

DECISION

No. 9/26.06.2009

on the approval of the new Romanian Standard Terms for pharmaceutical forms, primary packages, closure systems and routes of administration, in accordance with those adopted by the Commission of the European Pharmacopoeia

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 26.06.2009, in accord 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 New Romanian Standard Terms for pharmaceutical forms, primary packages, closure systems and routes of administration, in accordance with those adopted by the Commission of the European Pharmacopoeia are approved, according to the Annex which is integral part of this Decision.

**PRESIDENT
of the National Medicines Agency
Scientific Council**

Acad. Prof. Dr. Victor Voicu

New Romanian Standard Terms

Part 1: Pharmaceutical forms

Preparate bucofaringiene <i>Oromucosal preparations</i>			
Normal terms		No.1)	Observations
Romanian	English	monogr. of Ph. Eur.	
Film bucal	<i>Buccal film</i>	-	bands/foils made up of one or several layers, in which active substances and excipients are dissolved or dispersed; to be administered orally, in view of obtaining a systemic effect.
Film orodispersabil	<i>Orodispersible film</i>	-	bands/foils made up of one or several layers, in which active substances and excipients are dissolved or dispersed; to be administered orally, where it disperses rapidly before being swallowed.
Preparate cutanate și transdermice <i>Cutaneous and transdermal preparations</i>			
Normal terms		No.1)	Observations
Romanian	English	monogr. of Ph. Eur.	
Spray cutanat, emulsie	<i>Cutaneous spray, emulsion</i>	No. 927	-
Plasture cutanat	<i>Cutaneous patch</i>	No. 132	-
Soluție perfuzabilă în sistem de administrare	<i>Solution for infusion in administration system</i>	-	-

Implanturi <i>Implants</i>			
Normal terms		No.1)	Observations
Romanian	English	monogr. of Ph. Eur.	
Suspensie de implantat	<i>Implantation suspension</i>	-	suspension to be implanted in the body
Varia <i>Miscellaneous</i>			
Normal terms		No.1)	Observations
Romanian	English	monogr. of Ph. Eur.	
Soluție pentru testul de provocare	<i>Solution for provocation test</i>	No. 1063	allergen products for nasal provocation tests, ocular or bronchial.

Part 2: Routes of administration

Căi de administrare <i>Routes of administration</i>		
Romanian	English	Observations
Lezională	<i>Epileisional use</i>	administration of a medicinal product on a wound.
Intraepidermică	<i>Intraepidermal use</i>	administration of a medicinal product in the derm.
Juxtasclerală posterioară	<i>Posterior juxtascleral use</i>	administration of a medicinal product adjacent to the macula.

Scarificarea pielii	<i>Skin scarification</i>	administration of a medicinal product via skin scarification.
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Part 3: Containers

Ambalaje primare, sisteme de închidere și de administrare <i>Containers</i>		
Romanian	English	Observations
Măsură dozatoare	<i>Cup</i>	device for administration of the liquid or solid multidose pharmaceutical forms, by measuring a more or less accurate quantity.
Sistem de administrare	<i>Administration system</i>	system containing syringes, sleeves etc. and which necessitate manipulation prior to the administration of the medicinal product.