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National Agency for Medicines and Medical Devices

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Decisions of the NAMMD Scientific Council

DECISION

No. 1/24.10.2017

on approval of amendment of Scientific Council Decision no. 4 of 27.03.2009 on approval of the Guideline for change of classification for supply of medicinal products for human use

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 24.10.2017, in accordance with provisions of 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, hereby adopts the following

DECISION

Article I: The title of NAMMD Scientific Council Decision (SCD) no. 4 of 27.03.2009 is hereby amended as follows:

- SCD no. 4 of 27.03.2009 on adoption of the Guideline for change of classification for supply of medicinal products for human use

Article II: The Annex to Decision of the NAMMD Scientific Council no. 4 of 27.03.2009 is hereby amended as follows:

1. Article 36 is amended and shall read as follows:

"Article 36 – (1) The package size as approved in the Marketing authorisation of any medicinal product shall be established based on the duration of the treatment as approved in the SmPC and Leaflet and in correlation with the daily maximum dose/ maximum active substance amount specified on the packaging recommended by the "*Council of Europe Committee of ministers Resolution ResAP (2007)1 on the Classification of Medicines as Regards their Supply*.

2. Article 60 is amended and shall read as follows:

„Art.60.
(2) Medicinal products for human use with different classification of supply may not share the same trade name."

Article III: After entry into force of this decision, the NAMMD shall re-evaluate all package sizes approved through Marketing Authorisation for over-the-counter medicines and shall accordingly change package sizes in line with provisions of this decision.

Article IV: After entry into force of this decision, all package sizes approved through Marketing Authorisation will be in line with the supply status of the respective medicine.

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

Prof Anca-Dana Buzoianu, MD, PhD

DECISION

No. 2/24.10.2017

on adoption of the Guideline on Good Clinical Practice

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 24.10.2017, in accordance with provisions of 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, hereby adopts the following

DECISION

Article 1. – Adoption of the Guideline on Good Clinical Practice, in accordance with the Annex, which is integral part of this Decision.

Article 2. - On entry into force of this Decision, Decision no. 39/27.10.2006 on approval of the Guideline on Good Clinical Practice shall be repealed.

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

Prof Anca-Dana Buzoianu, MD, PhD

Table of contents of investigator's brochure (example)

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These references should be found at the end of each chapter.
Appendices (if any)

Annex no. 2

Minimal list of essential documents for the conduct of a clinical trial

a) Before commencement of the clinical phase of the trial

During this planning stage the following documents should be generated and should be on file before the trial formally starts:

	Document Title	Purpose	Located in the Files of the	
			Investigator/ Institution	Sponsor
1	**Investigator's brochure**	To document that relevant and current scientific information about the investigational medicinal product has been provided to the investigator	X	X
2	**Signed protocol and amendments, if any, and sample case report form**	To document investigator and sponsor agreement	X	X
3	**Information given to trial subject** **- informed consent form (including all applicable translations)** **- any other written information** **- Advertisement for subject recruitment (if used)**	To document the informed consent To document that subject will be given appropriate written information (content and wording) to support their ability to give fully informed consent To document that recruitment measures are appropriate and not coercive	X X X	X X
4	**Financial aspects of the trial**	To document the financial agreement between the investigator/institution and the sponsor for the trial	X	X
5	**Insurance statement (where required)**	To document that compensation to subject(s) for trial-related injury will be available	X	X
6	**Signed agreement between involved parties, e.g.:** **- investigator/institution and sponsor** **- investigator/institution and CRO** **- sponsor and CRO** **- investigator/institution and authority(ies) (where required)**	To document agreements	X	X X (where required) X X

7	**Dated, documented approval/ favourable opinion of the independent ethics committee of the following:** **- protocol and any amendments** **- CRF (if applicable)** **- informed consent form(s)** **- any other written information to be provided to the subject(s)** **- advertisement for subject recruitment (if used)** **- subject compensation (if any)** **- any other documents given approval/ favourable opinion**	To document that the trial has been subject IEC review and given approval/favourable opinion. To identify the version number and date of the document(s)	X	X
8	**Institutional ethics committee composition**	To document that Institutional ethics committee is constituted in agreement with GCP	X	X (where required)
9	**Approval of protocol by the National Agency for Medicines and Medical Devices (where required)**	To document appropriate approval by the National Agency for Medicines and Medical Devices has been obtained prior to initiation of the trial in compliance with the applicable regulatory requirement(s)	X (where required)	X (where required)
10	**Curriculum vitae and/or other relevant documents evidencing qualifications of investigator(s) and sub-investigator(s)**	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects	X	X
11	**Normal value(s)/range(s) for medical/ laboratory/ technical procedure(s) and/or test(s) included in the protocol**	To document normal values and/or ranges of the tests	X	X
12	**Medical/laboratory/technical procedures /tests** **- certification or** **- accreditation or** **- established quality control and/or external quality assessment or** **- other validation (where required)**	To document competence of facility to perform required test(s), and support reliability of results	X (where required)	X
13	**Sample of label(s) attached to investigational product container(s)**	To document compliance with applicable labelling regulations and appropriateness of instructions provided to the subjects		X

14	**Instructions for handling of investigational product(s) and trial-related materials (if not included in protocol or Investigator's Brochure)**	To document instructions needed to ensure proper storage, packaging, dispensing and disposition of investigational products and trial- related materials	X	X
15	**Shipping records for investigational product(s) and trial-related materials**	To document shipment dates, batch numbers and method of shipment of investigational product(s) and trial-related materials. Allows tracking of product batch, review of shipping conditions, and accountability	X	X
16	**Certificate(s) of analysis of investigational product(s) shipped**	To document identity, purity, and strength of investigational product(s) to be used in the trial		X
17	**Decoding procedures for blinded trials**	To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining subjects' treatment	X	X (third party if applicable)
18	**Master randomisation list**	To document method for randomisation of trial population		X (third party if applicable)
19	**Pre-trial monitoring report**	To document that the site is suitable for the X trial (may be combined with 20.)		X
20	**Trial initiation monitoring report**	To document that trial procedures were X X reviewed with the investigator and the investigator's trial staff (may be combined with 19.)	X	X

b) During the Clinical Conduct of the Trial

In addition to having on file the above documents, the following should be added to the files during the trial as evidence that all new relevant information is documented as it becomes available.

1	**Investigator's brochure updates**	To document that investigator is informed in a timely manner of relevant information as it becomes available	X	X
2	**Any revision to:** **- protocol/amendment(s) and case report forms** **- informed consent form** **- any other written information provided to subjects** **- advertisement for subject recruitment (if used)**	To document revisions of these trial related documents that take effect during trial	X	X
3	**Dated, documented approval/favourable opinion of independent ethics committee of the following:** **- protocol amendment(s)** **- revision(s) of:** **- informed consent form** **- any other written information to be provided to the subject** **- advertisement for subject recruitment (if used)** **- any other documents given approval/favourable opinion** **- continuing review of trial (where required)**	To document that the amendment(s) and/or revision(s) have been subject to independent ethics committee review and were given approval/favourable opinion. To identify the version number and date of the document(s).	X	X
4	**Approvals/notifications by National Agency for Medicines and Medical Devices where required for:** **- protocol amendment(s) and other documents**	To document compliance with applicable regulatory requirements of the National Agency for Medicines and Medical Devices	X (where required)	X
5	**Curriculum vitae for new investigator(s) and/or sub- investigator(s)**	[see. a) 10.]	X	X
6	**Updates to normal value(s)/range(s) for**	To document that tests remain adequate throughout the	X	X

	medical/ laboratory/ technical procedure(s)/test(s) included in the protocol	trial period [see a) 11.]		
7	**Updates of medical/laboratory/ technical procedures/tests** **- certification or** **- accreditation or** **- established quality control and/or external quality assessment or** **- other validation (where required)**	To document that tests remain adequate throughout the trial period	X (where required)	X
8	**Documentation of investigational product(s) and trial-related materials shipment**	[see a), 15]	X	X
9	**Certificate(s) of analysis for new batches of investigational products**	[see a) 16.]		X
10	**Monitoring visit reports**	To document site visits by, and findings of, the monitor		X
11	**Relevant communications other than site visits** **- letters** **- meeting notes** **- notes of telephone calls**	To document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct, adverse event (AE) reporting	X	X
12	**Signed informed consent forms**	To document that consent is obtained in X accordance with GCP and protocol and dated prior to participation of each subject in trial. Also to document direct access permission [see a) 3.]	X	
13	**Source documents**	To document the existence of the subject and X substantiate integrity of trial data collected. To include original documents related to the trial, to medical treatment, and history of subject	X	
14	**Signed, dated and completed case report forms**	To document that the investigator or authorised member of the investigator's staff confirms the observations recorded	X (copy)	X (original)
15	**Documentation of case report form corrections**	To document all changes/additions or corrections made to Case Report Form after initial data were recorded	X (copy)	X (original)
16	**Notification by originating investigator to sponsor of serious adverse events and related**	Notification by originating investigator to sponsor of serious adverse events and related reports in accordance	X	X

	reports	with 4.11 “Safety reporting”		
17	**Notification by sponsor and/or investigator, where applicable, to the National Agency for Medicines and Medical Devices and the Independent Ethics Committee of unexpected serious adverse drug reactions and of other safety information**	Notification by sponsor and/or investigator, where applicable, to the National Agency for Medicines and Medical Devices and the Independent Ethics Committee of unexpected serious adverse drug reactions in accordance with 5.17 and 4.11.1 and of other safety information in accordance with Article 157.	X (where required)	X
18	**Notification by sponsor to investigators of safety information**	Notification by sponsor to investigators of safety information in accordance with provisions of Article 157.	X	X
19	**Interim or annual reports to the Independent Ethics Committee and the National Agency for Medicines and Medical Devices**	Interim or annual reports provided to Independent Ethics Committee in accordance with 5.10. and the National Agency for Medicines and Medical Devices in accordance with Article 160.	X	X (where required)
20	**Subject screening log**	To document identification of subjects who entered pre-trial screening	X	X (where required)
21	**Subject identification code list**	To document that investigator/institution keeps a confidential list of names of all subjects allocated to trial numbers on enrolling in the trial. Allows investigator/institution to reveal identity of any subject	X	
22	**Subject enrolment log**	To document chronological enrolment of subjects by trial number	X	
23	**Investigational products accountability at the site**	To document that investigational product(s) have been used according to the protocol	X	X
24	**Signature sheet**	To document signatures and initials of all persons authorised to make entries and/or corrections on case report forms	X	X
25	**Record of retained body fluids/ tissue samples (if any)**	To document location and identification of retained samples if assays need to be repeated	X	X

c) After completion or termination of the trial

After completion or termination of the trial, all of the documents identified in sections 8.2 and 8.3 should be in the file together with the following

1	**Investigational product(s) accountability at site**	To document that the investigational product(s) have been used according to the protocol. To documents the final accounting of investigational product(s) received at the site, dispensed to subjects, returned by the subjects, and returned to sponsor	X	X
2	**Documentation of investigational product destruction**	To document destruction of unused investigational products by sponsor or at site	X (if destroyed at site)	X
3	**Completed subject identification code list**	To allow identification of all subjects enrolled in the trial in case follow-up is required. List should be kept in a confidential manner and for agreed upon time	X	
4	**Audit certificate (if available)**	To document that audit was performed		X
5	**Final trial close-out monitoring report**	To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files		X
6	**Treatment allocation and decoding documentation**	Returned to sponsor to document any decoding that may have occurred		X
7	**Final report by investigator to the independent ethics committee where required, and where applicable, to the National Agency for Medicines and Medical Devices**	To document completion of the trial	X	
8	**Clinical trial report**	To document results and interpretation of trial	X (if applicable)	X

Guideline

on Good Clinical Practice

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the EMA/CHMP/ICH/135/1995 document *Guideline for good clinical practice E6(R2)* published by the European Medicines Agency (EMA).

Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.

Therefore, for the Annex to this Decision, please see the document *Guideline for good clinical practice E6(R2),* available at

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf

DECISION

No. 3/24.10.2017

on revision and approval of the Romanian version of certain Standard Terms approved by the European Pharmacopoeia Commission for routes and methods of administration and oral pharmaceutical dose forms

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 24.10.2017, in accordance with provisions of 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, hereby adopts the following

DECISION

Article 1 – The Romanian version is hereby revised and approved concerning certain Standard Terms approved by the European Pharmacopoeia Commission (available in the database of the *European Directorate for the quality of Medicines – EDQM*) for routes and methods of administration and oral pharmaceutical dose forms, in accordance with the Annexes, which are integral part of this Decision.

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

Prof Anca-Dana Buzoianu, MD, PhD

ROUTES AND METHODS OF ADMINISTRATION

No.	Status	Standard Term	
		English	Romanian
1	Current	***Auricular use***	***Administrare auriculară***
2	Current	***Buccal use***	***Administrare bucală***
3	Current	***Cutaneous use***	***Administrare cutanată***
4	Current	***Dental use***	***Administrare dentară***
5	Current	***Endocervical use***	***Administrare endocervicală***
6	Current	***Endosinusial use***	***Administrare endosinusală***
7	Current	***Endotracheopulmonary use***	***Administrare endotraheopulmonară***
8	Current	***Epidural use***	***Administrare epidurală***
9	Current	***Epilesional use***	***Administrare lezională***
10	Current	***Extraamniotic use***	***Administrare extraamniotică***
11	Current	***Extracorporeal use***	***Administrare extracorporală***
12	Current	***Gastric use***	***Administrare gastrică***
13	Current	***Gastroenteral use***	***Administrare gastrointestinală***
14	Current	***Gingival use***	***Administrare gingivală***
15	Current	***Haemodialysis***	***Hemodializă***
16	Current	***Implantation***	***Implantare***
17	Current	***Infiltration***	***Infiltratie***
18	Current	***Inhalation use***	***Administrare prin inhalare***
19	Current	***Intestinal use***	***Administrare intestinală***
20	Current	***Intraamniotic use***	***Administrare intraamniotică***
21	Current	***Intraarterial use***	***Administrare intraarterială***
22	Current	***Intraarticular use***	***Administrare intraarticulară***
23	Current	***Intrabursal use***	***Administrare intrabursală***
24	Current	***Intracameral use***	***Administrare intracameralã***
25	Current	***Intracardiac use***	***Administrare intracardiacă***
26	Current	***Intracartilaginous use***	***Administrare intracartilaginoasa***
27	Current	***Intracavernous use***	***Administrare intracavernoasă***
28	Current	***Intracerebral use***	***Administrare intracelebrală***
29	Current - New	***Intracerebroventricular use***	***Administrare intracerebroventriculara***
30	Current	***Intracervical use***	***Administrare intracervicală***
31	Current	***Intracholangiopancreatic use***	***Administrare intracolangiopancreatică***
32	Current	***Intracisternal use***	***Administrare intracisternală***
33	Current	***Intracoronary use***	***Administrare intracoronariană***
34	Current	***Intradermal use***	***Administrare intradermică***
35	Current	***Intradiscal use***	***Administrare intradiscală***
36	Current	***Intraepidermal use***	***Administare intraepidermică***
37	Current	***Intraglandular use***	***Administrare intraglandulară***
38	Current	***Intralesional use***	***Administrare intralezională***
39	Current	***Intralymphatic use***	***Administrare intralimfatică***
40	Current	***Intramuscular use***	***Administrare intramusculară***
41	Current	***Intraocular use***	***Administrare intraoculară***
42	Current	***Intraosseous use***	***Administrare intraosoasă***
43	Current	***Intrapericardial use***	***Administare intrapericardica***
44	Current	***Intraperitoneal use***	***Administrare intraperitoneală***
45	Current	***Intrapleural use***	***Administrare intrapleurală***
46	Current	***Intraportal use***	***Administrare intraportală***

47	Current	***Intraprostatic use***	***Administrare intraprostatică***
48	Current	***Intrasternal use***	***Administrare intrasternală***
49	Current	***Intrathecal use***	***Administrare intratecală***
50	Current	***Intratumoral use***	***Administrare intratumorală***
51	Current	***Intrauterine use***	***Administrare intrauterină***
52	Current	***Intravenous use***	***Administrare intravenoasă***
53	Current	***Intravesical use***	***Administrare intravezicală***
54	Current	***Intravitreal use***	***Administrare intravitreana***
55	Current	***Iontophoresis***	***Iontoforeză***
56	Current	***Laryngopharyngeal use***	***Administrare faringolaringiană***
57	Rejected	***Nail use***	
58	Current	***Nasal use***	***Administrare nazală***
59	Current	***Ocular use***	***Administrare oftalmică***
60	Current	***Oral use***	***Administrare orală***
61	Current	***Oromucosal use***	***Administrare bucofaringiană***
62	Current	***Oropharyngeal use***	***Administrare orofaringiană***
63	Current	***Periarticular use***	***Administrare periarticulară***
64	Current	***Perineural use***	***Administrare perineurală***
65	Current	***Periodontal use***	***Administrare periodontală***
66	Current	***Periosseous use***	***Administrare periosoasă***
67	Current	***Peritumoral use***	***Administrare peritumorală***
68	Current	***Posterior juxtascleral use***	***Administrare juxtascleralăposterioară***
69	Current	***Rectal use***	***Administrare rectală***
70	Current	***Retrobulbar use***	***Administrare retrobulbară***
71	Current	***Route of administration not applicable***	***Administrare nespecifică***
72	Current	***Skin scarification***	***Administrare prin scarificarea pielii***
73	Current	***Subconjunctival use***	***Administrare subconjunctivală***
74	Current	***Subcutaneous use***	***Administrare subcutanată***
75	Current	***Sublingual use***	***Administrare sublinguală***
76	Current	***Submucosal use***	***Administrare submucoasă***
77	Current - New	***Subretinal use***	***Administrare subretiniana***
78	Current	***Transdermal use***	***Administrare transdermică***
79	Current	***Urethral use***	***Administrare uretrală***
80	Current	***Vaginal use***	***Administrare vaginală***

Status definition:

Current = Standard Term approved for use by the European Pharmacopoeia Commission;
Romanian version approved by the NMA/NAMMD Scientific Council.

Rejected = Proposed term rejected during evaluation and not approved for use as a Standard Term;
included in the database for information purposes to avoid submission to the PhEur Commission of new requests for similar terms.

Current – NEW = Standard Term approved for use by the PhEur Commission,
Romanian version submitted for approval by the NAMMD Scientific Council in the meeting of 24.10.2017.

PHARMACEUTICAL DOSE FORMS BY INTENDED SITE

AURICULAR PHARMACEUTICAL DOSE FORMS

		Full Standard Terms	
No.	**Status**	***English***	***Romanian***
1	Deprecated	***Cutaneous/ear drops suspension***	***Picaturi auriculare / cutanate, suspensie***
2	Current	***Ear cream***	***Crema auriculara***
3	Current	***Ear drops, emulsion***	***Picaturi auriculare emulsie***
4	Current	***Ear drops, powder for suspension***	***Picaturi auriculare, pulbere pentru suspensie***
5	Current	***Ear drops, solution***	***Picaturi auriculare, solutie***
6	Current	***Ear drops, suspension***	***Picaturi auriculare, suspensie***
7	Current	***Ear gel***	***Gel auricular***
8	Current	***Ear ointment***	***Ointment auricular***
9	Current	***Ear powder***	***Pulbere auriculara***
10	Current	***Ear spray, emulsion***	***Spray auricular, emulsie***
11	Current	***Ear spray, solution***	***Spray auricular, solutie***
12	Current	***Ear spray, suspension***	***Spray auricular, suspensie***
13	Current	***Ear stick***	***Creion auricular***
14	Current	***Ear tampon***	***Tampon auricular***
15	Current	***Ear wash, emulsion***	***Emulsie pentru spalaturi auriculare***
16	Current	***Ear wash, solution***	***Solutie pentru spalaturi auriculare***
17	Current	***Ear/eye drops, solution***	***Picaturi auriculare / oftalmice, solutie***
18	Current	***Ear/eye drops, suspension***	***Picaturi auriculare / oftalmice, suspensie***
19	Current	***Ear/eye ointment***	***Ointment auricular / oftalmic***
20	Current	***Ear/eye/nasal drops, solution***	***Picaturi auriculare / oftalmice / nazale, solutie***
21	Deprecated	***Ear/eye/nose drops, solution***	***Picaturi auriculare / oftalmice / nazale, solutie***
22	Current	***Ear/nasal drops, suspension***	***Picaturi auriculare / nazale, suspensie***

Status definition:
Current = Standard Term approved for use by the European Pharmacopoeia Commission; Romanian version approved by the NMA/NAMMD Scientific Council.
Deprecated = Standard Term no longer approved for use by the PhEur Commission; not physically removed from the database and maintained to cover legacy data.

PHARMACEUTICAL DOSE FORMS BY INTENDED SITE

NASAL PHARMACEUTICAL DOSE FORMS

		Full Standard Term	
No.	**Status**	**English**	**Romanian**
1	Deprecated	***Cutaneous and nasal ointment***	***Ointment cutanat si nazal***

2	Current	***Cutaneous/nasal ointment***	***Ointment cutanat / nazal***
3	Current	***Ear/eye/nasal drops, solution***	***Picaturi auriculare / oftalmice / nazale, solutie***
4	Deprecated	***Ear/eye/****nose* ***drops, solution***	
5	Current	***Ear/nasal drops, suspension***	***Picaturi auriculare / nazale, suspensie***
6	Current	***Endosinusial solution***	***Solutie endosinusala***
7	Current	***Endosinusial wash, suspension***	***Suspensie pentru spalaturi endosinusale***
8	Current	***Gargle/nasal wash***	***Solutie pentru gargarisme / spalaturi nazale***
9	Current	***Nasal cream***	***Crema nazala***
10	Current	***Nasal drops, emulsion***	***Picaturi nazale, emulsie***
11	Current	***Nasal drops, powder for solution***	***Picaturi nazale, pulbere pentru solutie***
12	Current	***Nasal drops, solution***	***Picaturi nazale, solutie***
13	Current	***Nasal drops, suspension***	***Picaturi nazale, suspensie***
14	Current	***Nasal gel***	***Gel nazal***
15	Current	***Nasal ointment***	***Ointment nazal***
16	Current	***Nasal powder***	***Pulbere nazala***
17	Deprecated	***Nasal spray and oromucosal solution***	***Spray nazal si solutie bucofaringiana***
18	Current	***Nasal spray, emulsion***	***Spray nazal, emulsie***
19	Current	***Nasal spray, powder for solution***	***Spray nazal, pulbere pentru solutie***
20	Current	***Nasal spray, solution***	***Spray nazal, solutie***
21	Current	***Nasal spray, solution/oromucosal solution***	***Spray nazal, solutie / solutie bucofaringiana***
22	Current	***Nasal spray, suspension***	***Spray nazal, suspensie***
23	Current	***Nasal stick***	***Creion nazal***
24	Current	***Nasal wash***	***Solutie pentru spalaturi nazale***
25	Current	***Nasal/oromucosal solution***	***Solutie nazala / bucofaringiana***
26	Current	***Nasal/oromucosal spray, solution***	***Spray nazal/bucofaringian, solutie***
27	Current	***Powder for endosinusial solution***	***Pulbere pentru solutie endosinusala***
28	Deprecated	***Powder for solution for nasal spray***	***Pulbere pentru solutie pentru spray nazal***
29	Current	***Solution for provocation test***	***Solutie pentru testul de provocare***
30	Rejected	***Solvent for nasal use***	***Solvent pentru administrare nazala***

Status definition:
Current = Standard Term approved for use by the European Pharmacopoeia Commission; Romanian version approved by the NMA/NAMMD Scientific Council.
Deprecated = Standard Term no longer approved for use by the PhEur Commission; not physically removed from the database and is maintained to cover legacy data.
Rejected = Proposed term rejected during evaluation and not approved for use as a Standard Term; included in the database for information purposes to avoid submission to the PhEur Commission of new requests for similar terms.

OCULAR PHARMACEUTICAL DOSE FORMS

		Full Standard Term	
No.	**Status**	***English***	***Romanian***
1	Current	***Concentrate for solution for intraocular irrigation***	***Concentrat pentru solutie de irigare intraoculara***
2	Current	***Ear/eye drops, solution***	***Picături auriculare/oftalmice, soluţie***
3	Current	***Ear/eye drops, suspension***	***Picături auriculare/oftalmice, suspensie***
4	Current	***Ear/eye ointment***	***Ointment auricular/oftalmic***
5	Current	***Ear/eye/nasal drops, solution***	***Picături auriculare/oftalmice /nazale, solutie***
6	Deprecated	***Ear/eye/*nose *drops, solution***	
7	Current	***Eye cream***	***Crema oftalmica***
8	Current	***Eye drops, emulsion***	***Picaturi oftalmice, emulsie***
9	Current	***Eye drops, powder for solution***	***Picaturi oftalmice, pulbere pentru solutie***
10	Current	***Eye drops, powder for suspension***	***Picaturi oftalmice, pulbere pentru suspensie***
11	Current	***Eye drops, prolonged-release***	***Picaturi oftalmice cu eliberare prelungita***
12	Current	***Eye drops, solution***	***Picaturi oftalmice, solutie***
13	Current	***Eye drops, solvent for reconstitution***	***Solvent oftalmic pentru reconstituire***
14	Current	***Eye drops, suspension***	***Picaturi oftalmice, suspensie***
15	Current	***Eye gel***	***Gel oftalmic***
16	Current	***Eye lotion***	***Solutie pentru baie oculara***
17	Current	***Eye lotion, solvent for reconstitution***	***Solvent pentru baie oculara***
18	Current	***Eye ointment***	***Ointment oftalmic***
19	Current	***Intraocular instillation solution***	***Solutie pentru instilatie intraoculara***
20	Current	***Ophthalmic insert***	***Insert oftalmic***
21	Current	***Ophthalmic strip***	***Banda oftalmica***
22	Current	***Powder for intraocular instillation solution***	***Pulbere pentru solutie pentru instilatie intraoculara***
23	Current	***Powder for solution for intraocular irrigation***	***Pulbere pentru solutie pentru irigare intraoculara***
24	Current	***Solution for intraocular irrigation***	***Solutie pentru irigare intraoculara***
25	Current	***Solution for provocation test***	***Solutie pentru testul de provocare***
26	Current	***Solvent for solution for intraocular irrigation***	***Solvent pentru solutie pentru irigare intraoculara***

Status definition:
Deprecated = Standard Term no longer approved for use by the PhEur Commission;

OROMUCOSAL PHARMACEUTICAL DOSE FORMS

		Full Standard Term	
No.	**Status**	**English**	**Romanian**
1	Current	***Buccal film***	***Film bucal***
2	Current	***Buccal tablet***	***Comprimat bucal***
3	Current	***Compressed lozenge***	***Comprimat de supt***
4	Current	***Concentrate for gargle***	***Solutie concentrata pentru gargarisme***
5	Current	***Concentrate for oromucosal solution***	***Solutie concentrata pentru solutii bucogaringiene***
6	Current	***Cutaneous solution/concentrate for oromucosal solution***	***Solutie cutanata / concentrat pentru solutie bucofaringiana***
7	Rejected	***Cutaneous/oromucosal spray***	***Spray cutanat / bucofaringian***
8	Rejected	***Cutaneous/oromucosal/oral solution***	***Solutie cutanata/bucofaringiana/orala***
9	Rejected	***Effervescent buccal tablet***	***Tablets bucale efervescente***
10	Current	***Gargle***	***Solutie pentru gargarisme***
11	Current	***Gargle, powder for solution***	***Pulbere pentru solutie pentru gargarisme***
12	Current	***Gargle, tablet for solution***	***Comprimat pentru solutie pentru gargarisme***
13	Current	***Gargle/mouthwash***	***Solutie pentru gargarisme / apa de gura***
14	Current	***Gargle/nasal wash***	***Solutie pentru gargarisme/spalaturi nazale***
15	Current	***Gingival gel***	***Gel gingival***
16	Current	***Gingival paste***	***Pasta gingivala***
17	Current	***Gingival solution***	***Solutie gingivala***
18	Current	***Laryngopharyngeal solution***	***Solutie faringolaringiana***
19	Current	***Laryngopharyngeal spray, solution***	***Spray faringolaringian, solutie***
20	Current	***Lozenge***	***Pastila***
21	Current	***Medicated chewing-gum***	***Guma masticabila medicamentoasa***
22	Current	***Mouthwash***	***Apa de gura***
23	Current	***Mouthwash, powder for solution***	***Apa de gura, pulbere pentru solutie***
24	Current	***Mouthwash, tablet for solution***	***Apa de gura, comprimat pentru solutie***
25	Rejected	***Muco-adhesive buccal prolonged-release tablet***	***Comprimat bucal mucoadeziv cu eliberare prelungita***
26	Current	***Muco-adhesive buccal tablet***	***Comprimat bucal mucoadeziv***
27	Deprecated	***Nasal spray and oromucosal solution***	***Spray nazal si solutie bucofaringiana***
28	Current	***Nasal spray, solution/oromucosal solution***	***Spray nazal, solutie / solutie bucofaringiana***
29	Current	***Nasal/oromucosal solution***	***Solutie nazala / bucofaringiana***
30	Current	***Nasal/oromucosal spray, solution***	***Spray nazal / bucofaringian, solutie***
31	Current	***Oromucosal capsule***	***Capsula bucofaringiana***
32	Current	***Oromucosal cream***	***Crema bucofaringiana***
33	Current	***Oromucosal drops***	***Picaturi bucofaringiene***
34	Current	***Oromucosal gel***	***Gel bucofaringian***
35	Current	***Oromucosal ointment***	***Ointment bucofaringian***
36	Current	***Oromucosal paste***	***Pasta bucofaringiana***
37	Current	***Oromucosal patch***	***Plasture bucofaringian***
38	Current	***Oromucosal solution***	***Solutie bucofaringiana***
39	Deprecated	***Oromucosal spray***	***Spray bucofaringian***

40	Current	***Oromucosal spray, emulsion***	***Spray bucofaringian, emulsie***
41	Current	***Oromucosal spray, solution***	***Spray bucofaringian, solutie***
42	Current	***Oromucosal spray, suspension***	***Spray bucofaringian, suspensie***
43	Current	***Oromucosal suspension***	***Suspensie bucofaringiana***
44	Current	***Oromucosal/laryngopharyngeal solution***	***Soluţie bucofaringiană /faringolaringiană***
45	Deprecated	***Oromucosal/laryngopharyngeal solution/spray***	***Soluţie bucofaringiană /faringolaringiană / spray***
46	Current	***Oromucosal/laryngopharyn geal solution/spray, solution***	***Spray bucofaringian / faringolaringian, soluţie***
47	Current	***Pastille***	***Pastila moale***
48	Current	***Pillules***	***Granule homeopate***
49	Current	***Powder for gingival gel***	***Pulbere pentru gel gingival***
50	Deprecated	***Powder for mouth wash***	***Pulbere pentru apa de gura***
51	Current	***Sublingual film***	***Film sublingual***
52	Deprecated	***Sublingual spray***	***Spray sublingual***
53	Current	***Sublingual spray, emulsion***	***Spray sublingual, emulsie***
54	Current	***Sublingual spray, solution***	***Spray sublingual, solutie***
55	Current	***Sublingual spray, suspension***	***Spray sublingual, suspensie***
56	Current	***Sublingual tablet***	***Comprimat sublingual***

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PHARMACEUTICAL DOSE FORMS BY INTENDED SITE

ORAL PHARMACEUTICAL DOSE FORMS

		Full Standard Term	
No.	**Status**	***English***	***Romanian***
1	Current	***Cachet***	***Caşetă***
2	Current	***Capsule, hard***	***Capsulă***
3	Current	***Capsule, soft***	***Capsulă moale***
4	Current	***Chewable capsule, soft***	***Capsula moale masticabila***
5	Current	***Chewable tablet***	***Comprimat masticabil***
6	Current	***Chewable/dispersible tablet***	***Comprimat masticabil / dispersabil***
7	Current	***Coated granules***	***Granule drajefiate***
8	Current	***Coated tablet***	***Drajeu***
9	Current	***Concentrate for oral solution***	***Concentrat pentru solutie orala***

10	Current	***Concentrate for oral suspension***	***Concentrat pentru oral susp.***
11	Current	***Concentrate for oral/rectal solution***	***Concentrat pentru solutie orala / rectala***
12	Rejected	***Cutaneous / oromucosal / oral solution***	***Solutie cutanata/bucofaringiana/orala***
13	Current	***Dispersible tablet***	***Comprimat pentru dispersie orala***
14	Current	***Dispersible tablets for dose dispenser***	***Tablets dispersabile pentru dozatoare***
15	Current	***Effervescent granules***	***Effervescent granules***
16	Current	***Effervescent granules for oral suspension***	***Effervescent granules pentru oral susp.***
17	Current	***Effervescent powder***	***Pulbere efervescenta***
18	Current	***Effervescent tablet***	***Comprimat efervescent***
19	Rejected	***Film coated gastro-resistant tablet***	***Comprimat filmat gastrorezistent***
20	Current	***Film-coated tablet***	***Comprimat filmat***
21	Current	***Gastro-resistant capsule, hard***	***Capsula gastrorezistenta***
22	Current	***Gastro-resistant capsule, soft***	***Capsula moale gastrorezistenta***
23	Deprecated	***Gastro-resistant coated tablet***	***Drajeu gastrorezistent***
24	Current	***Gastro-resistant granules***	***Granule gastrorezistente***
25	Current	***Gastro-resistant granules for oral suspension***	***Granule gastrorezistente pentru suspensie orală***
26	Deprecated	***Gastro-resistant prolonged-release tablet***	***Comprimat gastrorezistent cu eliberare prelungita***
27	Current	***Gastro-resistant tablet***	***Comprimat gastrorezistent***
28	Current	***Granules***	***Granule***
29	Deprecated	***Granules for oral and rectal suspension***	***Granule pentru oral susp. si rectala***
30	Deprecated	***Granules for oral drops, solution***	***Granule pentru picaturi orale, solutie***
31	Current	***Granules for oral solution***	***Granule pentru solutie orala***
32	Current	***Granules for oral suspension***	***Granule pentru oral susp.***
33	Current	***Granules for oral/rectal suspension***	***Granule pentru oral susp. / rectala***
34	Current	***Granules for syrup***	***Granule pentru syrup***
35	Rejected	***Hard capsules with gastro-resistant pellets***	***Capsula cu pelete gastrorezistente***
36	Current	***Herbal tea***	***Produse vegetale pentru ceai***
37	Current	***Instant herbal tea***	***Produs vegetal instant pentru ceai***
38	Current	***Medicated chewing-gum***	***Guma masticabila medicamentoasa***
39	Current	***Modified-release capsule, hard***	***Capsula cu eliberare modificata***
40	Current	***Modified-release capsule, soft***	***Capsula moale cu eliberare modificata***
41	Deprecated	***Modified-release film-coated tablet***	***Comprimat filmat cu eliberare modificata***
42	Current	***Modified-release granules***	***Granule cu eliberare modificata***
43	Current	***Modified-release granules for oral suspension***	***Granule cu eliberare modificată pentru suspensie orală***
44	Current	***Modified-release tablet***	***Comprimat cu eliberare modificata***
45	Current	***Oral drops, emulsion***	***Picaturi orale, emulsie***
46	Current	***Oral drops, granules for solution***	***Picături orale, granule pentru soluţie***
47	Current	***Oral drops, liquid***	***Picaturi orale, lichid***
48	Current	***Oral drops, powder for suspension***	***Picaturi orale, pulbere pentru suspensie***
49	Current	***Oral drops, solution***	***Picaturi orale, solutie***
50	Current	***Oral drops, suspension***	***Picaturi orale, suspensie***
51	Current	***Oral emulsion***	***Emulsie orala***
52	Current	***Oral gel***	***Gel oral***
53	Current	***Oral gum***	***Guma orala***
54	Current	***Oral liquid***	***Lichid oral***

55	Current	***Oral lyophilisate***	***Liofilizat oral***
56	Current	***Oral paste***	***Pasta orala***
57	Current	***Oral powder***	***Oral powder***
58	Current	***Oral solution***	***Solutie orala***
59	Current	***Oral solution/concentrate for nebuliser solution***	***Oral solution/concentrat pentru soluţie de inhalat prin nebulizator***
60	Current	***Oral suspension***	***Oral susp.***
61	Current	***Oral/rectal solution***	***Solutie orala / rectala***
62	Current	***Oral/rectal suspension***	***Oral susp. / rectala***
63	Current	***Orodispersible film***	***Film orodispersabil***
64	Current	***Orodispersible tablet***	***Comprimat orodispersabil***
65	Rejected	***Pill***	
66	Current	***Pillules***	***Granule homeopate***
67	Current	***Powder for oral solution***	***Powder for oral sol.***
68	Current	***Powder for oral suspension***	***Pulbere pentru oral susp.***
69	Current	***Powder for oral/rectal suspension***	***Pulbere pentru oral susp. / rectala***
70	Current	***Powder for syrup***	***Pulbere pentru syrup***
71	Current	***Prolonged-release capsule, hard***	***Capsula cu eliberare prelungita***
72	Current	***Prolonged-release capsule, soft***	***Capsula moale cu eliberare prelungita***
73	Rejected	***Prolonged-release film-coated tablet***	***Comprimat filmat cu eliberare prelungita***
74	Current	***Prolonged-release granules***	***Granule cu eliberare prelungita***
75	Current	***Prolonged-release granules for oral suspension***	***Granule cu eliberare prelungită pentru suspensie orală***
76	Current	***Prolonged-release tablet***	***Comprimat cu eliberare prelungita***
77	Current	***Soluble tablet***	***Comprimat solubil***
78	Deprecated	***Solution for infusion and oral solution***	***Soluţie perfuzabilă and oral solution***
79	Current	***Suspension for oral suspension***	***Suspensie pentru oral susp.***
80	Current	***Syrup***	***Syrup***
81	Current	***Tablet***	***Comprimat***
82	Deprecated	***Tablet for oral suspension***	***Comprimat pentru oral susp.***

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ORAL PHARMACEUTICAL DOSE FORMS

		Full Standard Term	
No.	**Status**	***English***	***Romanian***
13	Current	***Dispersible tablet***	***Initial: Comprimat pentru dispersie orală***
			Revised: Comprimat dispersabil

DECISION

No. 4/24.10.2017

on revision and approval of the Romanian version of certain Standard Terms approved by the European Pharmacopoeia Commission for administration devices, closures and packaging

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 24.10.2017, in accordance with provisions of 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, hereby adopts the following

DECISION

Article 1 - The Romanian version is hereby revised and approved concerning certain Standard Terms approved by the European Pharmacopoeia Commission (available in the fully revised database of the European Directorate for the quality of Medicines – EDQM) for pentru administration devices, closures and packaging, 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,

Prof Anca-Dana Buzoianu, MD, PhD

ADMINISTRATION DEVICES

No.	Status	*Standard Term*		EDQM Definition	Current definition	Definition status	Initial definition
		English	***Romanian***				
1	Current	***Administration system***	***Sistem de administrare***	System including syringes, cartridges ..., that requires manipulation prior to administration of the medicinal product	Sistem care include seringi, cartuse..., care necesita manipulare inainte de administrarea medicamentului	Revised definition	sistem care conţine seringi, cartuşe etc.si care presupune o prealabilă manipulare înainte de administrarea medicamentului
2	Current	***Applicator***	***Aplicator***	Administration device used to apply a drug to or into a certain site of the body.	Dispozitiv de administrare utilizat pentru aplicarea unui medicament pe sau intr-o anumita parte a corpului		dispozitiv de administrare utilizat pentru aplicarea unui medicament pe sau într-o anumită parte a corpului
3	Current	***Brush***	***Initial: Pensula aplicatoare Revised: Pensula***	Administration device fitted with a fine brush used for the application of liquid pharmaceutical forms	Dispozitiv de administrare prevazut cu o pensula fina utilizat pentru aplicarea formelor farmaceutice lichide	Revised definition	dispozitiv de aplicare prevăzut cu o pensulă fină, utilizat pentru aplicarea formelor farmaceutice lichide
4	Current	***Cannula***	***Canula***	Administration device, tubular with a conical tip used for the application of liquid or semi-solid pharmaceutical forms.	Dispozitiv de administrare tubular cu varf conic utilizat la aplicarea formelor farmaceutice lichide sau semisolide.	Revised definition	dispozitiv de administrare tubular cu vârf conic, utilizat pentru aplicarea formelor farmaceutice semisolide.
5	Current	***Cup***	***Masura dozatoare***	Administration device used for the administration of a quantity, whether or not accurately measured, of a liquid or multidose solid pharmaceutical form.	Dispozitiv de administrare utilizat pentru administrarea unei cantitati mai mult sau mai putin exact masurate, dintr-o forma farmaceutica lichida sau solida multidoza.	Revised definition	dispozitiv de administrare a formelor farmaceutice lichide sau solide multidoză, prin măsurarea unei cantităţi mai mult sau mai puţin exacte.
6	Current	***Dabbing applicator***	***Aplicator pentru tamponare***	Closure with dabbing device.	Sistem de inchidere cu dispozitiv pentru tamponare		sistem de închidere cu dispozitiv pentru tamponare.

7	Current - NEW	***Dose dispenser***	***Dozator***	Device for the dispensing of a specified quantity of a medicinal product, for example an automatic electronic counter. Comment Pre-filled pens, pre-filled syringes, inhalers, metering pumps, etc. are excluded	Dispozitiv pentru eliberarea unei cantitati specifice dintr-un medicament, ca de exemplu, un sistem electronic automat de numarare. Comentariu: stilou injector (pen) preumplut, seringa preumpluta, inhalator, pompa dozatoare sunt excluse.		
8	Current	***Dredging applicator***	***Aplicator pentru pudrare***	Closure with dredging device	Sistem de inchidere cu dispozitiv pentru pudrare		sistem de închidere cu dispozitiv pentru pudrare
9	Current	***Dropper applicator***	***Aplicator pentru picurare***	Screw cap with dropper.	Capac filetat cu picurator		capac filetat cu picurător.
10	**Deprecated**	***High pressure transdermal delivery device***	***dispozitiv transdermic de eliberare cu presiune mare***		utilizare nerecomandata inlocuit cu "**injector fara ac "**		
11	Current	***Inhaler***	***Inhalator***	Device for administration of a medicinal product for inhalation. Nebuliser is excluded	Dispozitiv de administrare a unui medicament prin inhalare. Exclus nebulizatorul	Revised definition	dispozitiv pentru administrarea unui medicament de inhalat. Este exclus nebulizatorul.
12	Current	***Injection needle***	***Ac pentru injectie***	Hollow needle with a locking device intended for the administration of liquid pharmaceutical forms.	ac gol în interior, cu dispozitiv de blocare, pentru administrarea formelor farmaceutice lichide	Revised definition	ac gol în interior, cu dispozitiv de fixare, pentru administrarea formelor farmaceutice lichide.

13	Current	***Injection syringe***	***Seringă***	Administration device, cylindrical, with a cannula-like nozzle, with or without a fixed needle, and a movable piston with piston rod used for the administration, usually parenteral, of an accurately measured quantity of a liquid pharmaceutical form.	Dispozitiv de administrare cilindric, cu un vârf gen canulă, cu sau fără ac fix and cu un piston mobil cu tijă, utilizat pentru administrarea parenterală cu acuratete, a unei cantităţi măsurate, dintr-o formă farmaceutică lichidă		dispozitiv de administrare cilindric, cu un vârf gen canulă, cu sau fără ac fix and cu un piston mobil cu tijă, utilizat pentru administrarea parenterală a unei cantităţi măsurată cu acurateţe, dintr-o formă farmaceutică lichidă
14	Current	***Measuring device***	***Dispozitiv de masurat***	Device for the administration of a measured quantity of a product. Only to be used when other terms are not applicable.	Dispozitiv pentru administrarea unor cantităţi măsurate de medicament; se utilizează numai când nu se pot aplica alţi termeni		dispozitiv pentru administrarea unor cantităţi măsurate de medicament; se utilizează numai când nu sunt aplicabili alţi termeni
15	Current	***Measuring spoon***	***Lingurita dozatoare***	Spoon for the administration of liquid and multidose solid pharmaceutical forms	Linguriţă pentru administrarea formelor farmaceutice lichide and solide multidoză.		linguriţă pentru administrarea formelor farmaceutice lichide and solide multidoză.
16	Current	***Mouthpiece***	***Aplicator bucal***	Aid used for the administration or inhalation of a medicinal product by mouth	Dispozitiv ajutător pentru administrarea sau inhalarea unui medicament prin gură		dispozitiv ajutător pentru administrarea sau inhalarea unui medicament pe gură
17	Current	***Multipuncturer***	***Initial: Dispozitiv multipunctional Revised: Dispozitiv pentru puncții multiple***	Device for puncturing the skin, normally used for immunological products, especially diagnostics	Dispozitiv pentru strapungerea pielii utilizat in mod normal pentru produse imunologice, in special pentru diagnostic.	Revised definition	dispozitiv pentru punctionarea pielii, de obicei utilizat pentru medicamentele imunologice, in special pentru diagnosticare
18	Current	***Nasal applicator***	***Aplicator nazal***	Aid used for the administration of a drug by nose	Dispozitiv ajutător pentru administrarea unui medicament prin nas		

19	Current	***Nebuliser***	***Nebulizator***	Device for converting liquids into aerosols. Pressurised containers are excluded.	Dispozitiv pentru transformarea lichidelor in aerosoli. Sunt excluse recipientele sub presiune.	Revised definition	aparat pentru transformarea lichidelor în aerosoli; sunt excluse flacoanele presurizate
20	Current - NEW	***Needle-free injector***	***Injector fara ac***	Device for injecting a medicinal product, usually a liquid, by means of high pressure without a needle, through the skin barrier. This term replaces 'High-pressure transdermal delivery device'	Dispozitiv de injectare a unui medicament, de obicei lichid, cu ajutorul unei presiuni mari, fara ac, prin bariera de la nivelul pielii. Acest termen inlocuieste termenul **"dispozitiv transdermic de eliberare cu presiune mare"**		
21	Current	***Nozzle***	***Varf aplicator***	Aid for the directed/targetted administration of a liquid or a semi-solid preparation to a specific site	Dispozitiv ajutator pentru administrarea directa / tintita a unui lichid sau preparat semisolid intr-un anumit loc.	Revised definition	ajută la administrarea directă/ ţintită a unui preparat lichid sau semisolid, într-o parte specifică a corpului.

22	Current - NEW	***Oral applicator***	***Aplicator oral***	Administration device for administering a liquid or semi-solid pharmaceutical form to the oral cavity. This term may be used to describe an oral syringe in cases where there is a risk of administration error, e.g. where a similar product is often administered by injection, such as with vaccines. It may contain one or more components necessary for the preparation of the final product (e.g. the solvent), but it does not contain the final preparation or all of its components; in such cases, use 'Pre-filled oral applicator' instead.	Dispozitiv pentru administrarea unei forme farmaceutice lichide sau semisolide in cavitatea orala. Termenul poate fi utilizat pentru descrierea unei seringi orale atunci cand exista riscul unei erori de administrare, de exemplu cand un produs similar este administrat adesea prin injectie, ca de exemplu vaccinurile. Poate contine una sau mai multe componente necesare pentru prepararea produsului final (de ex. solventul), dar nu contine preparatul final sau toate conponentele sale. In astfel de cazuri se utilizeaza termenul "*aplicator oral preumplut*"		

23	Current - NEW	***Oral syringe***	***Seringă orală***	Administration device for administering a liquid or semi-solid pharmaceutical form to the oral cavity. It may contain one or more components necessary for the preparation of the final product (e.g. the solvent), but it does not contain the final preparation itself or all of its components; in such cases, use 'Pre-filled oral syringe' instead. Comment For certain products that are usually associated with administration by injection, such as vaccines, the term 'Oral applicator' may be used instead in order to reduce any risk of administration by injection	Dispozitiv pentru administrarea unei forme farmaceutice lichide sau semisolide in cavitatea orala. Poate contine una sau mai multe componente necesare pentru prepararea produsului final (de ex. solventul), dar nu contine preparatul final sau toate componentele sale. In astfel de cazuri se utilizeaza termenul „seringă orală preumplută". *Comentariu*: pentru anumite produse care se asociaza de obicei cu administrarea prin injectie, cum ar fi vaccinurile, poate fi utilizat termenul "aplicator oral" pentru a reduce orice risc de administrare prin injectie.		
24	Current	***Pipette***	***Pipetă***	Administration device, tubular, used for the administration in drops or in accurately measured quantity of liquid pharmaceutical forms	Dispozitiv de administrare tubular, utilizat pentru administrarea în picături sau a unei cantitati precis masurate din formele farmaceutice lichide	Revised definition	dispozitiv de administrare tubular, utilizat pentru administrarea în picături sau pentru măsurarea cu acurateţe a formelor farmaceutice lichide
25	Current	***Prick test applicator***	***Initial: Aplicator pentru teste cu alergene prin intepare*** ***Revised: Aplicator***	Device for prick testing of allergen products	Dispozitiv pentru testarea prin înţepare a produselor alergene		dispozitiv pentru testarea prin înţepare a produselor alergene.

			pentru teste prin intepare				
26	Current	***Spatula***	***Spatulă***	Administration device with a flattened side used for the application of semi-solid pharmaceutical forms	Dispozitiv de administrare, cu o parte netedă, utilizat pentru aplicarea formelor farmaceutice semisolide		dispozitiv de administrare, cu o parte netedă, utilizat pentru aplicarea formelor farmaceutice semisolide.

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CLOSURE SYSTEMS

		Standard Terms		**EDQM Definition**	**Definition status**	**Initial definition**	**Revised definition**
		English	***Romanian***				
1	Current	***Brush applicator***	***Initial: Aplicator tip pensula Revised: sistem de inchidere cu pensula***	Closure with brush device	revised definition	sistem de inchidere cu dispozitiv cu pensula	sistem de inchidere cu un dispozitiv tip pensula

2	Current	***Cap***	***Capac fara filet***	Hollow object without screw thread, mostly cylindrical, meant to close a container.	revised definition	obiect de închidere cilindric, de formă concavă, gol pe dinăuntru, fără filet.	Obiect gol pe dinăuntru, fără filet, mai ales cilindric, destinat închiderii unui recipient
3	Current	***Child-resistant closure***	***Sistem de inchidere securizat pentru copii***	A closure which is difficult for young children to open but which is not difficult for adults to open properly.	revised definition	sistem de închidere greu de deschis de către copiii mici, dar uşor de deschis de adulţi	sistem de închidere greu de deschis de către copiii mici, dar pe care adulţii îl pot deschide în mod corespunzător, fără dificultate
4	Current	***Metering pump***	***Pompa dozatoare***	Closure whereby a measured quantity of the contents is supplyd by mechanical actuation of the pump.	revised definition	sistem de închidere cu dispozitiv de dozare	sistem de inchidere prin care o cantitate masurata din continut este eliberata prin actionarea mecanica a pompei
5	Current	***Metering valve***	***Valva dozatoare***	Closure whereby a measured quantity of the contents is supplyd by actuation of the valve	revised definition	sistem de închidere prin care o doză măsurată din conţinut este eliberată prin acţionarea valvei	sistem de inchidere prin care o cantitate masurata din continut este eliberata prin actionarea mecanica a valvei
6	Current	***Needle applicator***	***Initial: aplicator cu ac*** ***Revised: Sistem de inchidere cu ac***	Closure with a needle			Sistem de inchidere prevazut cu ac
7	Current	***Pipette applicator***	***Initial: aplicator tip pipeta*** ***Revised: sistem de inchidere cu pipeta***	Closure with pipette			Sistem de inchidere prevazut cu pipeta
8	Current	***Screw cap***	***Capac cu filet***	Hollow cylindrical object with screw thread, meant to close a container		obiect de închidere cilindric, de formă concavă, gol pe dinăuntru, cu filet	Obiect gol pe dinăuntru, cu filet, mai ales cilindric, destinat închiderii unui recipient

9	Current	***Spray pump***	***Pompa de pulverizare***	Closure whereby the contents are supplyd as a spray by mechanical actuation of the pump.	revised definition	sistem de inchidere prin care continutul este eliberat prin actionarea mecanica a pompei	Sistem de inchidere prin care continutul este eliberat sub forma de aerosol prin actionarea mecanica a pompei
10	Current	***Spray valve***	***Valva de pulverizare***	Closure whereby the contents are supplyd as a spray by mechanically actuation of the valve		sistem de închidere prin care conţinutul este eliberat sub formă de aerosol prin acţionarea mecanică a valvei	Sistem de închidere prin care conţinutul este eliberat sub formă de aerosol prin acţionarea mecanică a valvei
11	Current	***Stopper***	***Dop***	More or less solid cylindrical or conical object meant to close a container by insertion	revised definition	obiect de închidere de regulă solid, de formă conică sau cilindrică, utilizat pentru închiderea recipientelor prin inserţie.	Obiect mai mult sau mai putin solid, de formă conică sau cilindrică, utilizat pentru închiderea recipientelor prin inserţie.
12	Current-NEW	***Valve***	***Valvă***	Closure that regulates the supply of the contents from a container (e.g. a gas cylinder) by adjusting the opening of the exit duct, usually allowing a continuous flow of the contents out of the container; a device that controls the movement of the valve may be incorporated. 'Metering valve' and 'Spray valve' are excluded.			Sistem de inchidere care regleaza eliberarea continutului unui recipient (de exemplu un cilindru cu gaz) prin ajustarea deschiderii unui tub de iesire, permițând de obicei un flux continuu al conținutului; se poate încorpora un dispozitiv care controlează mișcarea valvei. Sunt excluse "valva dozatoare" and "valva de pulverizare"

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PACKAGING

No.	Status	*Standard Term*		EDQM Definition	Definition status	Initial definition	Current definition
		English	***Romanian***				
1	Current	***Ampoule***	***Fiolă***	Container sealed by fusion and to be opened exclusively by breaking. The contents are intended for use on one occasion only.	IDENTICAL	recipient închis prin termosudaresi care este deschis exclusiv prin rupere; conţinutul este destinat unei utilizări unice.	Recipient închis prin termosudaresi care este deschis exclusiv prin rupere; conţinutul este destinat unei utilizări unice

2	Current	***Bag***	***Pungă***	Container consisting of surfaces, whether or not with a flat bottom, made of flexible material, generally closed at the bottom and at the sides by sealing; at the top possibly to be closed by fusion of the material, depending on the intended use. Equipped with special attachments. Contains the final preparation in one compartment or the components necessary for its preparation in different compartments.	revised definition	ambalaj constituit din material flexibil cu sau fără bază plată, închis prin sigilare la bază and pe părţile laterale; partea superioară poate fi închisă prin diverse procedee (exemplu: termosudare), în funcţie de intenţia de utilizare.	Recipient din material flexibil, cu sau fără bază plată,în general închis la bază and pe părțile laterale prin sigilare; partea superioară poate fi închisă prin termosudarea materialului, în funcţie de intenţia de utilizare. Echipat cu accesorii speciale. Conține preparatul final într-un compartiment sau componentele necesare preparării acestuia în compartimente diferite
3	Current	***Barrel***	***Bidon***	Container of large size, suited for liquid, solid and semi-solid pharmaceutical forms.		recipient de dimensiune mare, utilizat pentru formele farmaceutice lichide, solide and semisolide	recipient de dimensiune mare, utilizat pentru formele farmaceutice lichide, solide and semisolide
4	Current	***Blister***	***Blister***	Container (usually multidose) consisting of two layers of which one is shaped to contain the individual doses. Strips and unit-dose blisters are excluded.	revised definition	ambalaj (de obicei, multidoză) constând din două straturi, dintre care unul este configurat pentru a conţine dozele; sunt excluse foliile termosudate.	ambalaj (de obicei, multidoză) constând din două straturi, dintre care unul este configurat pentru a conţine dozele individuale; sunt excluse foliile termosudate and blisterele doze unitare.
5	Current	***Bottle***	***Flacon***	Container with a more or less pronounced neck and usually a flat bottom.		recipient cu sau fără gât, de obicei cu baza plată.	recipient cu gât, de obicei cu baza plată
6	Current	***Box***	***Box***	Primary container consisting of one or more parts made of a light material, can be closed.		ambalaj primar format din una sau mai multe părţi din material uşor, care poate fi închis	ambalaj primar format din una sau mai multe părţi din material uşor, care poate fi închis

7	**Rejected**	***Calendar package***		**Term rejected. The specific characteristics of the packaging should be described in the product information.**			**Termen Rejected. Caracteristicile specifice ale ambalajului trebuie descrise în informțiile despre medicament**
8	Current	***Cartridge***	***Cartridge***	Usually cylindrical, suited for liquid or solid pharmaceutical forms; usually to be used in an apparatus especially designed for that purpose. It contains the final preparation in one compartment, or the components necessary for its preparation in different compartments.	revised definition	recipient de regulă cilindric, destinat formelor farmaceutice lichide sau solide, utilizat de obicei cu un aparat special	recipient de regulă cilindric, destinat formelor farmaceutice lichide sau solide, utilizat de obicei într-un aparat special destinat acestui scop. Conține preparatul final într-un compartiment, sau componentele necesare preparării acestuia în compartimente diferite
9	Current	***Container***	***Recipient***	An item of packaging that is used for the storage, identification and/or transport of a medicinal product. Only to be used where more-specific terms do not apply. Specific characteristics of the container are defined in the product information of the medicinal product.			Ambalaj utilizat pentru depozitarea, identificarea și/sau transportul unui medicament. Se folosește numai când nu pot fi utilizați termeni mai specifici. Caracteristicile specifice ale recipientului sunt definite in informațiile despre medicament
10	Current-NEW	***Dose-dispenser cartridge***	***Cartuș dozator***	Container intended for use in a dose dispenser, usually pre-filled with a medicinal product.			Recipient destinat utilizării într-un dispozitiv dozator, de obicei preumplut cu un medicament
11	Current	***Dredging container***	***Initial: Flacon de pudrat Revised: Recipient pentru pudrare***	Container for a pharmaceutical form to be applied by dredging.			recipient pentru o formă farmaceutică care se aplică prin pudrare
12	Current	***Dropper container***	***Initial: Flacon picurător Revised: Recipient***	A container, usually a bottle, fitted with a dropper applicator			recipient, de obicei flacon, prevăzut cu aplicator pentru picurare

			picurator				
13	Current	***Fixed cryogenic vessel***	***Recipient criogenic fix***	A static thermally insulated container designed to maintain the contents in the liquid state			recipient static izolat termic, destinat menţinerii conţinutului în stare lichidă.
14	Current	***Gas cylinder***	***Butelie pentru gaz***	Container usually cylindrical suited for compressed, liquefied or dissolved gas, fitted with a device to regulate the spontaneous outflow of gas at atmospheric pressure and room temperature.			recipient, de regulă cilindric, pentru gaz comprimat, lichefiat sau dizolvat, prevăzut cu un sistem de reglare a jetului de gaz la presiunea atmosferică and temperatura camerei.
15	Current	***Jar***	***Borcan***	Container, without a pronounced neck, with a wide opening at the top and a more-or-less flat bottom. It is suited for semi-solid and solid pharmaceutical forms (including those that are stored/supplied in a liquid medium, such as living tissue equivalents). It can be reclosed.	revised definition	recipient fără gât proeminent, cu deschidere mare în partea superioară and cu baza plată, indicat pentru formele farmaceutice semisolide and solide; poate fi reînchis	recipient fără gât proeminent, cu deschidere mare în partea superioară and cu baza plată, indicat pentru formele farmaceutice semisolide and solide (inclusiv cele care se depozitează/livrează în mediu lichid, ca de exp. echivalentele de țesut viu; poate fi reînchis
16	Current	***Mobile cryogenic vessel***	***Recipient criogenic mobil***	A mobile thermally insulated container designed to maintain the contents in a liquid state.		recipient mobil izolat termic, destinat menţinerii conţinutului în stare lichidă.	recipient mobil izolat termic, destinat menţinerii conţinutului în stare lichidă.
17	Current	***Multidose container***	***Recipient multidoză***	A container holding a quantity of the preparation suitable for 2 or more doses			recipient care conţine o cantitate de preparat corespunzătoare pentru 2 sau mai multe doze
18	Current	***Multidose container with airless pump***	***Recipient multidoză cu pompă pentru împiedicarea pătrunderii aerului***	Multidose container with an integral pump designed to protect the contents against in use-contamination.			recipient multidoză, cu o pompă integrată, destinată protejării conţinutului împotriva pătrunderii aerului în timpul utilizării

19	Current	***Multidose container with metering pump***	***Recipient multidoză cu pompă dozatoare***	Multidose container with integral metering pump.			recipient multidoză cu pompă dozatoare integrată
20	Current	***Multidose container with pump***	***Recipient multidoza cu pompa***	Multidose container with an integral pump. Metering pump, spray pump, and multidose container with airless pump are excluded.			Recipient multidoză cu pompă integrată. Sunt excluse: pompa dozatoare, pompa de pulverizare si recipientul multidoză cu pompă pentru împiedicarea pătrunderii aerului
21	**Rejected**	***Pack***		**Term rejected. Items of outer packaging that enclose the immediate container(s) are not within the scope of Standard Terms.**			Termen Rejected. Ambalajele exterioare care cuprind ambalajele primare nu intră în domeniul de aplicare al Termenilor Standard
22	Current	***Pre-filled gastroenteral tube***	***Initial: Tub gastroenteral preumplut Revised: Tub gastrointestinal preumplut***	Pre-filled tube for the administration of a medicinal product to the gastroenteral tract.			tub preumplut pentru administrarea medicamentului în tractul gastrointestinal.
23	Current-NEW	***Pre-filled injector***	***Injector preumplut***	Filled container, usually fitted with an injection needle, containing a sterile, single-dose parenteral preparation. This term is only to be used when a more-specific term such as 'Pre-filled syringe' or 'Pre-filled pen' is not appropriate. Comment This term may be used to describe, for example, an item of packaging that is intended to be used by puncturing the skin and squeezing a small reservoir			Recipient umplut. De obicei prevăzut cu un ac pentru injecție, care conține un preparat parenteral steril, unidoză. Acest termen trebuie să se folosească numai atunci când utilizarea unui termen mai specific, cum ar fi "seringă preumplută" sau " stilou injector (pen) preumplut" nu este adecvată. Comentariu: Acest termen poate fi folosit să descrie un ambalaj destinat

				to administer its contents.			utilizării prin străpungerea pielii and acumularea unui mic rezervor pentru administrarea continutului său
24	Current-NEW	***Pre-filled oral applicator***	***Aplicator oral preumplut***	Filled container for administering a liquid or semi-solid pharmaceutical form to the oral cavity, containing the final preparation in one compartment, or the components necessary for its preparation in different compartments. This term may be used to describe a pre-filled oral syringe in cases where there is a risk of administration error, e.g. where a similar product is often administered by injection, such as with vaccines.			Recipient umplut pentru administrarea unei forme farmaceutice lichide sau semisolide în cavitatea orală, care conține preparatul final într-un compartiment, sau componentele necesare preparării acestuia în compartimente diferite. Acest termen poate fi utilizat să descrie o seringă preumplută pentru administrare orală atunci când există un risc de eroare de administrare, de exemplu când un produs similar este administrat prin injecție, cum sunt vaccinurile
25	Current	***Pre-filled pen***	***Stilou injector (pen) preumplut***	Filled container consisting for example, of a cartridge, fitted with an injection needle. The cartridge contains a sterile single-dose or multidose parenteral preparation. It contains the final preparation in one compartment, or the components necessary for its preparation in different compartments.			Recipient umplut care constă, de exemplu, dintr-un cartuș prevăzut cu un ac pentru injecție. Cartușul conține un preparat steril unidoză sau multidoză. Conține preparatul final într-un compartiment, sau componentele necesare preparării acestuia în compartimente diferite.

26	Current-NEW	***Pre-filled oral syringe***	***Seringa preumpluta pentru administrare orala***	Filled container for administering a liquid or semi-solid pharmaceutical form to the oral cavity, containing the final preparation in one compartment, or the components necessary for its preparation in different compartments. Comment For certain products that are usually associated with administration by injection, such as vaccines, the term 'Pre-filled oral applicator' may be used instead in order to reduce any risk of administration by injection.			Recipient umplut pentru administrarea unei forme farmaceutice lichide sau semisolide in cavitatea orala, continand preparatul final intr-un compartiment, sau componentele necesare prepararii acestuia in compartimente diferite. Comment: Pentru unele produse care sunt asociate cu administrarea prin injectie, ca de exemplu vaccinurile, termenul de "aplicator oral preumplut" poate fi utilizat pentru a reduce orice risc de administrare prin injectie.
27	Current	***Pre-filled syringe***	***Seringa preumpluta***	Filled container, generally supplied with an injection needle. It contains a sterile single-dose or multidose parenteral preparation. It contains the final preparation in one compartment, or the components necessary for its preparation in different compartments.	revised definition	seringă ce conţine o doză sau mai multe doze din medicament.	Recipient umplut, în general livrat cu un ac pentru injecție. Conține preparatul final într-un compartiment, sau componentele necesare preparării acestuia în diferite compartimente

28	Current	***Pressurised container***	***Initial: Flacon presurizat revised: Recipient presurizat***	Container suited for compressed, liquefied or dissolved gas fitted with a device to enable, after its actuation, a controlled spontaneous supply of the contents at atmospheric pressure and room temperature.		recipient adecvat conţinând gaz comprimat, lichefiat sau dizolvat, prevăzut cu un sistem capabil să elibereze spontan după apăsare, o cantitate din conţinut, la presiunea atmosferică and temperatura camerei.	Recipient adecvat pentru gaze tablets, lichefiate sau dizolvate, prevăzut cu un sistem capabil să elibereze după actionarea sa, o cantitate controlata din conţinut, la presiunea atmosferică and temperatura camerei.
29	Current	***Roll-on container***	***Recipient cu bila***	A container, usually a bottle, fitted with a roll-on applicator		Un recipient, de obicei un flacon, prevăzut cu aplicator cu bilă (roll-on).	Un recipient, de obicei un flacon, prevăzut cu aplicator cu bilă (roll-on).
30	Current	***Sachet***	***Plic***	Container consisting of two surfaces made of flexible material to be closed only by sealing or folding over. The contents are intended for single use.	revised definition	ambalaj constituit din două feţe din material flexibil, închise numai prin sigilare (foarte rar prin pliere); conţinutul este destinat unei singure administrări	Ambalaj constituit din două feţe din material flexibil, închise numai prin sigilare sau prin pliere. Conţinutul este destinat unei singure administrări
31	Current	***Single-dose container***	***Recipient unidoza***	A container that holds a quantity of the preparation intended for total or partial use on one occasion only	revised definition	recipient care conţine o cantitate de preparat (solid, semisolid sau lichid) destinat pentru o singură administrare.	Recipient care conţine o cantitate de preparat destinat utilizării totale sau parţiale intr-o singură administrare.
32	Current	***Spray container***	***Initial: Flacon pulverizator Revised: Recipient pulverizator***	Container for a liquid pharmaceutical form to be converted into a spray by mechanical means.			Recipient pentru o formă farmaceutică lichidă care se transformă în aerosol prin mijloace mecanice
33	Current	***Straw***	***Pai***	Hollow tube containing a single dose of a medicinal product for oral administration by sucking		tub cilindric care conţine o singură doză de medicament, administrat oral, prin supt	Tub cilindric care conţine o singură doză de medicament, administrat oral, prin supt
34	Current	***Strip***	***Folie termosudata***	Multidose container consisting of two layers, usually provided with perforations, suited for containing single doses of solid or semi-solid preparations. Blisters are excluded.	revised definition	ambalaj multidoză format din două straturi, destinate condiţionării preparatelor solide sau semisolide unidoze; sunt excluse blisterele	Ambalaj multidoză format din două straturi, de obicei prevăzut cu perforaţii, destinat condiţionării preparatelor solide sau semisolide unidoza; sunt excluse blisterele

35	Current	***Tablet container***	***Flacon pentru tablets***	Container without neck and with a flat bottom, suited for tablets, capsules, etc., can be re-closed well.		recipient fără gât and cu baza plată, utilizat pentru tablets, capsule, etc.si care poate fi reînchis bine.	Recipient fără gât and cu baza plată, utilizat pentru tablets, capsule, etc.si care poate fi reînchis bine.
36	Current	***Tube***	***Tub***	Container for semi-solid pharmaceutical forms, usually multidose, consisting of collapsible material intended to supply the contents via a nozzle by squeezing the package	revised definition	recipient pentru condiţionarea formelor farmaceutice semisolide multidoze, constituit dintr-un material compresibil care să elibereze conţinutul prin presare.	Recipient pentru condiţionarea formelor farmaceutice semisolide, de obicei multidoză, constituit dintr-un material compresibil care să elibereze conţinutul printr-un orificiu, prin presare.
37	Current - NEW	***Unit - dose blister***	***Blister doze unitare***	Container consisting of two layers of which one is shaped to contain the individual unit, usually provided with perforations, the intention being to allow each individual unit to be separated for single unit administration. All the information required for blister packs must appear on each unit dose presentation. Blisters and strips are excluded.			Ambalaj care constă din două staturi din care unul conține unitatea individuală, de obicei prevăzut cu perforații, intenția fiind de a permite fiecărei doze individuale să fie separată pentru administrarea unei sigure unități. Toate informațiile cerute pentru blister trebuie să apară pe forma de prezentare a fiecărei doze. Blisterele and foliile termosudate sunt excluse
38	Current	***Vial***	***Flacon***	Small container for parenteral medicinal products, with a stopper and overseal; the contents are removed after piercing the stopper. Single-dose and multidose uses are included.		recipient mic pentru medicamentele parenterale, cu dop and închise etanş, conţinutul fiind extras prin perforarea dopului; sunt incluse flacoanele unidoză and multidoză	Recipient mic pentru medicamente parenterale, cu dop and capsa detasabila; conţinutul este extras prin perforarea dopului. Sunt incluse flacoanele unidoză and multidoză.

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DECISION

no. 5 /24.10.2017
on approval of change of supply classification status for Benfogamma 50 mg, lozenges (benfotiaminum)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 24.10.2017, in accordance with provisions of 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, hereby adopts the following

DECISION

Sole Article - Change of supply classification status from on-prescription to OTC medicinal product is hereby approved for **Benfogamma 50 mg, lozenges (benfotiaminum)**, Marketing Authorisation Holder: WORWAG PHARMA GMBH & CO. KG - GERMANY, subject to the following conditions:

1. package size: Box x 3 blist. PVC-PVDC/Al x 10 lozenges
2. indications restricted to:
   - prevention of B1 vitamin deficit
3. change of trade name.

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

Prof Anca-Dana Buzoianu, MD, PhD

DECISION

no. 6 /24.10.2017
on rejection of the application concerning change of supply classification status for Dona 1500 mg, powder for oral suspension (glucosaminum)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 24.10.2017, in accordance with provisions of 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, hereby adopts the following

DECISION

Sole Article - Change of supply classification status from on-prescription to OTC medicinal product is hereby rejected for **DONA 1500 mg (GLUCOSAMINUM)**, **powder for oral suspension**, Marketing Authorisation Holder: MEDA PHARMA GMBH & CO. KG – GERMANY.

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

Prof Anca-Dana Buzoianu, MD, PhD

DECISION

no. 7 /24.10.2017
on approval of change of supply classification status for Eptavit 2500 mg/880 UI, effervescent tablets (combinations)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 24.10.2017, in accordance with provisions of 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, hereby adopts the following

DECISION

Sole Article - Change of supply classification status from on-prescription to OTC medicinal product is hereby approved for **Eptavit 2500 mg/880 UI, effervescent tablets (combinations),** Marketing Authorisation Holder: BIOCODEX - FRANCE, in următoarele condiții:

1. package size: Box x 1 PP tube x 15 efferv. tabl.
2. Indications restricted to:

- vitamin-calcium intake in patients at high vitamin-calcium deficit risk
- change of trade name.

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

Prof. Anca-Dana Buzoianu, MD, PhD

DECISION

no. 8 /24.10.2017
on approval of change of supply classification status for Erdomed 225 mg, granules for oral suspension (erdosteinum)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 24.10.2017, in accordance with provisions of 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, hereby adopts the following

DECISION

Sole Article - Change of supply classification status from on-prescription to OTC medicinal product is hereby approved for Erdomed 225mg, granules for oral suspension **(**ERDOSTEINUM**)**, Marketing Authorisation Holder: ANGELINI PHARMA ÖSTERREICH GMBH - AUSTRIA, subject to the following conditions:

- package size: Box of 10 Al/PE sachets
- change of trade name.

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

Prof Anca-Dana Buzoianu, MD, PhD

DECISION

no. 9 /24.10.2017
on approval of change of supply classification status for Lagosa 150 mg, lozenges (silibinum)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 24.10.2017, in accordance with provisions of 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, hereby adopts the following

DECISION

Sole Article - Change of supply classification status from on-prescription to OTC medicinal product is hereby approved for **Lagosa 150 mg, lozenges (silibinum)**, Marketing Authorisation Holder: WORWAG PHARMA GMBH & CO. KG - GERMANY, subject to the following conditions:

1. package size: Box cu 1 blist. Al/PVC x 25 lozenges
2. indications restricted to: exposure to hepatotoxic substances
3. change of trade name.

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

Prof Anca-Dana Buzoianu, MD, PhD

DECISION

no. 10 /24.10.2017
on rejection of the application concerning change of supply classification status for
OMACOR 1000 mg, soft capsules (omega 3 acid ethyl ester 90)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 24.10.2017, in accordance with provisions of 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, hereby adopts the following

DECISION

Sole Article - Change of supply classification status from on-prescription to OTC medicinal product is hereby rejected for **OMACOR 1000 mg, soft capsules (OMEGA 3 ACID ETHYL ESTER 90)**, Marketing Authorisation Holder PRONOVA BIOPHARMA NORGE AS – NORWAY.

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

Prof Anca-Dana Buzoianu, MD, PhD

DECISION

no. 11 /24.10.2017
on rejection of the application concerning change of supply classification status for Robitussin junior 3.75 mg/ 5 ml, oral solution and Robitussin antitussicum 7.5 mg / 5 ml oral solution (dextromethorphanum)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 24.10.2017, in accordance with provisions of 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, hereby adopts the following

DECISION

Sole Article - Change of supply classification status from on-prescription to OTC medicinal products is hereby rejected for **Robitussin junior 3.75 mg/ 5 ml, oral solution and Robitussin antitussicum 7.5 mg / 5 ml oral solution (dextromethorphanum),** Marketing Authorisation Holder: PFIZER CORPORATION AUSTRIA GMBH – AUSTRIA**.**

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

Prof Anca-Dana Buzoianu, MD, PhD

DECISION

no. 12/24.10.2017
on approval of change of supply classification status for Vigantoletten 500 UI, tablets and Vigantoletten 1000 UI (colecalciferolum)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 24.10.2017, in accordance with provisions of 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, hereby adopts the following

DECISION

Sole Article - Change of supply classification status from on-prescription to OTC medicinal product is hereby approved for **Vigantoletten 500 UI, tablets and Vigantoletten 1000 UI (colecalciferolum)**, Marketing Authorisation Holder: MERCK KGAA – GERMANY, subject to the following conditions:

1. package size: Box cu 1 blist. Al/PVC x 15 tablets
2. indications restricted to:
- for prophylaxis of rickets in children
- for prophylaxis of vitamin D deficiency in children and adults with an identified risk
3. change of trade name

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

Prof Anca-Dana Buzoianu, MD, PhD

DECISION

NO. 1/19.12.2017

on approval of the Guideline on Excipients in the labelling and package leaflet of medicinal products for human use

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 19.12.2017, in accordance with provisions of 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, hereby adopts the following

DECISION

Sole Article – Adoption of the Guideline on Excipients in the labelling and package leaflet of medicinal products for human use, in accordance with the Annexes, which are integral part of this Decision.

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

Prof Anca-Dana Buzoianu, MD, PhD

ANNEX
to SCD no. 1/19.12.2017

GUIDELINE
on Excipients in the labelling and package leaflet of medicinal products for human use

Note:
The Annex to this Decision is a translation into Romanian and an adaptation of the EMA/CHMP/302620/2017 document Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668) - Excipients and information for the package leaflet.
Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.
Therefore, for the Annex to this Decision, please see the document Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use', available at
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003412.pdf

DECISION

No. 4/19.12.2017
on approval of change of supply classification status for Bilobil 40 mg capsules, Bilobil Forte 80 mg capsules and Bilobil Intens 120 mg capsules (Ginkgo Biloba)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 19.12.2017, in accordance with provisions of 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, hereby adopts the following

DECISION

Sole Article - Change of supply classification status from on-prescription to OTC medicinal product is hereby approved for **Bilobil 40 mg capsule, Bilobil Forte 80 mg, Bilobil Intens 120 mg capsules (Ginkgo Biloba)**, Marketing Authorisation Holder: KRKA, d.d. Novo Nesto Slovenia, subject to the following conditions:

1. indications restricted to:
   - memory impairment, attention deficit,
   - decrease in intellectual abilities in the elderly,
   - anxiety and depression.
2. change of trade name.

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

Prof Anca-Dana Buzoianu, MD, PhD

DECISION

No. 5/19.12.2017
on approval of change of supply classification status
for
Diosmina Remedia 600 mg film-coated tablets
(diosminum)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 19.12.2017, in accordance with provisions of 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, hereby adopts the following

DECISION

Sole Article – Change of supply classification status from on-prescription to OTC medicinal product is hereby approved for **Diosmină Remedia 600 mg, film-coated tablets (diosminum)**, Marketing Authorisation Holder **Laboratoires Innothera**.

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

Prof Anca-Dana Buzoianu, MD, PhD

DECISION

No. 6/19.12.2017
on approval of change of supply classification status for Fucidin 20 mg/g, cream and Fucidin 20 mg/g, ointment (acidum fusidicum)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 19.12.2017, in accordance with provisions of 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, hereby adopts the following

DECISION

Sole Article – Change of supply classification status from on-prescription to OTC medicinal product is hereby approved for **Fucidin 20 mg/g, cream and Fucidin 20 mg/g, ointment (acidum fusidicum)**, Marketing Authorisation Holder: LEO Pharma A/S, subject to the following conditions:

1. indications restricted to:
- infected cuts/abrasions,
- boils,
- folliculitis.

2. change of trade name.

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

Prof Anca-Dana Buzoianu, MD, PhD

DECISION

no. 7/19.12.2017
on approval of the Guideline on the drafting of the marketing authorisation and related annexes

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 19.12.2017, in accordance with provisions of 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, hereby adopts the following

DECISION

Article 1. - The Guideline on the writing of the marketing authroisation and related annexes, is hereby approved in accordance with the Annexes, which are integral part of this Decision.

Article 2. - On entry into force of this Decision, SCD no. 21/03.09.2010 on approval of the Guideline on the drafting of the marketing authorisation and annexes to the marketing authorisation shall be repealed.

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

Prof Anca-Dana Buzoianu, MD, PhD

Guideline on the drafting of the marketing authroisation and related annexes

Article 1. – (1) This Guideline has been developed in accordance with provisions of Law No.
95/2006 on healthcare reform, republished as amended, Title XVIII – The medicinal product (hereinafter "the Law"), transposing Directive 2001/83/EC, as amended;
(2) This Guideline applies to medicinal products authorised for marketing in Romania through national, decentralised or mutual recognition procedure.
Article 2. – In accordance with Article 704 of the Law, transposing Article 6. of Directive 2001/83/EC, no medicinal product may be placed on the market of Romania unless a marketing authorisation has been issued by the National Agency for Medicines and Medical Devices (NAMMD) or by the European Medicines Agency (EMA).
Article 3. – This Guideline provides recommendations concerning the drafting of the marketing authorisation and annexes to the marketing authorisation, replacing previous related norms for medicinal products authorised by the NAMMD through national, decentralised or mutual recognition procedure.
Article 4. – Within the section on the legal grounds for marketing authorisation, a combination of the following legal bases is to be selected, as required: <Article 704 (1), <Article 706 (4)>, <Article 708 (1) and (2)>, <Article 708 (3)>, <Article 708 (4)>, <Article 709>, <Article 710>, <Article 711>, <Article 714>, <Article 718>, <Article 732>, <Article 738 (2)>, <Article 738 (4)>, <Article 743 (2)>, <Article 743 (3)> or <Article 743 (4)>.
Article 5. – (1) According to Article 738 (1) of the Law, marketing authorisations shall be valid for five years.
(2) The marketing authorisation shall contain the following specification: "This marketing authorisation is valid for 5 years as of the date of its issue".
Article 6. – (1) In accordance with Article 738 (4) of the Law, once renewed, the marketing authorisation is valid for an unlimited period, in which case the marketing authorisation shall not specify anything related to the validity of the marketing authorisation.
(2) Pursuant to Article 738 (2) of the Law, in cases where the National Agency for Medicines and Medical Devices decides on justified grounds relating to pharmacovigilance, including exposure of an insufficient number of patients to the medicinal product concerned, to proceed with one additional five-year renewal, the marketing authorisation shall make a specification of the 5-year validity thereof.
Article 7. – (1) Under the heading "Registration name", the trade name, including the strength and pharmaceutical form of the medicinal product shall be specified.
(2) In accordance with Article 699, point 22 of the Law, the trade name of the medicinal product may be an invented name not liable to confusion with the name

of a different medicinal product or a Non-proprietary or a scientific name, accompanied by the trademark or the name of the Marketing Authorisation Holder;
(3) The active substance included in the trade name of a medicinal product shall be written in Romanian;
(4) Not more than three active substances expressed as their respective INNs may be included in the trade name of a medicinal product, separated by „ / „;
(5) The trade name of medicinal products containing several active substances shall be an invented name;
(6) Trademarks shall be accepted based on inclusion of the certificate granted by the OSIM or other similar international bodies in medicinal product documentation and the Marketing Authorisation Holder's (MAH's) undertaking for compliance with certificate conditions and term of validity;
(7) Trade names shall be accepted compliant with national regulations in force;
(8) The strength is expressed in accordance with the "Guideline on the expression of strength in the tradename of medicinal products for human use", approved through Scientific Council Decision no. 11/07.06.2010;
(9) Strengths of medicinal products containing several active substances shall be followed by respective units of measurement and separated by „/", e.g., x mg/y mg;
(10) The registered mark symbol, ®, TM, is not included in medicinal product invented trade names;
(11) The pharmaceutical form shall be named in accordance with Regulations in force concerning the Romanian version of standard terms adopted by the European Pharmacopoeia Commission for pharmaceutical forms, routes of administration, closure systems and administration devices;
Article 8. – (1) The following shall be included in the marketing authorisation under the section "Composition": active substance(s) in terms of quality and quantity and auxiliary substance(s) in terms of quality, all in Romanian;
(2) The quantity of active substance is expressed per dosage unit, volume unit or weight unit, depending on the type of pharmaceutical form;
(3) Where the active substance(s) is present as a salt, ester, hydrated form etc., the quantity of the respective substance and its equivalent in anhydrous base are included;
(4) Components are included using their Non-proprietary name as recommended by the WHO or the scientific name according to the European Pharmacopoeia or a different international pharmacopoeia where the respective component holds official status (names of the components shall be entered in this order);
(5) For excipients, provisions of the European Pharmacopoeia or the Romanian Pharmacopoeia shall be applied, as required;
(6) For certain excipients, inclusion of the trade name next to the scientific name is allowed;
(7) For mixtures of excipients (e.g., coating films, sealant support layers), inclusion of the trade name is acceptable for composition, accompanied by specification of each component in European Pharmacopoeia terms;

Article 9. – The section “Marketing Authorisation Holder” shall include the full name and address of the Marketing Authorisation Holder, according to data stated in the marketing authorisation/marketing authorisation renewal dossier.
Article 10. – The section “Manufacturer(s)” shall include the name and address of the manufacturer(s) responsible for batch release in accordance with data stated in the marketing authorisation/marketing authorisation renewal dossier.
Article 11. – Where possible, the section “ATC Classification” shall include the ATC (Anatomic – Therapeutic – Chemical) code up to 5th level (chemical substance) of the World Health Organisation (WHO) ATC Index in force.
Article 12. – The section “Supply” requires ticking of the option corresponding to medicinal product classification for supply.
(2) A marketing authorisation for a medicinal product shall specify a single type of classification for supply, i.e. either "prescription" or "non-prescription".
Article 13. – The section “Packaging”, shall include information on immediate packaging (type of packaging, material, closure system) intermediary packaging, outer packaging administration device(s) included and package size.
a) E.g.:
Box with 2 Al/PVC 10-tablet blisters
b) E.g.:
Box with one brown glass vial with child resistant closure system, containing 100ml syrup, box, together with a syringe for oral administration.
Article 14. - The section “Shelf life” shall indicate the shelf life of the medicinal product after packaging for commercial use specified in years/months where specification in years is not feasible) as well as the shelf life after the first opening (if necessary).
Article 15. – (1) The section “Storage conditions” shall specify medicinal product storage conditions as resulting from assessment of stability studies conducted on the finished product; mention of other specific storage statements relevant for the medicinal product Package Leaflet and Labelling is not mandatory.
Article 16. – The section "Other conditions and requirements of the marketing authorisation/Periodic safety update reports" shall include the requirement concerning submission of Periodic Safety Update Reports;
(2) Where the active substance or combination of active substances is found in the List of Union reference dates and frequency of submission of periodic safety update reports (the EURD list) referred to in Article 838 (7) of the Law, the first paragraph of Annex no. II to this Decision shall be only included;
(3) Where the active substance or combination of active substances is not included in the EURD list, a Periodic Safety Update Reports submission frequency and date shall be established in accordance with provisions of Article 838 (2) and paragraph (3) of the Law; this section shall only include the second paragraph of Annex no. II to this Decision.
Article 17. - The section "Conditions or restrictions with regard to the safe and effective use of the medicinal product" shall make reference to the Risk Management Plan mentioned in m) (4) and (6) of Article 706 of the Law and to Additional risk minimization measures, if established.

Article 18. - The section "Specific obligation to complete post-authorisation measures for the marketing authorisation under exceptional circumstances" shall only be included where the marketing authorisation has been granted under exceptional conditions, according to provisions of Article 732 of the Law.
Article 19. – Where studies have been conducted in accordance with Paediatric Investigation Plans, the section "Summary of Product Characteristics" shall specify that "The paediatric studies mentioned in section 5.1 Pharmacodynamic properties of the Summary of Product Characteristics have been performed in accordance with the Paediatric Investigation Plan agreed by the EMA Paediatric Committee (PDCO)".
Article 20. – Annex 1 to the marketing authorisation (the leaflet) shall be drafted in accordance with provisions of Article 781 of the Law, transposing Article 59 of Directive 2001/83/EC, while mentioning that the section "Manufacturer" data shall be included related to the name and address of the manufacturer(s) responsible for finished product batch release;
Article 21. – Annex 2 to the marketing authorisation (the Summary of Product Characteristics) shall be drafted pursuant to provisions of Article 712 of the Law, transposing Article 11 of Directive 2001/83/EC.
Article 22. – (1) Information mentioned in Annex 3 to the marketing authorisation ("Labelling and Package Leaflet") refers to immediate, intermediate and outer packaging of medicinal products; inscription of immediate, intermediate and outer packaging is performed based on provisions of Article 774 and Article 7775 of the Law, transposing Article 54 and Article 55 of Directive 2001/83/EC, respectively;
(2) Where the trade name includes of the International Non-proprietary Name or scientific name, the name of the active substance shall be given in Romanian, except for packaging for which writing in several languages has been approved, in which cases the International Non-proprietary Name (INN) may be accepted in English; for instance, the term used shall be "simvastatin" and not "simvastatina";
(3) Annex 3 to the marketing authorisation shall include specifications regarding immediate packaging (e.g., blister, vial label), intermediary packaging (e.g., sachet) and outer packaging (e.g., box);
(4) For medicinal products subject to medical prescription, the type of medical prescription shall be mentioned, according to Order of the Minister of Health no. 1602 of 31 December 2010;
(5) Immediate packaging, intermediary packaging and outer packaging may include the trademark/logo of the Marketing Authorisation Holder.
Article 23. – (1) For prescription medicinal products, issue of the Marketing Authorisation, Patient Leaflet, Summary of Product Characteristics and Labelling (MA annexes) shall be performed for all package sizes approved at the end of the European procedure; therefore, applicants shall correlate information included in their application with the end-of-procedure documentation.
(2) For non-prescription medicinal products, issue of the Marketing Authorisation, Patient Leaflet, Summary of Product Characteristics and Labelling (MA annexes) shall be performed for package sizes established as per Article II of Scientific

Council Decision 1/24.10.2017; subsequent inclusion of different package sizes approved at the end of European procedure is not accepted in Romania.
Article 24. – (1) The templates for the Patient Leaflet, Summary of the Product Characteristics and the Labelling (MA annexes) shall be in line with European rules in force (QRD - Quality Review of Documents) and shall be updated as soon as updated European templates have been adopted;
(2) The templates for the Patient Leaflet, Summary of the Product Characteristics and the Labelling (MA annexes) are posted on the NAMMD website (https://www.anm.ro/) and are outside the scope of Annex II to the Scientific Council Decision.
Article 25. – (1) Annex 4 to the marketing authorisation "Qualitative and quantitative composition" shall include the active substance(s) and excipient(s) in terms of quality and quantity as well as particulars of what the authorised medicinal product looks like;
(2) Contents are expressed by weight, by volume or by unit, depending on pharmaceutical form; for instance:
- Qualitative and quantitative composition for one tablet (mg)
- Qualitative and quantitative composition for 5ml oral suspension (mg/5ml)
- Qualitative and quantitative composition for 1 g ointment (mg/g)
- Qualitative and quantitative composition for 1000ml solution for infusion (g/1000ml);
(3) Active substance(s) overdose shall be specified, where necessary;
(4) Where required, components used for technological purposes shall be included as well, followed by an explanation (asterisk) "eliminated during manufacture, not found in the finished product";
(5) The section "Qualitative and quantitative composition" of Annex 4 to the marketing authorisation shall be drafted compliant with requirements of this Annex.
(6) The section "Description of the authorised medicinal product" of Annex 4 shall describe product appearance (colour, markings, appearance prior to reconstitution etc.); similarly, information shall be provided on actual size of an oral solid formulation, as in, e.g.:
"Tablet
Round, white, flat, bevelled-edged, 5-mm diameter tablets, engraved with "100" on one side".
Article 26. – (1) The section "Medicinal product manufacturing" of Annex 5 to marketing authorisation shall include information on any manufacturer involved in the process of the finished product manufacture, manufacturer(s) of active substance(s) included;
(2) Where the finished product manufacturing process involves a single manufacturer for the entire manufacturing process/batch release, Annex 5 to marketing authorisation shall include the respective manufacturer's name, followed by the address of the manufacturing site;
(3) Where the finished product manufacturing process involves several manufacturers, Annex 5 to marketing authorisation shall include the name of all

manufactures involved, specifying the address of the manufacturing site and indicating all operations performed (obtaining of the active substance(s), bulk product, immediate packaging, outer packaging, batch testing, finished product batch release);
Article 27. – The marketing authorisation number is made up of 3 groups of numbers, representing:
- the marketing authorisation number;
- the year of marketing authorisation issue;
- the number of authorised package sizes and/or presentation forms, coded as 01-02…
Article 28. – The pharmaceutical form, immediate packaging, closure system and administration device shall be named in agreement with the Regulations in force related to Romanian standard terms for pharmaceutical forms, administration routes, closure systems and administration devices as adopted by the Commission of the European Pharmacopoeia.
Article 29. – The MA template together with Annexes 4 and 5 are included in Annex II of the Scientific Council Decision.

MARKETING AUTHORISATION

The National Agency for Medicines and Medical Devices, set up based on the Emergency Government Ordinance No. 72/2010 on reorganisation of certain healthcare institutions, as well as on amendment of regulatory acts in the healthcare field, based on Article 4 (2) b) of Government Decision no. 734/2010 on the set up and functioning of the National Agency for Medicines and Medical Devices, based on provisions of Article 704, (1) and <Article 706 (4)>, <Article 708 (1) and (2)>, <Article 708 (3)>, <Article 708 (4)>, <Article 709>, <Article 710>, <Article 711>, <Article 714>, <Article 718>, <Article 732>, <Article 738 (2), <Article 738 (4)>, <Article 743 (2)>, <Article 743 (3)> or <Article 743(4)> of Law no. 95/2006 on healthcare reform, Title XVIII - The medicinal product and based on the submitted documentation, decides the authorisation in Romania of the following medicinal product:

Registration name

{Trade name, strength, pharmaceutical form}

Composition

{Qualitative/quantitative data for active substance(s), qualitative data for excipient(s)}
{The quantity of active substance specified per dose, volume or mass unit, depending on pharmaceutical form}

Marketing Authorisation Holder

{Full name and address}

Manufacturer(s) responsible for finished product batch release

{Full name and address}

ATC Classification

{ATC code (Anatomical-Therapeutic-Chemical) up to level 5 (chemical substance), if feasible}

Supply

<☑ **on prescription**
☐ non-prescription>

or

<☐ on prescription
☑ **non-prescription**}>

Packaging

{Immediate packaging (packaging type, material, closure system, administration device, packaging size) and outer packaging}

Shelf life

{Shelf life after packaging for trade use expressed in X months/year(s)}
{Shelf life after first opening}

Storage conditions

{Storage conditions after packaging for trade use}
{Storage conditions after first opening}

Other conditions and requirements of the marketing authorisation

- **Periodic safety update reports**

Requirements for submission of Periodic safety update reports for this medicinal product are as specified in the List of Union reference dates and frequency of submission of periodic safety update reports (the EURD list) referred to in Article 838 (7) of Law no. 95/2006 on healthcare reform, republished as amended and any further updates thereof, posted on the European web portal on medicinal products.

or

- The Periodic safety update report for this medicinal product shall be submitted every <months/years> in accordance with provisions of Article 838, (2) and (3) of Law no. 95/2006 on healthcare reform, republished as amended.
- The MAH shall conduct periodic monitoring of the List of Union reference dates and frequency of submission (the EURD list) specified

under Article 838 (7) of Law no. 95/2006 on healthcare reform to check entry into the List of the substance/combination of substances.

Conditions or restrictions with regard to the safe and effective use of the medicinal product

Risk Management Plan (MRP)

The MAH undertakes to conduct pharmacovigilance activities and interventions required as detailed in the MRP approved and submitted in Module 1.8.2 of the Marketing Authorisation and any further MRP updates.

Updated RMP versions shall be submitted:

- On request by the National Agency for Medicines and Medical Devices;
- On revision of the risk management system, particularly triggered by new information leading to significant changes in benefit/risk ratio or by meeting of an important goal (pharmacovigilance or risk minimisation).

- **Additional risk minimisation measures**

Specific obligations for conduct of post-authorisation measures for authorisation under exceptional circumstances

This is an authorisation under "exceptional circumstances" pursuant to provisions of Article 732 (1), (2) of Law no. 95/2006 on healthcare reform, republished as amended and MAH shall accordingly implement the following measures in the specified timeframe:

Measure outline	Implementation deadline

Patient Leaflet

According to Annex 1 posted on the NAMMD website: https://www.anm.ro/

Summary of Product Characteristics

According to Annex 2 posted on the NAMMD website: https://www.anm.ro/

<The paediatric studies mentioned in section 5.1 Pharmacodynamic properties of the Summary of Product Characteristics have been performed in accordance with the Paediatric Investigation Plan agreed by the EMA Paediatric Committee (PDCO)>

Labelling

According to Annex 3 posted on the NAMMD website: https://www.anm.ro/

Medicinal product qualitative and quantitative composition

According to Annex 4

Medicinal product manufacturing

According to Annex 5

marketing authorisation number

{NNNN/YYYY/01-02-..... }

Any change to data in the Marketing Authorisation and Annexes or data in the Authorisation Documentation shall be communicated to the National Agency for Medicines and Medical Devices in accordance with applicable legislation.
<This authorisation shall be valid for 5 years as of its date of issue.>

PRESIDENT,

{DD.MM.YYYY}

MARKETING AUTHORISATION no. NNNN/YYYY/01-02-.... *ANNEX 4* **Medicinal product qualitative and quantitative composition**

{Trade name, strength, pharmaceutical form}
{active substance(s)}

Qualitative and quantitative composition

{active substance(s) and excipient(s) in terms of quantity and quality}
{quantity of active substance specified per dose, volume or mass unit, depending on pharmaceutical form}
{components used for technological purposes shall be included as well, followed by an explanation (asterisk) "eliminated during manufacture, not found in the finished product"

Description of the authorised medicinal product

{Description of the authorised medicinal product (colour, markings, appearance prior to reconstitution etc.), information on actual size of an oral solid formulation}

{Trade name, strength, pharmaceutical form}
{active substance(s)}

Active substance(s) manufacturer(s)

{Full name and address}

< Manufacturer(s) involved in bulk product manufacture>

< Manufacturer(s) involved in <immediate> <and> <outer> packaging

< Manufacturer(s) involved in batch testing >

< Manufacturer(s) involved in finished product batch release >

{Full name and address}

Medicinal product batches recalled in the 4th quarter of 2017

No.	Product recalled/ withdrawn	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall/withdrawal	Action proposed	Recall/ Withdrawal date
1	EGOLANZA 15 mg	film-coated tablets	15 mg	olanzapine	Egis Pharmaceuticals PLC Hungary	all batches MA no. 2828/2010/01	expiry of the 2-year period established pursuant to Order of the Minister of Health no.279/2005 after NAMMD approval of MA change (25.09.2015)	Voluntary recall and destruction	26.10.2017
2	EGOLANZA 20 mg	film-coated tablets	20 mg	olanzapine	Egis Pharmaceuticals PLC Hungary	all batches MA no. 2829/2010/01	expiry of the 2-year period established pursuant to Order of the Minister of Health no.279/2005 after NAMMD approval of MA change (25.09.2015)	Voluntary recall and destruction	26.10.2017
3	FLERADAY 500 mg	film-coated tablets	500 mg	levofloxacin	Dr. Reddy's Laboratories Ltd UK/Dr. Reddy's Laboratories Romania SRL	C700180	inappropriate customs warehouse release to a wholesaler of 2100 boxes in the absence of signed batch release certificate signed by the Qualified Person	Voluntary recall and destruction	26.10.2017
4	SCOBUTIL 10 mg	tablets	10 mg	butyl-scopolammonium bromide	Takeda Pharma SP. Z.O.O. Poland/ Takeda GmbH Germany	347402, 364334, 364333, 328924, 321441, 320405, 300186	out-of-specification result during stability studies for tablet active substance consistency in one of the batches; remaining batches recalled as precautionary measure	Voluntary recall and destruction	26.10.2017
5	CLORURA DE POTASIU 74,56 mg/ml	conc. for sol. for inf.	74,56 mg/ml	potassium chloride	B.Braun Melsungen AG Germany	144648091, 150558091, 151718091, 152648091, 153868091	product batches found with potential incipient particle formation in the concentrate for solutions for infusion	Voluntary recall and destruction	27.10.2017

6	OMEPRAZOL LPH 20 mg	gastro-resistant caps.	20 mg	omeprazole	Labormed Pharma S.A.	7010160131, 5110231179, 5110241180, 5110251181, 5110261182, 5110271183, 5110281184, 5110291185, 5110301301, 5110311302, 5110321303, 5120331304, 5120341305, 5120351306, 5120361307, 5120371308, 5120381309, 5120391310, 6010010079, 6010020080, 6010030081, 6010040082, 6010050083, 6010060084, 6020100248, 6020110249, 6020120250, 6020130260, 6020140261, 6020150262, 6020160263, 6050170610, 6050180611, 6050190612, 6050200613, 6050210614, 6050220615, 6050230616, 6050240617, 6050250618,	product with one batch out-of-specification results for the “Dissolution" parameter during stability studies; remaining batches withdrawn as precaution	Voluntary recall and destruction	27.10.2017

						6050260619, 6060270813, 6060280814, 6060290815, 6060300816, 6080310840, 6080320841, 6080330842, 6080340843, 6080350858, 6080360865, 6080370866, 6080380867, 6080390868, 6090401061, 6090411062, 6090421063, 6100431153, 6100441154, 6100451155, 6110461341, 6110471342, 6110481343, 6110491344, 6110501345, 6110511346, 6110521347, 6110531348 6110541349, 6110551350, 6110561351, 6120571461, 6120581462, 6120591463, 6120601464, 6120611465, 6120621466, 6120631467, 6120641468, 6120651521,			

						6120661522, 7010010085, 7010020086, 7010030087, 7010040088, 7010050089, 7010060090, 7010070091, 7010080092, 7010090093, 7010100107, 7010110108, 7010120109, 7010130110, 7010140129, 7010150130.			
7	VIBROCIL DUO 0,5 mg/ml+ 0,6 mg/ml	nasal spray sol.	0.5 mg/ml + 0,6 mg/ml	xylometazoline+ ipratropium	Novartis Consumer Health GmbH Germany/ GSK Consumer Healthcare SRL Romania	T02622B, T03602D	expiry of the 1-year period established pursuant to Order of the Minister of Health no. 1810/2006 after NAMMD approval of MA change (21.10.2016)	Voluntary recall and destruction	31.10.2017
8	ALPRAZOLAM 0,25 mg	tablets	0,25 mg	alprazolam	Labormed Pharma S.A.	4070060711, 4070070712, 4090080898, 4070069023, 4070079024, 4090089029, 5010010063, 5010020064, 5020030192, 5030040315, 5050050533, 5080060670, 5080070791, 5090080942, 5100091081, 5100101082, 6010010074,	product with out-of-specification results in certain batches for the “Individual impurity" and “Total impurities” parameters at the end of shelf life; remaining batches withdrawn as precaution	Voluntary recall and destruction	20.11.2017

						6010020118, 6020030191, 6040040424, 6040050425, 6040060521, 6040070522, 6050090657, 6050100693, 6090111057, 6090121059, 6090131060, 6100141130, 6100151131, 6110161352, 6110171353, 6110181354, 6110191419, 6120201436, 7010010007, 7010020008, 7010030009, 7040040520, 7040050521, 7040060435, 7040070485, 7040080486, 7050090572, 7050100573, 7050110574, 7050120649			
9	ALPRAZOLAM 0,50 mg	tablets	0,50 mg	alprazolam	Labormed Pharma S.A.	4070070713, 4070080714, 4070090725, 4070079025, 4070089026, 4070099027, 4120151356, 5010010065, 5010020066, 5030030316,	product with out-of-specification results in certain batches for the “Individual impurity" and “Total impurities” parameters at the end of shelf life; remaining batches withdrawn as precaution	Voluntary recall and destruction	20.11.2017

						5030040317, 5050050534, 5050060535, 5080070671, 5080080672, 5080090792, 5080100793, 5090110943, 5100121083, 5100131084, 5100141085, 6010010075, 6010020076, 6010030119, 6020040192, 6020050193, 6040060426, 6040070427, 6040080431, 6040090523, 6040100524, 6040110525, 6050120658, 6050130694, 6050140695, 6090151064, 6090161065, 6100171132, 6100181133, 6100191134, 6110201360, 6110211361, 6110221362, 6110231420, 6110241421, 6120251437, 7010010010, 7010020011, 7010030012, 7010040013,			

						7010050014, 7010060015, 7040070454, 7040080455, 7040090456, 7040100487, 7040110488, 7040120489, 7050130580, 7050140581, 7050150582, 7050160583, 7050170584, 7050180585, 7050190648, 7080200781			
10	THERAFLU MAX RACEALA SI TUSE	powder for oral sol.	1000 mg/ 200 mg/ 12,2 mg	paracetamol, guaifenesin, phenylephrine	Novartis Consumer Health GmbH Germany/ GSK Consumer Healthcare SRL Romania	7EW0181, 7EW0182, 7EW0189, 7EW0208, 7EW0209, 7EW0214, 7EW0220, 7EW0221, 7GW0116, 7GW0157	potential stainless-steel metal particles in a few finished product packs	Voluntary recall and destruction	12.12.2017
11	URICOL 5 g	effervescent granules	5 g	combinations	Pharco Impex ' 93 S.R.L.	All batches	application for related MA renewal deregistered in August 2016	Voluntary recall and destruction	14.12.2017
12	PANADOL BABY 120 mg/ 5ml	oral susp.	120 mg/ 5ml	paracetamol	Farmaclair France/GSK Consumer Healthcare UK	P025, P026, P052, P054, P055, P062, P063, P064, P087, P088, P089, P090, P091, P109, P110, P111, P112, P113, P140, P141, P142, P147, P148, P149, P150, P181, P182, P183, P198, P199, P200, R012, R013, R015, R016, R017, R018	expiry of the 2-year period established pursuant to Order of the Minister of Health no.279/2005 after NAMMD approval to MA changes on 24.09.2015	Voluntary recall and destruction	14.12.2017

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD in the 3rd quarter of 2017

In the 3rd quarter of 2017, 203 marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been received

A01 – STOMATOLOGICAL PREPARATIONS
A02 – DRUGS FOR ACID RELATED DISORDERS
A03 – DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS
A09 – DIGESTIVES, INCLUDING ENZYMES
A10 – DRUGS USED IN DIABETES
B01 – ANTITHROMBOTIC AGENTS
B05 – BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS
C01 – CARDIAC THERAPY
C02 – ANTIHYPERTENSIVES
C07 – BETA BLOCKING AGENTS
C08 – CALCIUM CHANNEL BLOCKERS
C09 – AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
C10 – LIPID MODIFYING AGENTS
G02 – OTHER GYNECOLOGICALS
G03 – SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM
G04 – UROLOGICALS
H01 – PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES
H05 – CALCIUM HOMEOSTASIS
J01 – ANTIBACTERIALS FOR SYSTEMIC USE
J02 – ANTIMYCOTICS FOR SYSTEMIC USE
J05 – ANTIVIRALS FOR SYSTEMIC USE
J06 – IMMUNE SERA AND IMMUNOGLOBULINS
L01 – ANTINEOPLASTIC AGENTS
L02 – ENDOCRINE THERAPY
L04 – IMMUNOSUPPRESSANTS
M01 – ANTI-INFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
M03 – MUSCLE RELAXANTS
M04 – ANTIGOUT PREPARATIONS
M05 – DRUGS FOR TREATMENT OF BONE DISEASES
N02 – ANALGESICS
N03 – ANTIEPILEPTICS
N05 – PSYCHOLEPTICS
N06 – PSYCHOANALEPTICS
R01 – NASAL PREPARATIONS
R03 – DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES
R05 – COUGH AND COLD PREPARATIONS
R06 – ANTIHISTAMINES FOR SYSTEMIC USE

S01 – OPHTHALMOLOGICALS
V01 – ALLERGENS
V08 – CONTRAST MEDIA

Medicinal products authorised for marketing in the 3rd quarter of 2017

INN	Trade name	Pharm. form	Strength	MAH	Country	MA No.		
ACICLOVIRUM	ACICLOVIR ARENA 200 mg	caps.	200mg	ARENA GROUP S.A.	ROMANIA	10147	2017	01
ACICLOVIRUM	ACICLOVIR ARENA 400 mg	caps.	400mg	ARENA GROUP S.A.	ROMANIA	10148	2017	01
ACIDUM ACETYLSALICYLICUM	ASPIRIN 500 mg	tablets	500mg	BAYER S.R.L.	ROMANIA	10166	2017	01
ACIDUM ALENDRONICUM+ COLECALCIFEROLUM	ACID ALENDRONIC/ COLECALCIFEROL AUROBINDO 70 mg/2800 UI	tablets	70mg/2800UI	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	10123	2017	01
ACIDUM ALENDRONICUM+ COLECALCIFEROLUM	ACID ALENDRONIC/ COLECALCIFEROL AUROBINDO 70 mg/5600 UI	tablets	70mg/5600UI	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	10124	2017	01
ACIDUM ALENDRONICUM+ COLECALCIFEROLUM	ACID ALENDRONIC/ COLECALCIFEROL ZENTIVA 70 mg/2800 UI	tablets	70mg/2800UI	ZENTIVA, K.S.	CZECH REPUBLIC	10144	2017	01
ACIDUM ALENDRONICUM+ COLECALCIFEROLUM	ACID ALENDRONIC/ COLECALCIFEROL ZENTIVA 70 mg/5600 UI	tablets	70mg/5600UI	ZENTIVA, K.S.	CZECH REPUBLIC	10145	2017	01
ACIDUM IBANDRONICUM	OSSICA 3 mg	sol. for inj. in pre-filled syringe	3mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	10131	2017	01
ACIDUM ZOLEDRONICUM	ACID ZOLEDRONIC GENTHON 4 mg/5 ml	conc. for sol. for inf.	4mg/5ml	GENTHON BV	NETHERLANDS	10234	2017	01
ACIDUM ZOLEDRONICUM	ACID ZOLEDRONIC GENTHON 5 mg	sol. for inf.	5mg	GENTHON BV	NETHERLANDS	10235	2017	01
AMLODIPINUM	ALMIDEN 5 mg	tablets	5mg	ACCORD HEALTHCARE LIMITED	UK	10207	2017	01
AMLODIPINUM	ALMIDEN 10 mg	tablets	10mg	ACCORD HEALTHCARE LIMITED	UK	10208	2017	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOXICILINA/ACID CLAVULANIC DSM SINOCHEM 125 mg/31,25 mg/5 ml	powder for oral susp.	125mg/ 31,25mg/5ml	DSM SINOCHEM PHARMACEUTICALS NETHERLANDS B.V.	NETHERLANDS	10254	2017	01

AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOXICILINA/ACID CLAVULANIC DSM SINOCHEM 250 mg/62,5 mg/5 ml	powder for oral susp.	250mg/ 62,5mg/5ml	DSM SINOCHEM PHARMACEUTICALS NETHERLANDS B.V.	NETHERLANDS	10255	2017	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOXICILINA/ACID CLAVULANIC DSM SINOCHEM 400 mg/57 mg/5 ml	powder for oral susp.	400mg/ 57mg/5ml	DSM SINOCHEM PHARMACEUTICALS NETHERLANDS B.V.	NETHERLANDS	10256	2017	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOXICILINA/ACID CLAVULANIC DSM SINOCHEM 600 mg/42,9 mg/5 ml	powder for oral susp.	600mg/ 42,9mg/5ml	DSM SINOCHEM PHARMACEUTICALS NETHERLANDS B.V.	NETHERLANDS	10257	2017	01
AMPICILLINUM	AMPICILINA ATB 500 mg	caps.	500mg	ANTIBIOTICE S.A.	ROMANIA	10152	2017	01
AMPICILLINUM	AMPICILINA ATB 250 mg	caps.	250mg	ANTIBIOTICE S.A.	ROMANIA	10151	2017	01
APOMORFINUM	DACEPTON 10 mg/ml	sol. for inj. in cartridge	10mg/ml	EVER NEURO PHARMA GMBH	AUSTRIA	10101	2017	01
ATORVASTATINUM	ATORVILBITIN 10 mg	film-coated tablets	10mg	STADA ARZNEIMITTEL AG	GERMANY	10191	2017	01
ATORVASTATINUM	ATORVILBITIN 20 mg	film-coated tablets	20mg	STADA ARZNEIMITTEL AG	GERMANY	10192	2017	01
ATORVASTATINUM	ATORVILBITIN 40 mg	film-coated tablets	40mg	STADA ARZNEIMITTEL AG	GERMANY	10193	2017	01
BETAHISTINUM	VERTISAN 24 mg	tablets	24 mg	HENNIG ARZNEIMITTEL GMBH & CO.KG	GERMANY	10100	2017	01
BIMATOPROSTUM	BIMATOPROST MYLAN 0,1 mg/ml	eye drops, sol.	0,1mg/ml	MYLAN S.A.S.	FRANCE	10243	2017	01
BISOPROLOLUM	BOREZ 5 mg	film-coated tablets	5mg	ALKALOID-INT D.O.O.	SLOVENIA	10221	2017	01
BISOPROLOLUM	BOREZ 10 mg	film-coated tablets	10mg	ALKALOID-INT D.O.O.	SLOVENIA	10222	2017	01
BISOPROLOLUM	BOREZ 2,5 mg	film-coated tablets	2,5mg	ALKALOID-INT D.O.O.	SLOVENIA	10220	2017	01
BROMAZEPAMUM	BROMAZEPAM SLAVIA 3 mg	tablets	3mg	SLAVIA PHARMA S.R.L.	ROMANIA	10170	2017	01
CANDESARTANUM CILEXETIL	KARBIS 4 mg	tablets	4mg	KRKA D.D. NOVO MESTO	SLOVENIA	10244	2017	01
CANDESARTANUM	KARBIS 8 mg	tablets	8mg	KRKA D.D. NOVO MESTO	SLOVENIA	10245	2017	01

CILEXETIL								
CANDESARTANUM CILEXETIL	KARBIS 16 mg	tablets	16mg	KRKA D.D. NOVO MESTO	SLOVENIA	10246	2017	01
CANDESARTANUM CILEXETIL	KARBIS 32 mg	tablets	32mg	KRKA D.D. NOVO MESTO	SLOVENIA	10247	2017	01
CAPECITABINUM	CEREX 500 mg	film-coated tablets	500mg	TERAPIA SA	ROMANIA	10211	2017	01
CARVEDILOLUM	CARVEDILOL AUROBINDO 3,125mg	film-coated tablets	3,125mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	10175	2017	01
CARVEDILOLUM	CARVEDILOL AUROBINDO 6,25mg	film-coated tablets	6,25mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	10176	2017	01
CARVEDILOLUM	CARVEDILOL AUROBINDO 12,5mg	film-coated tablets	12,5mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	10177	2017	01
CARVEDILOLUM	CARVEDILOL AUROBINDO 25mg	film-coated tablets	25mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	10178	2017	01
CEFUROXIMUM	APROKAM 50 mg	powder for sol. for inj.	50mg	LABORATOIRES THEA	FRANCE	10108	2017	01
CLARITHROMYCINUM	ROCLARIN 500 mg	film-coated tablets	500mg	ANTIBIOTICE S.A.	ROMANIA	10149	2017	01
CLINDAMYCINUM	DALACIN C 300 mg	caps.	300mg	PFIZER EUROPE MA EEIG	UK	10142	2017	01
CLINDAMYCINUM	DALACIN C 150 mg	caps.	150mg	PFIZER EUROPE MA EEIG	UK	10141	2017	01
COMBINATIONS	COLDREX MAXGRIP LEMON	powder for oral susp.		HIPOCRATE 2000 S.R.L.	ROMANIA	10133	2017	01
COMBINATIONS	BALANCE 1,5% GLUCOZA, 1,75 mmol/l calciu	sol. for perit. dial.		FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	GERMANY	10088	2017	01
COMBINATIONS	BALANCE 4,25% GLUCOZA, 1,75 mmol/l calciu	sol. for perit. dial.		FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	GERMANY	10090	2017	01
COMBINATIONS	BALANCE 2,3% GLUCOZA, 1,75 mmol/l calciu	sol. for perit. dial.		FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	GERMANY	10089	2017	01
COMBINATIONS	AMINOMIX 1 NOVUM	sol. for inf.		FRESENIUS KABI DEUTSCHLAND GMBH	GERMANY	10162	2017	01
COMBINATIONS	AMINOMIX 2 NOVUM	sol. for inf.		FRESENIUS KABI DEUTSCHLAND GMBH	GERMANY	10163	2017	01

COMBINATIONS	NEFROSOL cu 2 mmol/l potasiu	sol. for haemofiltr.		B. BRAUN AVITUM AG	GERMANY	10112	2017	01
COMBINATIONS	NEFROSOL cu 4 mmol/l potasiu	sol. for haemofiltr.		B. BRAUN AVITUM AG	GERMANY	10113	2017	01
COMBINATIONS	NEFROSOL FARA POTASIU	sol. for haemofiltr.		B. BRAUN AVITUM AG	GERMANY	10111	2017	01
COMBINATIONS	ADDAMEL NOVUM	powder for sol. for inf.		FRESENIUS KABI AB	SWEDEN	10206	2017	01
COMBINATIONS (BETAMETHASONUM +ACIDUM SALICYILICUM)	DIPROSALIC 0,64 mg+20 mg/g	cut. sol.	0,64mg+ 20mg/g	MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	10102	2017	01
COMBINATIONS (BIMATOPROSTUM + TIMOLOLUM)	BIMATOPROST/TIMOLOL ROMPHARM 0,3 mg/5 mg/ml	eye drops	0,3mg/ 5mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	10190	2017	01
COMBINATIONS (EZETIMIBUM + SIMVASTATINUM)	VASITIMB 10 mg/10 mg	tablets	10mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10179	2017	01
COMBINATIONS (EZETIMIBUM + SIMVASTATINUM)	VASITIMB 10 mg/20 mg	tablets	10mg/20mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10180	2017	01
COMBINATIONS (EZETIMIBUM + SIMVASTATINUM)	VASITIMB 10 mg/40 mg	tablets	10mg/40mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10181	2017	01
COMBINATIONS (FERROSI SULFAS+ ACIDUM FOLICUM)	TARDYFERON FOL 80 mg+0,350 mg	prolonged-release tablets	80mg+ 0,350mg	PIERRE FABRE MEDICAMENT	FRANCE	10104	2017	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM)	ISICOM 250 mg/25 mg	tablets	250mg/ 25mg	DESITIN ARZNEIMITTEL GMBH	GERMANY	10140	2017	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM)	NAKOM 250 mg/25 mg	tablets	250mg+ 25mg	LEK PHARMACEUTICALS D.D.	SLOVENIA	10259	2017	01

COMBINATIONS (OXICODONUM+ NALOXONUM)	DOLNADA 10 mg/5 mg	prolonged-release tablets	10mg/5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10097	2017	01
COMBINATIONS (OXICODONUM+ NALOXONUM)	DOLNADA 20 mg/10 mg	prolonged-release tablets	20mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10098	2017	01
COMBINATIONS (OXICODONUM+ NALOXONUM)	DOLNADA 40 mg/20 mg	prolonged-release tablets	40mg/20mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10099	2017	01
DACARBAZINUM	DACARBAZINA LIPOMED 500 mg	powder for sol. for inf.	500mg	LIPOMED GMBH	GERMANY	10125	2017	01
DACARBAZINUM	DACARBAZINA LIPOMED 1000 mg	powder for sol. for inf.	1000mg	LIPOMED GMBH	GERMANY	10126	2017	01
DARUNAVIRUM	DARUNAVIR SANDOZ 75 mg	film-coated tablets	75mg	SANDOZ S.R.L.	ROMANIA	10114	2017	01
DARUNAVIRUM	DARUNAVIR SANDOZ 400 mg	film-coated tablets	400mg	SANDOZ S.R.L.	ROMANIA	10115	2017	01
DARUNAVIRUM	DARUNAVIR SANDOZ 600 mg	film-coated tablets	600mg	SANDOZ S.R.L.	ROMANIA	10116	2017	01
DARUNAVIRUM	DARUNAVIR SANDOZ 800 mg	film-coated tablets	800mg	SANDOZ S.R.L.	ROMANIA	10117	2017	01
DARUNAVIRUM	DARUNAVIR ZENTIVA 75 mg	film-coated tablets	75mg	ZENTIVA, K.S.	CZECH REPUBLIC	10200	2017	01
DARUNAVIRUM	DARUNAVIR ZENTIVA 400 mg	film-coated tablets	400mg	ZENTIVA, K.S.	CZECH REPUBLIC	10201	2017	01
DARUNAVIRUM	DARUNAVIR ZENTIVA 600 mg	film-coated tablets	600mg	ZENTIVA, K.S.	CZECH REPUBLIC	10202	2017	01
DARUNAVIRUM	DARUNAVIR ZENTIVA 800 mg	film-coated tablets	800mg	ZENTIVA, K.S.	CZECH REPUBLIC	10203	2017	01
DESLORATADINUM	DESLORATADINA AMRING 5 mg	film-coated tablets	5mg	AMRING FARMA SRL	ROMANIA	10092	2017	01
DEXIBUPROFENUM	SERACTIL 200 mg	film-coated tablets	200mg	GALENICA S.A.	GREECE	10251	2017	01
DEXIBUPROFENUM	SERACTIL 300 mg	film-coated tablets	300mg	GALENICA S.A.	GREECE	10252	2017	01

DEXIBUPROFENUM	SERACTIL 400 mg	film-coated tablets	400mg	GALENICA S.A.	GREECE	10253	2017	01
DEXTROMETHORPHA-NUM	DINAREX 1,5 mg/ml	syrup	1,5mg/ml	MEDOCHEMIE ROMANIA SRL	ROMANIA	10258	2017	01
DIOSMINUM	DIOSMINA REMEDIA 600 mg	film-coated tablets	600mg	FARMACEUTICA REMEDIA DISTRIBUTION&LOGISTICS S.R.L.	ROMANIA	10155	2017	01
DONEPEZILUM	YASNAL 5 mg	orodisp. tablets	5 mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10160	2017	01
DONEPEZILUM	YASNAL 10 mg	orodisp. tablets	10 mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10161	2017	01
DONEPEZILUM	YASNAL 5 mg	film-coated tablets	5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10158	2017	01
DONEPEZILUM	YASNAL 10 mg	film-coated tablets	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10159	2017	01
DULOXETINUM	DOZZEX 30 mg	gastrores. caps.	30mg	TERAPIA S.A.	ROMANIA	10228	2017	01
DULOXETINUM	DOZZEX 60 mg	gastrores. caps.	60mg	TERAPIA S.A.	ROMANIA	10229	2017	01
DUTASTERIDUM	DUTASTERIDA AUROBINDO 0,5 mg	soft caps.	0,5mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	10091	2017	01
DUTASTERIDUM	DUSTAR 0,5 mg	soft caps.	0,5mg	ACCORD HEALTHCARE LIMITED	UK	10130	2017	01
EMTRICITABINUM+ TENOFOVIRUM DISOPROXIL	EMTRICITABINA/ TENOFOVIR DISOPROXIL ACCORD 200 mg/245 mg	film-coated tablets	200mg/ 245mg	ACCORD HEALTHCARE LIMITED	UK	10094	2017	01
ENTACAPONUM	ENTACAPONA MYLAN 200 mg	film-coated tablets	200mg	GENERIC (UK) LTD.	UK	9922	2017	01
ENTECAVIRUM	ENTECAVIR DR. REDDY'S 0,5 mg	film-coated tablets	0,5mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	10134	2017	01
ENTECAVIRUM	ENTECAVIR DR. REDDY'S 1 mg	film-coated tablets	1mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	10135	2017	01
ENTECAVIRUM	ENTECAVIR ALVOGEN 0,5 mg	film-coated tablets	0,5mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	10095	2017	01

ENTECAVIRUM	ENTECAVIR ALVOGEN 1 mg	film-coated tablets	1mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	10096	2017	01
ENTECAVIRUM	ENTECAVIR PHARMASCIENCE INTERNATIONAL LTD 0,5 mg	film-coated tablets	0,5mg	PHARMASCIENCE INTERNATIONAL LTD	CYPRUS	10136	2017	01
ENTECAVIRUM	ENTECAVIR PHARMASCIENCE INTERNATIONAL LTD 1 mg	film-coated tablets	1mg	PHARMASCIENCE INTERNATIONAL LTD	CYPRUS	10137	2017	01
ENTECAVIRUM	ENTECAVIR SANDOZ 0,5 mg	film-coated tablets	0,5mg	SANDOZ S.R.L.	ROMANIA	10172	2017	01
ENTECAVIRUM	ENTECAVIR SANDOZ 1 mg	film-coated tablets	1mg	SANDOZ S.R.L.	ROMANIA	10173	2017	01
ENTECAVIRUM	ENTECAVIR AUROBINDO 0,5 mg	film-coated tablets	0,5mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	10223	2017	01
ENTECAVIRUM	ENTECAVIR AUROBINDO 1 mg	film-coated tablets	1mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	10224	2017	01
ENTECAVIRUM	ENTECAVIR PHARMATHEN 0,5 mg	film-coated tablets	0,5mg	PHARMATHEN S.A.	GREECE	10232	2017	01
ENTECAVIRUM	ENTECAVIR PHARMATHEN 1 mg	film-coated tablets	1mg	PHARMATHEN S.A.	GREECE	10233	2017	01
EPINEPHRINUM	ADRENALINA TERAPIA 1 mg/ml	sol. for inj.	1mg/ml	TERAPIA SA	ROMANIA	10171	2017	01
ERLOTINIBUM	ERLOTINIB RATIOPHARM 25 mg	film-coated tablets	25mg	RATIOPHARM GMBH	GERMANY	10118	2017	01
ERLOTINIBUM	ERLOTINIB RATIOPHARM 100 mg	film-coated tablets	100mg	RATIOPHARM GMBH	GERMANY	10119	2017	01
ERLOTINIBUM	ERLOTINIB RATIOPHARM 150 mg	film-coated tablets	150mg	RATIOPHARM GMBH	GERMANY	10120	2017	01
ERLOTINIBUM	ERLOTINIB MYLAN 50 mg	film-coated tablets	50mg	MYLAN S.A.S.	FRANCE	10187	2017	01
ERLOTINIBUM	ERLOTINIB MYLAN 100 mg	film-coated tablets	100mg	MYLAN S.A.S.	FRANCE	10188	2017	01
ERLOTINIBUM	ERLOTINIB MYLAN 150 mg	film-coated tablets	150mg	MYLAN S.A.S.	FRANCE	10189	2017	01
ERLOTINIBUM	ERLOTINIB SANDOZ 25 mg	film-coated tablets	25mg	SANDOZ S.R.L.	ROMANIA	10217	2017	01

ERLOTINIBUM	ERLOTINIB SANDOZ 100 mg	film-coated tablets	100mg	SANDOZ S.R.L.	ROMANIA	10218	2017	01
ERLOTINIBUM	ERLOTINIB SANDOZ 150 mg	film-coated tablets	150mg	SANDOZ S.R.L.	ROMANIA	10219	2017	01
ERTAPENEMUM	ERTAPENEM FRESENIUS KABI 1 g	powder for conc.for sol. for inf.	1g	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	10127	2017	01
ETIFOXINUM	STRESAM 50 mg	caps.	50mg	BIOCODEX	FRANCE	10139	2017	01
ETOPOSIDUM	SINTOPOZID 100 mg/5 ml	conc. for sol. for inf.	100mg/5ml	ACTAVIS S.R.L.	ROMANIA	10164	2017	01
ETORICOXIBUM	GEROCOXAN 30 mg	film-coated tablets	30mg	G.L. PHARMA GMBH	AUSTRIA	10059	2017	01
ETORICOXIBUM	GEROCOXAN 60 mg	film-coated tablets	60mg	G.L. PHARMA GMBH	AUSTRIA	10060	2017	01
ETORICOXIBUM	GEROCOXAN 90 mg	film-coated tablets	90mg	G.L. PHARMA GMBH	AUSTRIA	10061	2017	01
ETORICOXIBUM	GEROCOXAN 120 mg	film-coated tablets	120mg	G.L. PHARMA GMBH	AUSTRIA	10062	2017	01
EZETIMIBUM	EZETIMIB ACCORD 10 mg	tablets	10mg	ACCORD HEALTHCARE LIMITED	UK	10216	2017	01
FACTOR IX DE COAGULARE	BETAFACT 50 UI/ml	powder+solv. for sol. for inj.	50UI/ml	LFB - BIOMEDICAMENTS	FRANCE	10093	2017	01
IBUPROFENUM	PADUDEN SR 300 mg	prolonged-release caps.	300mg	TERAPIA S.A.	ROMANIA	10103	2017	01
IBUPROFENUM	FASPIC 600 mg	gran. for oral sol.	600mg	ZAMBON S.P.A.	ITALY	10106	2017	01
IBUPROFENUM	FASPIC 400 mg	gran. for oral sol.	400mg	ZAMBON S.P.A.	ITALY	10105	2017	01
IBUPROFENUM	BUPROFESS 200 mg	oral powder	200mg	STADA M&D S.R.L.	ROMANIA	10209	2017	01
IBUPROFENUM	BUPROFESS 400 mg	oral powder	400mg	STADA M&D S.R.L.	ROMANIA	10210	2017	01
ISOTRETINOINUM	ISOTRETINOIN TERAPIA 10 mg	soft caps.	10mg	TERAPIA S.A.	ROMANIA	10194	2017	01
ISOTRETINOINUM	ISOTRETINOIN TERAPIA 20 mg	soft caps.	20mg	TERAPIA S.A.	ROMANIA	10195	2017	01
IVABRADINUM	IVABRADINA AUROBINDO 5 mg	film-coated tablets	5mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	10121	2017	01

IVABRADINUM	IVABRADINA AUROBINDO 7,5 mg	film-coated tablets	7,5mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	10122	2017	01
IVABRADINUM	IVABRADINA LICONSA 5 mg	film-coated tablets	5mg	LABORATORIOS LICONSA S.A.	SPAIN	10156	2017	01
IVABRADINUM	IVABRADINA LICONSA 7,5 mg	film-coated tablets	7,5mg	LABORATORIOS LICONSA S.A.	SPAIN	10157	2017	01
LAMIVUDINUM	LAMIVUDINA AUROBINDO 150 mg	film-coated tablets	150mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	10132	2017	01
LEVOCETIRIZINUM	ZENARO 0,5 mg/ml	syrup	0,5mg/ml	ZENTIVA, K.S.	CZECH REPUBLIC	10212	2017	01
LINEZOLIDUM	LINEZOLID FRESENIUS KABI 600 mg	film-coated tablets	600mg	FRESENIUS KABI ROMANIA	ROMANIA	10250	2017	01
METOPROLOLUM	METOPROLOL LPH 50 mg	tablets	50mg	LABORMED PHARMA S.A.	ROMANIA	10168	2017	01
METOPROLOLUM	METOPROLOL LPH 100 mg	tablets	100mg	LABORMED PHARMA S.A.	ROMANIA	10169	2017	01
METOPROLOLUM	METOPROLOL LPH 25 mg	tablets	25mg	LABORMED PHARMA S.A.	ROMANIA	10167	2017	01
MIFEPRISTONUM	MIFEGYNE 200 mg	tablets	200mg	EXELGYN	FRANCE	10129	2017	01
MILRINONUM	UNACOR 1 mg/ml	conc. for sol. for inf.	1mg/ml	PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	AUSTRIA	10226	2017	01
MIRTAZAPINUM	VALDREN 30 mg	film-coated tablets	30mg	G.L. PHARMA GMBH	AUSTRIA	10204	2017	01
MIRTAZAPINUM	VALDREN 45 mg	film-coated tablets	45mg	G.L. PHARMA GMBH	AUSTRIA	10205	2017	01
MOMETASONUM	FUROAT DE MOMETAZONA SANDOZ 50 micrograms/doza	nasal spray susp.	50microgra-me/doza	SANDOZ S.R.L.	ROMANIA	10128	2017	01
MONTELUKASTUM	MONTELUKAST ALVOGEN 4 mg	chewable tablets	4mg	ALVOGEN IPCO S.AR.L.	LUXEMBOURG	10185	2017	01
MONTELUKASTUM	MONTELUKAST ALVOGEN 5 mg	chewable tablets	5mg	ALVOGEN IPCO S.AR.L.	LUXEMBOURG	10186	2017	01
MOXIFLOXACINUM	MOXIFLOXACINA ROMPHARM 400 mg/250 ml	sol. for inf.	400mg/ 250ml	ROMPHARM COMPANY S.R.L.	ROMANIA	10110	2017	01
NEBIVOLOLUM	NEBINORM 5 mg	tablets	5mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	10174	2017	01
OFLOXACINUM	ROMACIN 3 mg/ml	eye drops, sol.	3mg/ml	BIOOS ITALY S.R.L.	ITALY	10248	2017	01
OXALIPLATINUM	OXALIPLATIN KABI 5 mg/ml	conc. for sol. for inf.	5mg/ml	FRESENIUS KABI ONCOLOGY PLC.	UK	10109	2017	01

PALONOSETRONUM	PALONOSETRON ALVOGEN 250 micrograms		250 micrograms	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	10107	2017	01
PEMETREXEDUM	PEMETREXED DITROMETAMINA DR. REDDY'S 500 mg	powder for conc. for sol. for inf.	500mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	10236	2017	01
PEMETREXEDUM	PEMETREXED NOVAMED 100 mg	powder for conc. for sol. for inf.	100mg	NOVAMED TRADING EOOD	BULGARIA	10237	2017	01
PEMETREXEDUM	PEMETREXED NOVAMED 500 mg	powder for conc. for sol. for inf.	500mg	NOVAMED TRADING EOOD	BULGARIA	10238	2017	01
PHENYTOINUM	FENITOINA SODICA ACCORD 50 mg/ml	sol for inj./perf.	50mg/ml	ACCORD HEALTHCARE LIMITED	UK	10225	2017	01
POVIDONUM IODINATUM	OCULOTECT FLUID 50mg/ml	eye drops, sol.	50mg/ml	S.A. ALCON-COUVREUR N.V.	BELGIUM	10153	2017	01
POVIDONUM IODINATUM	OCULOTECT FLUID 50mg/ml	eye drops, sol.	50mg/ml	S.A. ALCON-COUVREUR N.V.	BELGIUM	10154	2017	01
ROPINIROLUM	ROLPRYNA EP 2 mg	prolonged-release tablets	2 mg	KRKA D.D., NOVO MESTO	SLOVENIA	10182	2017	01
ROPINIROLUM	ROLPRYNA EP 4 mg	prolonged-release tablets	4 mg	KRKA D.D., NOVO MESTO	SLOVENIA	10183	2017	01
ROPINIROLUM	ROLPRYNA EP 8 mg	prolonged-release tablets	8 mg	KRKA D.D., NOVO MESTO	SLOVENIA	10184	2017	01
ROSUVASTATINUM	ROSTAT 15 mg	film-coated tablets	15mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	10196	2017	01
ROSUVASTATINUM	ROSTAT 30 mg	film-coated tablets	30mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	10197	2017	01
ROSUVASTATINUM	ROSUVASTATINA NEWLINE PHARMA 5 mg	film-coated tablets	5mg	NEWLINE PHARMA, S.L.	SPAIN	10239	2017	01
ROSUVASTATINUM	ROSUVASTATINA NEWLINE PHARMA 10 mg	film-coated tablets	10mg	NEWLINE PHARMA, S.L.	SPAIN	10240	2017	01
ROSUVASTATINUM	ROSUVASTATINA NEWLINE PHARMA 20 mg	film-coated tablets	20mg	NEWLINE PHARMA, S.L.	SPAIN	10241	2017	01
ROSUVASTATINUM	ROSUVASTATINA NEWLINE PHARMA 40 mg	film-coated tablets	40mg	NEWLINE PHARMA, S.L.	SPAIN	10242	2017	01
SERTRALINUM	SERTRALINA ACCORD 50 mg	film-coated tablets	50mg	ACCORD HEALTHCARE LIMITED	UK	10198	2017	01

SERTRALINUM	SERTRALINA ACCORD 100 mg	film-coated tablets	100mg	ACCORD HEALTHCARE LIMITED	UK	10199	2017	01
TAMSULOSINUM	SELDONO 0,4 mg	modif. release caps.	0,4mg	ALKALOID - INT D.O.O.	SLOVENIA	10249	2017	01
TELMISARTANUM	TANYDON 40 mg	film-coated tablets	40mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	10230	2017	01
TELMISARTANUM	TANYDON 80 mg	film-coated tablets	80mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	10231	2017	01
TELMISARTANUM	TELMISARTAN TORRENT 40 mg	tablets	40mg	TORRENT PHARMA S.R.L.	ROMANIA	10214	2017	01
TELMISARTANUM	TELMISARTAN TORRENT 80 mg	tablets	80mg	TORRENT PHARMA S.R.L.	ROMANIA	10215	2017	01
TENOFOVIRUM DISOPROXIL	TENOFOVIR DISOPROXIL AUROBINDO 245 mg	film-coated tablets	245mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	10227	2017	01
TIOTROPIUM	SPIRIVA RESPIMAT 2,5 micrograms	inhal. sol.	2,5 micrograms	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	10138	2017	01

Centrally authorised medicinal products notified for marketing in Romania during the 3rd quarter of 2017

INN	Trade name	Pharm. form	Strength	MAH	Country	MA No.		
ATEZOLIZUMAB	TECENTRIQ 1200 mg	conc. for sol. for inf.	1200mg/20ml	ROCHE REGISTRATION LIMITED	UK	1220	2017	01
AVELUMABUM	BAVENCIO 20 mg/ml	conc. for sol. for inf.	20mg/ml	MERCK SERONO EUROPE LIMITED	UK	1214	2017	01
BECLOMETASONUM+ FORMOTEROLUM+ GLICOPIRONIU BROMIDUM	TRIMBOW 87micrograms/ 5 micrograms/ 9 micrograms	pressurised inhal., sol.	87micrograms/ 5micrograms/ 9micrograms	CHIESI FARMACEUTICI S.P.A.	ITALY	1208	2017	02
CARIPRAZINUM	REAGILA 1,5 mg	caps.	1,5mg	GEDEON RICHTER PLC.	HUNGARY	1209	2017	01
CARIPRAZINUM	REAGILA 3 mg	caps.	3mg	GEDEON RICHTER PLC.	HUNGARY	1209	2017	11
CARIPRAZINUM	REAGILA 4,5 mg	caps.	4,5mg	GEDEON RICHTER PLC.	HUNGARY	1209	2017	21
CARIPRAZINUM	REAGILA 6 mg	caps.	6mg	GEDEON RICHTER PLC.	HUNGARY	1209	2017	29
EFAVIRENZUM+ EMTRICITABINUM+ TENOFOVIRUM DISOPROXIL	EFAVIRENZ/ EMTRICITABINA/ TENOFOVIR DISOPROXIL MYLAN 600 mg/200 mg/245 mg	film-coated tablets	600mg/200mg/ 245mg	MYLAN S.A.S	FRANCE	1222	2017	01
ENTECAVIRUM	ENTECAVIR MYLAN 0,5 mg	film-coated tablets	0,5mg	MYLAN S.A.S.	FRANCE	1227	2017	02
ENTECAVIRUM	ENTECAVIR MYLAN 1 mg	film-coated tablets	1mg	MYLAN S.A.S.	FRANCE	1227	2017	07
ENTECAVIRUM	ENTECAVIR ACCORD 0,5 mg	film-coated tablets	0,5mg	ACCORD HEALTHCARE LIMITED	UK	1211	2017	02
ENTECAVIRUM	ENTECAVIR ACCORD 1 mg	film-coated tablets	1mg	ACCORD HEALTHCARE LIMITED	UK	1211	2017	05
MIDOSTAURINUM	RYDAPT 25 mg	soft caps.	25mg	NOVARTIS EUROPHARM LIMITED	UK	1218	2017	01
RIBOCICLIBUM	KISQALI 200 mg	film-coated tablets	200mg	NOVARTIS EUROPHARM LIMITED	UK	1221	2017	05
SOFOSBUVIRUM+ VELPATASVIRUM + VOXILAPREVIRUM	VOSEVI 400 mg/100 mg/100 mg	film-coated tablets	400mg/100mg/ 100mg	GILEAD SCIENCES INTERNATIONAL LTD.	UK	1223	2017	01