

## **DECISION**

**no. 32/30.09.2015**

**on approval of the Romanian version of Standard Terms for pharmaceutical dosage forms for pulmonary use, as approved 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. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 30.09.2015, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

## **DECISION**

**Sole article** – The Romanian version of Standard Terms for pharmaceutical dosage forms for pulmonary use, as approved by the European Pharmacopoeia Commission (available in the *database of the European Directorate for the Quality of Medicines & Healthcare – EDQM, completely revised, version 14 of November 2014*) is 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**

No.	Status	Full standard term	
		English	Romanian
1	Rejected	Aerosol	Aerosol
2	Current-new	Concentrate for nebuliser solution	Concentrat pentru soluție pentru nebulizator
3	Currently revised	Endotracheopulmonary instillation, powder for solution	<b>Initial:</b> Pulbere pentru soluție destinată instilației endotraheopulmonară <b>Revised:</b> Pulbere pentru soluție pentru instilație endotraheopulmonară
4	Current-new	Endotracheopulmonary instillation, powder for suspension	Pulbere pentru suspensie pentru instilație endotraheopulmonară
5	Current	Endotracheopulmonary instillation, solution	Soluție pentru instilație endotraheopulmonară
6	Current	Endotracheopulmonary instillation, suspension	Suspensie pentru instilație endotraheopulmonară
7	Deprecated	Inhalation gas	Gaz de inhalat
8	Deprecated	Inhalation impregnated pad	
9	Current	Inhalation powder	Pulbere de inhalat
10	Currently revised	Inhalation powder, hard capsule	<b>Initial :</b> Capsula cu pulbere de inhalat <b>Revised:</b> Pulbere de inhalat, capsulă
11	Current	Inhalation powder, pre-dispensed	Pulbere de inhalat unidoza
12	Currently revised	Inhalation powder, tablet	<b>Initial:</b> Comprimat pentru pulbere de inhalat <b>Revised:</b> Pulbere de inhalat, comprimat
13	Current	Inhalation solution	Soluție de inhalat
14	Currently revised	Inhalation vapour, capsule	<b>Initial:</b> Capsula pentru inhalation vapours <b>Revised:</b> Inhalation vapours, capsula
15	Currently revised	Inhalation vapour, effervescent tablet	<b>Initial:</b> Comprimat efervescent pentru inhalation vapours <b>Revised:</b> Inhalation vapours, comprimat efervescent
16	Currently revised	Inhalation vapour, emulsion	<b>Initial:</b> Emulsie pentru inhalation vapours <b>Revised:</b> Inhalation vapours, emulsie
17	Currently revised	Inhalation vapour, impregnated pad	<b>Initial:</b> Tampon impregnat pentru inhalation vapours <b>Revised:</b> Inhalation vapours, tampon impregnat

18	Currently revised	<i>Inhalation vapour, impregnated plug</i>	<b>Initial :</b> Suport impregnat pentru inhalation vapours <b>Revised:</b> Inhalation vapours, suport impregnat
19	Currently revised	<i>Inhalation vapour, liquid</i>	<b>Initial:</b> Lichid pentru inhalation vapours <b>Revised:</b> Inhalation vapours, lichid
20	Currently revised	<i>Inhalation vapour, ointment</i>	<b>Initial:</b> Ointment pentru inhalation vapours <b>Revised:</b> Inhalation vapours, ointment
21	Currently revised	<i>Inhalation vapour, powder</i>	<b>Initial:</b> Pulbere pentru inhalation vapours <b>Revised:</b> Inhalation vapours, pulbere
22	Currently revised	<i>Inhalation vapour, solution</i>	<b>Initial:</b> Soluție pentru inhalation vapours <b>Revised:</b> Inhalation vapours, soluție
23	Currently revised	<i>Inhalation vapour, tablet</i>	<b>Initial:</b> Comprimat pentru inhalation vapours <b>Revised:</b> Inhalation vapours, comprimat
24	Deprecated	<i>Liquefied gas for dental use</i>	<i>Gaz lichefiat pentru uz dentar</i>
25	Currently revised	<i>Medicinal gas, compressed</i>	<b>Initial:</b> Gaz medicinal, comprimat <b>Revised:</b> Compressed medicinal gas
26	Currently revised	<i>Medicinal gas, cryogenic</i>	<b>Initial:</b> Gaz medicinal, criogenic <b>Revised:</b> Gaz medicinal criogenic
27	Currently revised	<i>Medicinal gas, liquefied</i>	<b>Initial:</b> Gaz medicinal, lichefiat <b>Revised:</b> Gaz medicinal lichefiat
28	Currently revised	<i>Nebuliser emulsion</i>	<b>Initial:</b> Emulsie de inhalat prin nebulizator <b>Revised:</b> Emulsie pentru nebulizator
29	Currently revised	<i>Nebuliser solution</i>	<b>Initial:</b> Soluție de inhalat prin nebulizator <b>Revised:</b> Soluție pentru nebulizator
30	Currently revised	<i>Nebuliser suspension</i>	<b>Initial:</b> Suspensie de inhalat prin nebulizator <b>Revised:</b> Suspensie pentru nebulizator
31	Currently revised	<i>Oral solution/concentrate for nebuliser solution</i>	<b>Initial:</b> Soluție orală/concentrat pentru soluție de inhalat prin nebulizator <b>Revised:</b> Soluție orală/concentrat pentru soluție pentru nebulizator
32	Currently revised	<i>Powder for nebuliser solution</i>	<b>Initial:</b> Pulbere pentru soluție de inhalat prin nebulizator <b>Revised:</b> Pulbere pentru soluție pentru nebulizator
33	Rejected	<i>Powder for nebuliser solution/solution for inj./inf.</i>	<i>Pulbere pentru soluție pentru nebulizator / soluție injectabilă / perfuzabilă</i>
34	Currently revised	<i>Powder for nebuliser suspension</i>	<b>Initial:</b> Pulbere pentru suspensie de inhalat prin nebulizator <b>Revised:</b> Pulbere pentru suspensie pentru nebulizator
35	Current	<i>Pressurised inhalation, emulsion</i>	<i>Emulsie de inhalat presurizată</i>
36	Current	<i>Pressurised inhalation, solution</i>	<i>Soluție de inhalat presurizată</i>

37	Current	<i>Pressurised inhalation, suspension</i>	<i>Pressurised suspension for inhalation</i>
38	Current	<i>Solution for provocation test</i>	<i>Solutie pentru testul de provocare</i>

**Legend:**

**Current** = Standard Term (ST) approved for use by the European Pharmacopoeia (PhEur) Commission; the Romanian version has been approved in a previous meeting of the NMA/NAMMD Scientific Council

**Current – New** = Standard Term approved for use by the European Pharmacopoeia Commission, the Romanian version is submitted for approval in the meeting of the NAMMD Scientific Council of 30.09.2015.

**Deprecated** = **The Standard Term is not approved for use by the European Pharmacopoeia Commission;** it is not physically rejected from the database; kept in order to ensure traceability of the Standard Term.

**Rejected** = the Standard Term was rejected following assessment within the Standard Terms Working Party of the EDQM and is not approved for use as an ST; included in the database in order to avoid transmission of new requests to the PhEur Commission for this term

**Draft** = the definition undergoes assessment within the Standard Terms Working Party of the EDQM

**Currently revised** = Standard Term approved for use by the European Pharmacopoeia Commission;  
A new translation into Romanian of the Standard Term is submitted for approval during the Scientific Council session of 30.09.2015