

**DECISION**  
**No. 16/22.04.2013**

**on approval of new Romanian standard terms for pharmaceutical forms,  
primary packaging, closure systems and administration devices, routes and  
manners of administration, in line with terms adopted by the European  
Pharmacopoeia Commission**

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 158/18.02.2013, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 22.04.2013, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organisation and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following

**DECISION**

**Sole article.** - The new Romanian standard terms for pharmaceutical forms, primary packaging, closure systems and administration devices, routes and manners of administration, in line with terms adopted by the European Pharmacopoeia Commission are approved, in accordance with the Annex which is integral part of this Decision.

**PRESIDENT**  
**of the Scientific Council**  
**of the National Agency for Medicines and Medical Devices,**

**Acad. Prof. Dr. Leonida Gherasim**

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

<b>Preparate bucofaringiene</b> <i>Oromucosal preparations</i>			
<b>Normal terms</b>		No.1) monogr. of Ph.Eur.	<b>Remarks</b>
<b>Romanian</b>	<b>English</b>		
Film sublingual	<i>Sublingual film</i>	No. 1807	Fasciae/films made of one or several layers of appropriate material(s); to be administered in the oral cavity for systemic effect.
Spray sublingual, soluție	<i>Sublingual spray, solution</i>	No. 1807	
Spray sublingual, suspensie	<i>Sublingual spray, suspension</i>	No. 1807	
Spray sublingual, emulsie	<i>Sublingual spray, emulsion</i>	No. 1807	
Spray sublingual	<i>Sublingual spray</i>	No. 1807	<b>- use of the term “sublingual spray” is no longer recommended;</b> - as required, use of terms such as sublingual spray, sublingual spray/solution, sublingual spray/suspension, sublingual spray, emulsion is recommended .
Spray bucofaringian	<i>Oromucosal spray</i>	No. 1807	<b>- use of the term “oromucosal spray” is no longer recommended;</b> - as required, use of terms to use terms such as oromucosal spray, oromucosal spray/solution, oromucosal spray/suspension, oromucosal spray, emulsion is recommended.

<b>Preparate dentare</b> <i>Preparations for dental use</i>			
Normal terms		No.1) monogr. of Ph.Eur.	Remarks
Romanian	English		
Pastă dentară	<i>Dental paste</i>	-	Single dose or multidose semi-solid preparation containing particles finely dispersed into an appropriate basis, administered on the tooth or inside it. Toothpaste is excluded
<b>Preparate orale – forme lichide și semisolide</b> <i>Oral preparations – liquid and semi-solid forms</i>			
Normal terms		No.1) monogr. of Ph.Eur.	Remarks
Romanian	English		
Concentrat pentru soluție orală	<i>Concentrate for oral solution</i>	nr. 672	Liquid preparation diluted into a prescribed liquid, for oral solution
Concentrat pentru suspensie orală	<i>Concentrate for oral suspension</i>	nr. 672	Liquid preparation diluted into a prescribed liquid, for oral suspension
<b>Preparate cutanate și transdermice</b> <i>Cutaneous and transdermal preparations</i>			
Normal terms		No.1) monogr. of Ph.Eur.	Remarks
Romanian	English		
Soluție transdermică	<i>Transdermal solution</i>	nr. 927, 523	Single- or multidose preparation containing one or several active substances dissolved in an appropriate solvent, meant for transdermal administration.

<b>Preparate parenterale</b> <i>Parenteral preparations</i>			
Normal terms		No.1) monogr. of Ph.Eur.	Remarks
Romanian	English		
Suspensie injectabilă cu eliberare prelungită	<i>Prolonged-release suspension for injection</i>	No. 520	Single- or multidose preparation containing a suspension meant for administration by injection; the active substance is released over a longer period of time.

## Part 2: Routes of administration

<b>Căi și moduri de administrare</b> <i>Routes and method of administration</i>		
Romanian	English	Remarks
Submucoasă	<i>Submucosal use</i>	Injection of a medicinal product directly under the mucous membrane
Intracamerală	<i>Intracameral use</i>	Administration of a medicinal product directly in the anterior chamber of the eyeball.

## Part 3: Containers, closures and administration devices

<b>Ambalaje primare, sisteme de închidere și dispozitive de administrare</b> <i>Containers, closures and administration devices</i>		
Romanian	English	Remarks
Recipient multidoză cu pompă dozatoare	<i>Multidose container with metering pump</i>	Multidose container with integrated dosing pump.