

DECISION

No. 23/07.11.2008

on approval of the new Romanian Standard Terms for pharmaceutical forms, routes of administration and primary packaging, in compliance with those adopted 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, changed and completed through Minister of Public Health Order No. 159/22.02.2006, reunited on summons of the National Medicines Agency President in the ordinary meeting of 07.11.2008 in accordance with Art. 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 amended, agrees on the following

DECISION

Single Art. - The new and revised Romanian Standard Terms for pharmaceutical forms, routes of administration and primary packaging are approved, in accordance with those adopted by the Commission of the European Pharmacopoeia in accordance with the Annex, which is integral part of the present decision.

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

Acad. Prof. Dr. Victor Voicu

New Romanian standard terms**Part 1: Pharmaceutical forms**

Preparate oftalmice <i>Eye preparations</i>			
Normal Terms		Number 1) monogr. of Ph. Eur.	Observations
Romanian	English		
Bandă oftalmică	<i>Ophthalmic strip</i>	-	Strip made of an adequate material, usually impregnated with active substance(s), to be administered on the eyeball.

Varia <i>Miscellaneous</i>			
Normal Terms		Number monogr. of Ph. Eur.	Observations
Romanian	English		
Adeziv tisular	<i>Sealant</i>		Tissue adhesive
Pulbere și solvent pentru adeziv tisular	<i>Powder and solvent for sealant</i>		-

Part 3: Containers

Ambalaje primare, sisteme de închidere și de administrare <i>Containers</i>		
Romanian	English	Observations
Săculeț	<i>Pouch</i>	Small sachet made of an adequate material, containing a single dose of a medicinal product, made for the administration via insertion into a cavity of the body, in view of the release of the active substances.
Pai	<i>Straw</i>	Cylindrical tube containing a single dose of a medicinal product, orally administered, used for sucking.