturer*	Device for skin puncture, usually employed for immunological products, especially in view of diagnosis.
Aplicator nazal	*Nasal applicator*	Device for the administration of a medicinal product via nasal route.
Aplicator tip pipetă	*Pipette applicator*	Closure system with pipette.
Aplicator pentru picurare	*Dropper applicator*	Fillet cap with dropper.
Aplicator pentru pudrare	*Dredging applicator*	Closure system with a dredging device.
Aplicator pentru tamponare	*Dabbing applicator*	Closure system with a dabbing device.
Aplicator pentru teste cu alergene prin înţepare	*Prick test applicator*	Prick device for allergenic products.
Aplicator tip pensulă	*Brush applicator*	Closure system with a brush device.
Bidon	*Barrel*	Large container, used for the pharmaceutical/solid/semisolid forms.
Blister	*Blister*	packaging (usually, multidose) consisting of two layers, one being configured in order to contain the doses; blisters excluded.
Borcan	*Jar*	Container without a prominent neck, with large opening in the upper part, with a flat basis, indicated for the semisolid and solid pharmaceutical forms; may be resealed.
Butelie pentru gaz	*Gas cylinder*	Container, usually cylindrical, for compressed/liquefied/dissolved gas, having a control system of the gas jet at atmospheric pressure and room temperature.

Canulă	*Cannula*	Tubular administration device with a conical peak, used in the application of semisolid pharmaceutical forms.
Capac cu filet	*Screw cap*	Cylindrical closure object, concave, void inside, with fillet.
Capac fără filet	*Cap*	Cylindrical closure object, concave, void inside, without fillet.
Cartuş	*Cartridge*	A usually cylindrical container, meant for the liquid/solid pharmaceutical forms, usually employed with a special device.
Cutie	*Box*	Primary packaging made of one or several parts of light material, allowing closure.
Dispozitiv de măsurat	*Measuring device*	Device for the administration of measured medicinal product amounts; to be used only when other terms are not applicable.
Dop	*Stopper*	A usually solid closure object, having a conical/cylindrical form, used in view of container closure via insertion.
Fiolă	*Ampoule*	Container closed by thermofusion and opened exclusively by breakage; its content is meant for single use.
Flacon	*Vial*	Small airtight container of parenteral medicinal products, having a cap; the content is extracted by perforating the cap; single- and multidose vials included.
Flacon	*Bottle*	Container with or without neck, usually having a flat foundation.
Flacon de pudrat	*Dredging container*	-
Flacon picurător	*Dropper container*	Container, usually a vial, having a dropper device.
Flacon pentru comprimate	*Tablet container*	Container without neck having a flat foundation, used for tablets, capsules, etc. and which can be thoroughly closed.

Flacon presurizat	*Pressurised container*	Adequate container having compressed/liquefied/dissolved gas, having a system able to do a spontaneous release after being pressed, releasing an amount of the respective content, at atmospheric pressure and room temperature.
Flacon pulverizator	*Spray container*	-
Folie termosudată	*Strip*	Multidose packaging containing two layers, meant for the conditioning of single dose solid/semisolid preparations; blisters excluded.
Inhalator	*Inhaler*	Device for the administration of an inhalation medicinal product. Nebuliser excluded.
Injector transdermic sub presiune	*High pressure transdermal delivery device*	-
Linguriţă dozatoare	*Measuring spoon*	Spoon for the administration of multidose liquid and solid pharmaceutical forms.
Măsură dozatoare	*Cup*	Device for the administration of multidose liquid and solid pharmaceutical forms, by measurement of a more or less precise amount.
Nebulizator	*Nebuliser*	Device for the transformation of liquids into nebulisers; pressurised vials excluded.
Pai	*Straw*	Cylindrical tube containing a single dose of medicinal product, orally administered, by sucking.
Pensulă aplicatoare	*Brush*	Application device having a fine brush, used in the administration of liquid pharmaceutical forms.
Pipetă	Pipette	Tubular device for administration, used in the administration by drops or for the accurate dosage of liquid pharmaceutical forms.
Plic	*Sachet*	Packaging made of two sides of flexible fabric, closed only by sealing (rarely by folding); the content is meant for a single administration.
Pompă dozatoare	*Metering pump*	Closure system with dosing device.
Pompă de pulverizare	*Spray pump*	Closure system by which the content is released through the pump’s mechanical action.

Pungă	*Bag*	Packaging made of a flexible material with or without a flat foundation, closed by sealing at the foundation and on its lateral sides; its superior part may be closed via various procedures (e.g. thermosealing), depending on the intention for use.
Recipient criogenic fix	*Fixed cryogenic vessel*	Thermally isolated static container, meant for preserving the content in a liquid state.
Recipient criogenic mobil	*Mobile cryogenic vessel*	Thermally isolated mobile container, meant for preserving the content in a liquid state.
Recipient multidoză	*Multidose container*	Recipient containing an adequate amount of preparation for 2 or more doses.
Recipient multidoză cu pompă pentru împiedicarea pătrunderii aerului	*Multidose container with airless pump*	Multidose container, with an integrated pump, meant to preserve the content against air during use.
Recipient unidoză	*Single-dose container*	Recipient containing an amount of preparation (solid, semisolid or liquid) meant for a single administration.
Săculeţ	*Pouch*	Small sachet made of an adequate fabric, containing a single dose of a medicinal product, meant for the administration via the introduction in the cavity of the body, in view of releasing their active substance(s).
Seringă	*Injection syringe*	Cylindrical device for administration, with a nozzle – like peak, with or without a fixed needle and a rod mobile piston, used in the parenteral administration of an accurately dosed quantity amount of a liquid pharmaceutical form.
Seringă pentru administrare orală	*Oral syringe*	-
Seringă pre-umplută	*Pre-filled syringe*	Syringe containing a dose or several doses of a medicinal product.
Closure system securizat pentru copii	*Child-resistant closure*	Closure system hard to open by small children, but easy to close by adults.

Sistem de administrare	*Administration system*	System containing syringes, receptacles etc. assuming handling prior to the medicinal product's administration.
Spatulă	*Spatula*	Administration device, with a fine side, used for the application of semisolid pharmaceutical forms.
Stilou injector (pen) preumplut	*Pre-filled pen*	-
Tub	*Tube*	Recipient for the conditioning of multidose semisolid pharmaceutical terms, made up of a compressible material, releasing the content by pressing.
Tub gastroenteral preumplut	*Pre-filled gastroenteral tube*	Pre-filled tube for the administration of the medicinal product in the gastroenteral tract.
Valvă dozatoare	*Metering valve*	Closure system by which a measured dose of the content is released by pressing the valve.
Valvă de pulverizare	*Spray valve*	Closure system by which the content is released as a nebuliser (by mechanically operating the valve).
Vârf aplicator	*Nozzle*	Ensures the direct/targeted administration of a liquid/semisolid preparation, in a specific body part.