ROMANIA

Newsletter

Year 17, No. 3 (67), 3rd quarter of 2015

National Agency for Medicines and Medical Devices

Orders of the Minister of Health

Decisions of the NAMMD Scientific Council

Medicinal product batches recalled during the 3rd quarter of 2015

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 2nd quarter of 2015

Medicinal products authorised for marketing during the 2nd quarter of 2015

Medicinal products authorised through centralised procedure by the EMA notified for marketing in Romania during the 2nd quarter of 2015

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TABLE OF CONTENTS

The Ministry of Health – MoH – Order no. 874/10 July 2015

Order no. 874 of 10 July 2015 on approval of forms for declaration of sponsoring related to medical devices and healthcare materials

Published in the Official Gazette of Romania, no. 550 of 24 July 2015

On seeing the report for approval No. 7.313/2015 of the Directorate for Medicinal Product and Medical Devices,

Taking into account provisions of Articles 799^1 and 894 of Law 95/2006 on healthcare reform, as amended,

Considering provisions of Article 2 of the Methodological norms for enforcement of Title XIX of Law 95/2006 on healthcare reform on approval of activities in the field of medical devices, approved through Order of the Minister of Health no. 309/2015,

based on Article 7(4) of Government Decision No. 144/2010 on the organisation and operation of the Ministry of Health, as amended,

the minister of health hereby issues the following order:

Article 1. - (1) Through the National Agency for Medicines and Medical Devices, the specialist structure subordinated to the Ministry of Health, the competent and decision-making authority in the field of medical devices, manufacturers or their representatives in Romania as well as wholesale and retail manufacturers of medical devices and healthcare materials shall report to the Ministry of Health, until 31 March of the current year, all sponsoring and other expenses paid during the year prior to reporting for physicians, nurses, professional organisations, patient organisations and any other type of health organisation.

(2) The provision made under (1) also applies to recipients of sponsoring such as physicians, nurses, professional organisations, patient organisations and any other type of health organisation.

(3) Herein, the term healthcare organisation shall refer to any legal entity (profit/non-profit), performing human healthcare related activities, medical or pharmaceutical care.

Article 2. – The declaration forms for activities mentioned under Article 1 are available in Annexes 1 and 2, which are integral parts of this Order.

Article 3. - (1) The information included in the forms mentioned under Article 2 shall be published on the website of the Ministry of Health, of the sponsoring body and of their recipients, as required, during the second quarter of the year, for the previous year.

(2) In 2015, declarations are submitted to the Ministry of Health, through the National Agency for Medicines and Medical Devices, the specialist structure subordinated to the Ministry of Health, the competent and decision-making authority in the field of medical devices, before 31 July, and the information

included in the forms mentioned under Article 3 shall be published on the website of the Ministry of Health, of the sponsoring body and of their recipients, as required, before 31 October 2015.

Article 4. – Within 60 days after the deadline for receipt of declarations mentioned under Articles 1 and 3, the National Agency for Medicines and Medical Devices submits to the Ministry of Health the consolidated report of declarations collected, for publication on the website.

Article 5. - This Order is to be published in the Official Gazette of Romania, Part I.

On behalf of the Minister of Health,

Alin Iulian Tucmeanu,
Secretary of State

Bucharest, 10 July 2015.
No. 874.

ANNEX 1

FORM

for declaration of sponsoring in the field of medical devices

Reference of columns in the table below:

A – Name and surname/Name (professional/professional organisation/patient organisation/healthcare organisation)
B – Branch/Healthcare activity
C – Site of main activity
D – Type of sponsoring: financial/material
E – Description of sponsored activity
F – Sum (lei)
G – Contract period
H – Date of payment/Date of delivery of goods
I – Description of the activity
J – Fees for services stipulated in service contracts (transport and lodging) (sum)
K – Date of contract
L – Date of payment
M – Type of fee
N – Date of contract

No	Name of the sponsor (manufacturers or their representatives in Romania, wholesale and retail distributors of medical devices and healthcare materials)	Recipient of sponsoring			Sponsoring					Other costs									Total (lei)
					Sponsoring data					Fees for services					Other costs				
		A	B	C	D	E	F	G	H	I	F	J	K	L	M	F	N	L	

Signature .....
Date .....

ANNEX 2

FORM
for declaration of recipients of sponsoring in the field of medical devices

Reference of columns in the table below:
A - Name
B – Activity conducted
C – Address
D – Type of sponsorship (financial/material means)
E – Description of sponsored activity
F – Sum (lei)
G – Contract period
H – Date of payment/Date of delivery of goods
I – Description of the activity
J – Date of contract

No.	Name of the recipient of sponsoring	Name and surname of the declarant	Sponsor			Sponsoring data					Other costs				Total (lei)
			A	B	C	D	E	F	G	H	I	F	G	H	

Signature .....
Date .....

Issuer: Ministry of Health
Published in: the Official Gazette of Romania, no. 550 of 24 July 2015

DECISION
no. 20/03.07.2015

on repeal of SCD no. 13/15.06.2007, SCD no. 14/15.06.2007, SCD no. 24/28.09.2007 and SCD no. 25/28.09.2007 on conduct of pharmacovigilance activities

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 03.07.2015, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Sole article - The following NAMMD Scientific Council Decisions shall be repealed:

- **SCD no. 13/15.06.2007** on approval of Guideline on the procedure to be followed by marketing authorisation holders on undertaking the pharmacovigilance activities
- **SCD no. 14/15.06.2007** on approval of Guideline on pharmacovigilance systems, monitoring of compliance and pharmacovigilance inspections
- **SCD no. 24/28.09.2007** on approval of Guideline for procedure to be followed by competent authorities on undertaking pharmacovigilance activities
- **SCD no. 25/28.09.2007** on approval of Guideline on Rapid Alert and non-urgent information system in pharmacovigilance

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

DECISION

no. 23/03.07.2015

on approval of the Guideline on Good Manufacturing Practice for 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. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 03.07.2015, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Article 1. - The Guideline on Good Manufacturing Practice for Medicinal Products for human use is approved, in accordance with the Annex, which is integral part of this Decision.

Article 2. - On entry into force of this Decision, Scientific Council Decision no. 10/26.02.2015 on adoption of the Guideline on Good Manufacturing Practice (GMP) for medicinal products for human use is repealed, except for Annex 15 to the Guideline, "Qualification and validation", in force until 01.10.2015.

Article 3. - Annex 15 to the Guideline on Good Manufacturing Practice for medicinal products for human use, adopted through this Decision, shall enter into force on 01.10.2015.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

The ANNEX to SCD no. 23/03.07.2015, published in Newsletter no. 3/2015*, only contains the chapters/annexes different from those included in Annex to SCD no. 10/26.02.2015 on adoption of the* ***Guideline on Good Manufacturing Practice (GMP) for medicinal products for human use,*** namely:

- Document history – July 2015
- Amendment of Annex 2 – "Manufacture of biological active substances and medicinal products for human use"
- Amendment of Annex 15 – "Qualification and validation"
- Supplementation of Part III with the following documents:
  - Guidelines the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use
  - Template for the "written confirmation" for active substances exported to the European Union for medicinal products for human use, in accordance with Article 7551 (2) b) of Law 95/2006, Title XVII – The medicinal product

For the current version of *the* ***Guideline on Good Manufacturing Practice (GMP) for medicinal products for human use***, please see the **EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines**, available at http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm

DECISION
no. 24/03.07.2015

on approval of amendment of the Annex to SCD no. 2/22.04.2014 on approval of Regulations for authorisation of sites for conduct of clinical trials on 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. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 03.07.2015, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Sole article: Annex to NAMMD Scientific Council Decision (SCD) no. 2/2014 is amended as follows:

1. Article 5 (2) d) is amended and shall read as follows:

"d) - the List of Standard Operating Procedures (see Annex 2 for the minimal list of Standard Operating Procedures) or certification of implementation of a quality management system in accordance with ISO standards in force for clinical trials;

- ISO certification becomes mandatory as of 1 January 2017";

2. Article 11 d) is amended and shall read as follows:

"d) - the List of Standard Operating Procedures (see Annex 2 for the minimal list of Standard Operating Procedures) or certification of implementation of a quality management system in accordance with ISO standards in force for clinical trials;

- ISO certification becomes mandatory as of 1 January 2017";

3. Article 20 d) is amended and shall read as follows:

"d) - the List of Standard Operating Procedures (see Annex 2 for the minimal list of Standard Operating Procedures) or certification of implementation of a quality management system in accordance with ISO standards in force for clinical trials;

- ISO certification becomes mandatory as of 1 January 2017".

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

DECISION

no. 25/03/07/2015

on approval of amendment to Annex to SCD no. 6/22.04.2014 on approval of Regulations for authorisation by the National Agency for Medicines and Medical Devices of clinical trials/notification to the National Agency for Medicines and Medical Devices of non-interventional studies on medicinal products for human use in Romania

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 03.07.2015, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Sole article: The Annex to NAMMD Scientific Council Decision (SCD) no. 6/2014 is amended as follows:

1. Article 13 is supplemented with:

"3) The NAMMD shall make a single request for clarification/supplementation to the applicant;

4) The response to the NAMMD request shall be submitted no later than 30 days; submission of responses that are incomplete/unsatisfactory in terms of content, or failure to submit within the specific timeframe result in rejection of the application for authorisation."

2. Article 17 is amended and shall read as follows:

"The applicant submits to the NAMMD a copy of the favourable opinion expressed by the National Bioethics Committee for Medicines and Medical Devices (CNBMDM) as soon as it becomes available."

3. Article 18 is amended and shall read as follows:

"Clinical trials may only start on condition the NAMMD has granted the authorisation for clinical trial conduct and after grant of a favourable opinion by the National Bioethics Committee for Medicines and Medical Devices (CNBMDM)".

4. Article 26 is supplemented with:

"3) The NAMMD shall make a single request for clarification/supplementation;

4) The response to the NAMMD request shall be submitted no later than 30 days; submission of responses that are incomplete/unsatisfactory in terms of content, or failure to submit within the specific timeframe result in rejection of the application for authorisation.”

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

DECISION

no. 26/03.07.2015

on approval of the Romanian version of Standard Terms for pharmaceutical dosage forms for parenteral use, as approved by the European Pharmacopoeia Commission

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 03.07.2015, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Sole article - The Romanian version of Standard Terms for pharmaceutical dosage forms for parenteral use, as approved by the European Pharmacopoeia Commission (available in the EDQM database, *revised, the version of 14 November 2014*), is approved, in accordance with the Annex, which is integral part of this Decision.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

No.	*Status*	*English*	*Romanian*
1	Pending	***Concentrate for concentrate for solution for inf.***	***Concentrat pentru concentrat pentru a solution for inf.***
2	Current	***Concentrate for dispersion for inf.***	***Concentrat pentru dispersie perfuzabilă***
3	Current	***Concentrate for emulsion for inf.***	***Concentrat pentru emulsie perfuzabilă***
4	Current	***Concentrate for haemodialysis solution***	***Concentrat pentru soluţie pentru hemodializă***
5	Current	***Concentrate for solution for inf.***	***Concentrat pentru soluţie perfuzabilă***
6	Current	***Concentrate for solution for inj.***	***Concentrat pentru soluţie injectabilă***
7	Current	***Concentrate for solution for inj. / inf.***	***Concentrat pentru soluţie injectabilă perfuzabilă***
8	Deprecated	***Concentrate for suspension for inf.***	***Concentrat pentru suspensie perfuzabilă***
9	Pending	***Concentrate for suspension for inj.***	***Concentrat pentru suspensie injectabilă***
10	Pending	***Dispersion for concentrate for dispersion for inf.***	***Dispersie pentru concentrate for dispersion for inf.***
11	Current-new	***Dispersion for inf.***	***Dispersie perfuzabila***
12	Current	***Dispersion for inj.***	***Dispersie injectabilă***
13	Pending	***Dispersion for inj./inf.***	***Dispersie injectabilă / perfuzabila***
14	Pending	***Emulsion for emulsion for inj.***	***Emulsie pentru emulsie injectabila***
15	Current	***Emulsion for inf.***	***Emulsie perfuzabila***
16	Current-new	***Emulsion for inj.***	***Emulsie injectabila***
17	Current	***Emulsion for inj./inf.***	***Emulsie injectabilă / perfuzabila***
18	Pending	***Gas for dispersion for inf.***	***Gaz pentru dispersie perfuzabila***

19	Pending	***Gas for dispersion for inj.***	***Gaz pentru dispersion for inj. / perfuzabila***
20	Pending	***Gas for dispersion for inj./inf.***	***Gaz pentru dispersion for inj. / perfuzabila***
21	Current	***Gel for inj.***	***Gel injectabil***
22	Pending	***Granules for suspension for inj.***	***Granule pentru suspensie injectabila***
23	Current	***Implant***	***Implant***
24	Current-revised	***Implantation chain***	***Implantation chain***
25	Current-new	***Implantation matrix***	***Matrice implantabila***
26	Pending	***Implantation paste***	***Pasta implantabila***
27	Current-new	***Implantation suspension***	***Suspensie implantabila***
28	Current-new	***Implantation tablet***	***Comprimat implantabil***
29	Current	***Intravesical solution/solution for inj.***	***Soluţie intravezicală/soluţie injectabilă***
30	Rejected	***Kit for implant***	***Kit pentru implant***
31	Current-revised	***Living tissue equivalent***	***Echivalent tisular viu***
32	Pending	***Matrix for implantation matrix***	***Matrice pentru matrice implantabila***
33	Current-new	***Powder for concentrate for dispersion for inf.***	***Pulbere pentru concentrat pentru dispersie perfuzabilă***
34	Deprecated	***Powder for concentrate for haemodialysis solution***	***Pulbere pentru concentrat pentru soluţie de hemodializă***
35	Current	***Powder for concentrate for solution for haemodialysis***	***Pulbere pentru concentrat pentru soluţie pentru hemodializă***
36	Current	***Powder for concentrate for solution for inf.***	***Pulbere pentru concentrat pentru soluţie perfuzabilă***
37	Current	***Powder for concentrate for solution for inj./inf.***	***Pulbere pentru concentrat pentru soluţie injectabila / perfuzabilă***

38	Current-new	***Powder for dispersion for inf.***	***Pulbere pentru dispersie perfuzabilă***
39	Pending	***Powder for dispersion for inj.***	***Pulbere pentru dispersie injectabilă***
40	Pending	***Powder for emulsion for inj.***	***Pulbere pentru emulsie injectabilă***
41	Pending	***Powder for implantation matrix***	***Pulbere pentru matrice implantabila***
42	Pending	***Powder for implantation paste***	***Pulbere pentru pasta implantabila***
43	Current-revised	***Powder for implantation suspension***	***Pulbere pentru suspensie implantabila***
44	Current-new	***Powder for intravesical solution/solution for inj.***	***Pulbere pentru soluţie intravezicala / soluţie injectabila***
45	Rejected	***Powder for nebuliser solution/solution for inj./inf.***	***Pulbere pentru solutie de inhalat prin nebulizator / solutie injectabila / perfuzabila***
46	Current-new	***Powder for prolonged-release suspension for inj.***	***Pulbere pentru suspensie injectabila cu eliberare prelungita***
47	Current	***Powder for solution for inf.***	***Pulbere pentru a solution for inf.***
48	Current	***Powder for solution for inj.***	***Pulbere pentru soluţie injectabila***
49	Deprecated	***Powder for solution for inj./inf.***	***Pulbere pentru soluţie injectabila sau perfuzabila***
50	Current	***Powder for solution for inj./inf.***	***Pulbere pentru soluţie injectabila / perfuzabila***

51	Pending	***Powder for solution for inj./skin-prick test***	***Pulbere pentru soluţie injectabila / test cutanat prin intepare***
52	Deprecated	***Powder for solution/suspension for inj.***	***Pulbere pentru soluţie / suspensie injectabila***
53	Current	***Powder for suspension for inj.***	***Pulbere pentru suspensie injectabila***
54	Current	***Prolonged-release suspension for inj.***	***Suspensie injectabila cu eliberare prelungita***
55	Current-new	***Solution for cardioplegia***	***Soluţie pentru cardioplegie***
56	Current	***Solution for haemodiafiltration***	***Soluţie pentru hemodiafiltrare***
57	Current	***Solution for haemodialysis***	***Soluţie pentru hemodializă***
58	Current	***Solution for haemodialysis/haemofiltration***	***Soluţie pentru hemodializă/hemofiltrare***
59	Current-new	***Solution for haemofiltration***	***Soluţie pentru hemofiltrare***
60	Current	***Solution for inf.***	***Soluţie perfuzabilă***
61	Deprecated	***Solution for inf. and oral solution***	***Soluţie perfuzabilă şi soluţie orală***
62	Current	***Solution for inj.***	***Soluţie injectabilă***
63	Rejected	***Solution for inj./concentrate for solution for inf.***	***Soluţie injectabilă / concentrat pentru a solution for inf.***

64	Current	***Solution for inj./inf.***	***Soluţie injectabilă / perfuzabila***
65	Rejected	***Solution for inj./inf./rectal use***	***Soluţie injectabilă / perfuzabilă / administrare rectala***
66	Pending	***Solution for inj./skin-prick test***	***Soluţie injectabila / test cutanat prin intepare***
67	Pending	***Solution for solution for inj.***	***Soluţie pentru soluţie injectabilă***
68	Pending	***Solution for suspension for inj.***	***Soluţie pentru suspensie injectabilă***
69	Current-revised	***Solvent for parenteral use***	***Solvent pentru preparate parenterale***
70	Current	***Solvent for solution for inf.***	***Solvent pentru a solution for inf.***
71	Pending	***Suspension for emulsion for inj.***	***Suspensie pentru emulsie injectabila***
72	Deprecated	***Suspension for inf.***	***Suspensie perfuzabila***
73	Current	***Suspension for inj.***	***Suspensie injectabila***
74	Pending	***Suspension for suspension for inj.***	***Suspensie pentru suspensie injectabila***

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

Current – new = Standard Term approved for use by the European Pharmacopoeia Commission, the Romanian version has been approved in the session of the NAMMD Scientific Council of 03.07.2015.

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

Rejected = The Standard Term has been **rejected** during assessment within the *Standard Terms Working Party of the* EDQM and is not approved for use as a Standard Term; Included in the database in order to avoid transmission of new requests to the PhEur Commission for this term

Pending = the proposed term **undergoes assessment** by the *Standard Terms Working Party of the EDQM*.

Current-revised = Standard Term approved for use by the European Pharmacopoeia Commission; a new version of the translation into Romanian of the respective Standard Term has been approved

DECISION
no. 27/03.07.2015
on approval of switch of current classification for release of Lomexin 20 mg/gram cream (fenticonazole)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 03.07.2015, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Sole article - Switch of classification for release from on-prescription to over-the-counter release is approved for **Lomexin 20 mg/gram cream (fenticonazole)**, marketing authorisation holder: Recordati S.p.A., Italy, packaging size: 30 g Aluminium Ointment Tube.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

DECISION
no. 28/03.07.2015
on approval of switch of current classification for release of Kitonail 80 mg/g medicated nail lacquer (ciclopirox)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 03.07.2015, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Sole article - Switch of classification for release from on-prescription to over-the-counter release is approved for **Kitonail 80 mg/g medicated nail lacquer (ciclopirox)**, marketing authorisation holder: Polichem SA, Luxembourg, packaging size: 3.3 ml or 6.6 ml box or vial.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

DECISION

no. 29/30.09.2015

on adoption of the Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 30.09.2015, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Sole article - The Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms is adopted, in accordance with the Annex, which is integral part of this Decision.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

Guideline
on the pharmacokinetic and clinical evaluation of modified release dosage forms

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the EMA document **Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms**, published by the European Medicines Agency.

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

Therefore, for the Annex to this Decision, please see the **Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms**, available at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/11/WC500177884.pdf

DECISION
no. 30/30.09.2015

on adoption of the Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk management systems (Rev 1)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 30.09.2015, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Sole article - The Guideline on GOOD PHARMACOVIGILANCE PRACTICES (GVP) Module V – Risk management systems (Rev 1) is adopted, in accordance with the Annex, which is integral part of this Decision.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

ANNEX
to SCD no. 30/30.09.2015

GUIDELINE ON GOOD PHARMACOVIGILANCE PRACTICES (GVP)
Module V – Risk management systems (Rev 1)

Date of entry into force of Module V, Rev1: 28 April 2014

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the EMA document **Guideline on Good Pharmacovigilance Practices (GVP), Module V – Risk management systems (Rev 1)**, published by the European Medicines Agency.

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

Therefore, for the Annex to this Decision, please see the **Guideline on Good Pharmacovigilance Practices (GVP), Module V – Risk management systems (Rev 1)**, available at
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129134.pdf

DECISION

no. 31/30.09.2015

on basic criteria for NAMMD approval of supply of free samples, on establishment of conditions for grant of approval for supply of free samples of medicinal products for human use authorised for marketing in Romania and approval of the procedure for supply of free samples of medicinal products for human use authorised for marketing in Romania

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 30.09.2015, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Article 1 – The basic criteria for NAMMD approval of supply of free samples of medicinal products for human use authorised for marketing in Romania are approved, as shown in Annex 1, which is integral part of this Decision.

Article 2 – The conditions for grant of approval for supply of free samples of medicinal products for human use authorised for marketing in Romania are established, as shown in Annex 2, which is integral part of this Decision.

Article 3 – The procedure for supply of free samples of medicinal products for human use authorised for marketing in Romania is approved, as shown in Annex 3, which is integral part of this Decision.

Article 4. – On this Decision coming into force, SCDs 17/2009, 3/2010 and 4/2011 are repealed.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

ANNEX 1
to SCD no. 31/30.09.2015

Criteria for NAMMD approval of supply of free samples

of medicinal products for human use authorised for marketing in Romania

In accordance with provisions of Law No. 95/2006 on healthcare reform, as amended, NAMMD may, under exceptional circumstances, approve provision of free samples meant to support prescribers in becoming acquainted with a certain medicinal product, i.e. gain experience in its use and for emergency purposes.

The criteria according to which NAMMD approves supply of free samples of medicinal products for human use are as follows:

1. Medicinal products with a unique International Non-proprietary Name (INN) in Romania/the European Union, marketed in Romania for no longer than 3 years after actual introduction of the authorised products on the Romanian pharmaceutical market.

2. Medicinal products with new INN combination in Romania/the European Union, marketed in Romania for no longer than 3 years after actual introduction of the authorised products on the Romanian pharmaceutical market.

3. Advanced therapy medicinal products, orphan medicinal products, marketed in Romania for no longer than 3 years after actual introduction of the authorised products on the Romanian pharmaceutical market.

4. Original medicinal products authorised for marketing through national/centralised procedure, marketed in Romania for no longer than 3 years as of their inclusion in the list of reimbursable/free medicinal products.

5. Generic medicinal products authorised for marketing through national/centralised/ MRP/DCP procedure, marketed in Romania for no longer than 1 year after inclusion in the list of reimbursable/free medicinal products.

6. Medicinal products for which the NAMMD has approved a new therapeutic indication/pharmaceutical form for the same INN, if justified; in this case, the provision of free samples is allowed for no longer than 3 years after approval of variation to MA terms.

7. Biosimilar medicinal products, authorised for marketing through national/centralised/ MRP/DCP procedure, marketed in Romania for no longer than 1 year after actual introduction of the authorised products on the Romanian pharmaceutical market.

In support of the application for approval to provide free samples, the Marketing Authorisation Holder must prove actual introduction of the authorised medicinal product on the Romanian pharmaceutical market, as well as inform the NAMMD about the date of the respective medicinal product inclusion in the list of reimbursable/free of charge medicinal products.

ANNEX 2
to SCD no. 31/30.09.2015

Conditions for grant of approval for supply of free samples of medicinal products for human use authorised for marketing in Romania

Article 1. – For supply of free medicinal product samples of medicinal products for human use authorised for marketing in Romania, in accordance with provisions of Article 822 of Law 95/2006 on healthcare reform, republished, marketing authorisation holders (MAHs) are required to submit the following to the National Agency for Medicines and Medical Devices (NAMMD) – the Pharmaceutical Inspection Department (PID):

- the name of the distributor authorised by the NAMMD for storage of free medicinal product samples of the respective MAH's products, accompanied by the contract for provision of services signed with the respective company;
- the updated list of medicinal products supplied as free medicinal product samples;
- the procedure for MAH handling of supply of free medicinal product samples;
- the decision of the MAH/MAH representative in Romania concerning nomination of the person responsible for handling free medicinal product samples, stating their capacity and position as per the respective organisational chart, to demonstrate compliance with provisions of Article 3 a) of Annex 3 of this SCD;
- Mock-up of the secondary packaging imprinted with the specification as free sample;
- Statutory declaration of the MAH/MAH representative in Romania concerning actual introduction of the medicinal product on the Romanian pharmaceutical market.

Article 2. – The validity of the NAMMD approval for supply of free samples of medicinal products for human use is 1 calendar year (12 months) as of issuance.

Article 3. – At the end of the year of validity of approval for sample supply, the MAH shall submit a report to the NAMMD – PID on distribution of free medicinal product samples, as shown in the form below:

"Current status of handling of free medicinal product samples by the MAH/MAH representative in Romania ……., during ……..

No.	**Invented name**	**INN**	**Size of sample packaging**	**Sample manufacturing batch and expiry date**	**Number of samples received by the MAH**	**Recipient wholesale distributor**	**Number of samples provided to the distributor**	**Number of requests for samples received by the MAH**	**Physician requiring samples**
1.	……..								

Stock of samples on reporting date (fill in for each medicinal product approved for distribution as samples):

Date,

Print name and signature of the responsible person of the MAH/MAH representative in Romania"

Article 4. – In case of undistributed amounts of free medicinal product samples at the end of the year of NAMMD approval validity, in line with the criteria and conditions approved through this Decision, it is necessary to contact the NAMMD for a new approval for supply of free medicinal product samples.

ANNEX 3
to SCD no. 31/30.09.2015

Procedure for supply of free samples of medicinal products for human use authorised for marketing in Romania

Article 1. – This procedure establishes the handling of free samples of medicinal products for human use by Marketing Authorisation Holders (MAHs) provided only to persons qualified for their prescription/release.

Article 2. - This procedure applies to all Marketing Authorisation Holders and/or their representatives (agencies, providers of special services, wholesale distributors who are also MAHs).

Article 3. – For supply of free medicinal product samples, MAHs or their representatives in Romania shall meet the following conditions:

a) to nominate a person responsible for this activity (Product Director, Marketing Director, Logistics Director – in line with the organisational chart of each company);

b) to elaborate a procedure on handling of free medicinal product samples provided;

c) to sign a contract with a wholesale distributor authorised by the National Agency for Medicines and Medical Devices (NAMMD) for custody and supply of pharmaceutical logistics services;

d) to hold evidence of the amount of samples received from the MAH/manufacturer and quality documents accompanying the products;

e) to hold evidence of request of samples by persons authorised for prescription/release;

f) to hold consolidated evidence of free medicinal product samples provided in accordance with the requests confirmed by the nominated person.

Article 4. – All documents must be filled in, dated and signed by persons involved in this procedure, to be approved by the nominated person mentioned under Article 3 a) of this procedure.

Article 5. – Wholesale distributors storing and/or transporting free medicinal product samples have the same responsibilities as for storage/transport of medicinal products included in their distribution portfolio (i.e. to keep records on monitoring of storage conditions during storage and/or transport and evidence on quantitative handling of samples).

Article 6. - Records associated with the procedure for handling samples must contain enough information to allow traceability of each sample batch provided.

Article 7. – Free medicinal product samples provided to nominated persons must comply with all provisions of Article 822, Chapter IX of Law 95/2006, Title XVIII - The medicinal product, republished.

Article 8. – Manufacturer failure to imprint samples, as stipulated in Article 822 d) and e), with the inscription “free sample – not for sale” or a mention to the same effect, results in the obligation to label/relabel on a manufacturing flow authorised in accordance with provisions of Article 755 of Law 95/2006, republished.

Article 9. - In accordance with provisions of Article 822 of Law 95/2006, republished, “in exceptional cases, free samples are provided only to persons qualified to prescribe or distribute” medicinal products; the number of free samples provided must comply with the posology approved through the Summary of Product Characteristics, but must only allow treatment for maximum 3 months of no more than 10 patients/year/physician for each medicinal product for human use.

Article 10. – Prior to supply of free medicinal product samples, the MAH or their representative is required grant of NAMMD approval/renewal of approval on supply of respective samples, as required.

Article 11 – The obligation related to mandatory (yearly) reporting of the current status of handling of free medicinal product samples lies with the person nominated in accordance with Article 3 a) of this procedure.

Article 12. – MAHs who, on entry into force of this Decision, provide medicinal product samples based on NAMMD approvals issued in accordance with criteria 1, 2 or 3 in Annex 1 to SCD 4/2011, shall require for renewed approval within three months as of entry into force of this Decision.

Article 13. - Noncompliance with provisions of this Decision is subject to penalties in line with provisions of Law 95/2006 on healthcare reform, republished.

DECISION

no. 32/30.09.2015

on approval of the Romanian version of Standard Terms for pharmaceutical dosage forms for pulmonary use, as approved by the European Pharmacopoeia Commission

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 30.09.2015, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

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

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

No.	Status	Full standard term	
		English	Romanian
1	Rejected	*Aerosol*	*Aerosol*
2	Current-new	*Concentrate for nebuliser solution*	*Concentrat pentru soluţie pentru nebulizator*
3	Current-revised	*Endotracheopulmonary instillation, powder for solution*	***Initial:*** *Pulbere pentru solutie destinata instilatiei endotraheopulmonara* ***Revised:*** *Pulbere pentru soluţie pentru instilatie endotraheopulmonara*
4	Current-new	*Endotracheopulmonary instillation, powder for suspension*	*Pulbere pentru suspensie pentru instilatie endotraheopulmonara*
5	Current	*Endotracheopulmonary instillation, solution*	*Soluţie pentru instilatie endotraheopulmonara*
6	Current	*Endotracheopulmonary instillation, suspension*	*Suspensie pentru instilatie endotraheopulmonara*
7	Deprecated	*Inhalation gas*	*Gaz de inhalat*
8	Deprecated	*Inhalation impregnated pad*	
9	Current	*Inhalation powder*	*Pulbere de inhalat*
10	Current-revised	*Inhalation powder, hard capsule*	***Initial*** *: Capsula cu pulbere de inhalat* ***Revised:*** *Pulbere de inhalat, capsulă*
11	Current	*Inhalation powder, pre-dispensed*	*Pulbere de inhalat unidoza*
12	Current-revised	*Inhalation powder, tablet*	***Initial:*** *Comprimat pentru pulbere de inhalat* ***Revised:*** *Pulbere de inhalat, comprimat*
13	Current	*Inhalation solution*	*Soluţie de inhalat*
14	Current-revised	*Inhalation vapour, capsule*	***Initial****: Capsula pentru inhalation vapours* ***Revised:*** *Inhalation vapours, capsula*
15	Current-revised	*Inhalation vapour, effervescent tablet*	***Initial:*** *Comprimat efervescent pentru inhalation vapours* ***Revised:*** *Inhalation vapours, comprimat efervescent*
16	Current-revised	*Inhalation vapour, emulsion*	***Initial****: Emulsie pentru inhalation vapours* ***Revised:*** *Inhalation vapours, emulsie*
17	Current-revised	*Inhalation vapour, impregnated pad*	***Initial****: Tampon impregnat pentru inhalation vapours* ***Revised:*** *Inhalation vapours, tampon impregnat*
18	Current-revised	*Inhalation vapour, impregnated plug*	***Initial*** *: Suport impregnat pentru inhalation vapours* ***Revised:*** *Inhalation vapours, suport impregnat*
19	Current-revised	*Inhalation vapour, liquid*	***Initial:*** *Lichid pentru inhalation vapours* ***Revised:*** *Inhalation vapours, lichid*

20	Current-revised	*Inhalation vapour, ointment*	***Initial**: Ointment pentru inhalation vapours* ***Revised:** Inhalation vapours, ointment*
21	Current-revised	*Inhalation vapour, powder*	***Initial:** Pulbere pentru inhalation vapours* ***Revised:** Inhalation vapours, pulbere*
22	Current-revised	*Inhalation vapour, solution*	***Initial:**Solutie pentru inhalation vapours* ***Revised:** Inhalation vapours, solutie*
23	Current-revised	*Inhalation vapour, tablet*	***Initial:**Comprimat pentru inhalation vapours* ***Revised:** Inhalation vapours, comprimat*
24	Deprecated	*Liquefied gas for dental use*	*Gaz lichefiat pentru uz dentar*
25	Current-revised	*Medicinal gas, compressed*	***Initial**: Gaz medicinal, comprimat **Revised:** Compressed medicinal gas*
26	Current-revised	*Medicinal gas, cryogenic*	***Initial**: Gaz medicinal, criogenic **Revised:** Gaz medicinal criogenic*
27	Current-revised	*Medicinal gas, liquefied*	***Initial**: Gaz medicinal, lichefiat **Revised:** Gaz medicinal lichefiat*
28	Current-revised	*Nebuliser emulsion*	***Initial:** Emulsie de inhalat prin nebulizator* ***Revised:** Emulsie pentru nebulizator*
29	Current-revised	*Nebuliser solution*	***Initial:** Solutie de inhalat prin nebulizator* ***Revised:** Solutie pentru nebulizator*
30	Current-revised	*Nebuliser suspension*	***Initial:** Suspensie de inhalat prin nebulizator* ***Revised:** Suspensie pentru nebulizator*
31	Current-revised	*Oral solution/concentrate for nebuliser solution*	***Initial:** Soluţie orală/concentrat pentru soluţie de inhalat prin nebulizator* ***Revised:** Soluţie orală/concentrat pentru soluţie pentru nebulizator*
32	Current-revised	*Powder for nebuliser solution*	***Initial:** Pulbere pentru soluţie de inhalat prin nebulizator* ***Revised:** Pulbere pentru solutie pentru nebulizator*
33	Rejected	*Powder for nebuliser solution/solution for inj./inf.*	*Pulbere pentru soluţie pentru nebulizator / solutie injectabila / perfuzabila*
34	Current-revised	*Powder for nebuliser suspension*	***Initial:** Pulbere pentru suspensie de inhalat prin nebulizator* ***Revised:** Pulbere pentru suspensie pentru nebulizator*
35	Current	*Pressurised inhalation, emulsion*	*Emulsie de inhalat presurizata*
36	Current	*Pressurised inhalation, solution*	*Soluţie de inhalat presurizata*
37	Current	*Pressurised inhalation, suspension*	*Pressurised suspension for inhalation*
38	Current	*Solution for provocation test*	*Solutie pentru testul de provocare*

Legend:

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

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

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

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

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

DECISION

no. 33/30.09.2015

on approval of NAMMD principles for assessment of co-payment discount programmes to facilitate access to on-prescription medicinal products

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 30.09.2015, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Sole article - NAMMD principles for assessment of co-payment discount programmes to facilitate access to on-prescription medicinal products are approved, in accordance with the Annex, which is integral part of this Decision.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

ANNEX
to SCD no. 33/30.09.2015

NAMMD PRINCIPLES
for assessment of co-payment discount programmes
to facilitate access to on-prescription medicinal products

Facilitation of patient access to the prescribed treatment with lower costs, avoiding treatment discontinuation risk and resulting deterioration of patients' health condition requires implementation of programmes for partial/full discount for patients concerning treatments with certain medicinal products and medical devices.

The platform for a co-payment discount programme is a result of processes involving as actors Marketing Authorisation Holders or their representatives for products included in the co-payment discount programme, the programme administrator, related pharmacies and respective patients.

Respective cuts to co-payment may be applied to any on-prescription product included in the programme and may complement state or private insurer discounts. Costs implied are covered by respective Marketing Authorisation Holders or their representatives for products included in the co-payment discount programme.

To avoid inclusion of co-payment discount programmes into the category of "medicinal product advertising", in line with Law 95/2006 on healthcare reform, republished, deeming them as stimulants of medicinal product distribution, co-payment discount programmes must strictly comply with the following principles:

1- All patients are equally entitled to co-payment reductions granted within a programme. However, criteria for support of certain social categories may be defined. Each patient included into the programme benefits of a monthly (or quarterly, depending on prescription type) maximum (limitating) co-payment discount for a certain product, granted depending on the maximum monthly dose (quarterly) established in accordance with the treatment scheme and with the product's dosage indications.
2- The prescriber may inform patients on programmes and benefits deriving from participation in such programmes only after actual prescription of the medicinal product included in the programme, based on professional independence and the prescriber's freedom of medical decision.
3- All Marketing Authorisation Holders and their representatives have equal access to co-payment discount programmes, which are open for inclusion of any product whatsoever. The sum compensated by the Marketing Authorisation Holders or their representatives is established independently and represents the absolute number reported to the therapeutic unit of the respective medicinal products.
4- Co-payment discount programmes must be available to any pharmacy willing to participate in the programme.
5- No direct relationship or direct exchange of information is allowed within a co-payment discount programme between Marketing Authorisation Holders/Marketing Authorisation Holder representatives, and the pharmacy or patient. Neither is the between them.
6- Compliance with aforementioned requirements nomination of an independent administrator, able of direct management of the co-payment discount programme, while also ensuring a platform for

discount of sums for co-payment deductions. Reimbursement of co-payment discounts is only performed between Marketing Authorisation Holders and their representatives and the programme administrator and between the programme administrator and the related pharmacy, based on transactions reported by pharmacies. Involvement of other operators (distributors, economic agents etc.) is not allowed within the co-payment discount process.

7- Taking into account limited access to information about system transactions, Marketing Authorisation Holders or their representatives may assign an independent auditor to audit the accuracy of transactions reported by the programme administrator, but shall not have direct access to transaction details.

8- All co-payment discount programmes rely on a nominal card, unique for each patient, not containing information on a certain manufacturer, product or treatment.

9- Given their capacity to allow direct or indirect information transfer among participants, other systems for grant of co-payment discounts to patients (vouchers, coupons, value tickets or other commercial discount mechanisms etc.) are not allowed.

10- Patient enrolment in the programme, distribution and handling of cards is only performed by the programme administrator. Enrolment of patients, issue and release of cards to patients by Marketing Authorisation Holders and their representatives or prescribers are forbidden.

11- The programme administrator ensuring programme control and administration may be any independent legal person, unaffiliated to Marketing Authorisation Holders or their representatives.

12- The programme administrator must meet all requirements stipulated by the Law as regards processing of personal data. The administrator may not provide information related to pharmacies, patients or prescribers to the other participants in the programme.

13- It is the administrator's duty to ensure system safety and the confidentiality of processed information, thus ensuring control of information flows among various participants in the co-payment discount programme.

14- The programme administrator must ensure operation of the entire infrastructure (hardware, software etc.), as well as logistic support required for course of programmes and is responsible for the integrity and accuracy of processed information. To this purpose, to ensure improved safety of administered data, the programme administrator must have ISO certification (ISO 9001 and ISO 27001).

DECISION
no. 34/30.09.2015

on rejection of application for change of classification for release, from on-prescription to over-the-counter for Gingium 40 mg, 80 mg and 120 mg, film-coated tablets

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 30.09.2015, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Sole article - Switch of classification for release, from on-prescription to over-the-counter for Gingium 40 mg, 80 mg and 120 mg, film-coated tablets, is rejected, following non-compliance with the assessment criteria approved through SCD no. 4/2009 on approval of the Guideline on change of classification for supply of a medicinal product for human use.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

DECISION
no. 35/30.09.2015

on delayed adoption of a Decision on switch of classification for release, from on-prescription to over-the-counter for Lagosa 150 mg lozenges (silybin)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 30.09.2015, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Sole article - Adoption of a Decision on switch of classification for release, from on-prescription to over-the-counter for Lagosa 150 mg lozenges (silybin) is delayed, until adoption, by the Committee on Herbal Medicinal Products, of the EU monograph for *Silybum marianum, fructus.*

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

Medicinal product batches recalled during the 3rd quarter of 2015

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Proposed action	Date of recall
1	ACC JUNIOR	granules for oral suspension	20 mg/ml	acetylcysteinum	Salutas Pharma GmbH, Germany/ Hexal, Germany	DD8196, DD8197, DS2296, EC6799, DW3815, EB3707	„Out of specification" results obtained during long-term stability studies	Recall and destruction	29.06.2015
2	IRBESARTAN TORRENT	film-coated tablets	300 mg	irbesartanum	Torrent Pharma	1305000433	European Commission Decision no. C(2015)5100-final of 16.07.2015: suspension of MAs based on bioequivalence studies conducted at the GVK Biosciences Hyderabad site	Recall and destruction	30.07.2015
3	APSTAR	prolonged-release tablets	35 mg	trimetazidinum dichlorh.	Glenmark Pharmaceuticals S.R.O., the Czech Republic	G500108	European Commission Decision no. C(2015)5100-final of 16.07.2015: suspension of MAs based on bioequivalence studies conducted at the GVK Biosciences Hyderabad site	Recall and destruction	30.07.2015
4	DESLORATADINA ALVOGEN	film-coated tablets	5 mg	desloratadinum	Genepharm GREECE/ Alvogen IPCo S.ar.l, Luxembourg	141625	European Commission Decision no. C(2015)5100-final of 16.07.2015: suspension of MAs based on bioequivalence studies conducted at the GVK Biosciences Hyderabad site	Recall and destruction	30.07.2015
5	TELMISARTAN Dr. REDDY'S	tablets	40 mg	telmisartanum	Dr. Reddy's Laboratories	B401727	European Commission Decision no. C(2015)5100-final of 16.07.2015: suspension of MAs based on bioequivalence studies conducted at the GVK Biosciences Hyderabad site	Recall and destruction	30.07.2015
6	TELMISARTAN Dr. REDDY'S	tablets	80 mg	telmisartanum	Dr. Reddy's Laboratories	B401795	European Commission Decision no. C(2015)5100-final of 16.07.2015: suspension of MAs based on bioequivalence studies conducted at the GVK	Recall and destruction	30.07.2015

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Proposed action	Date of recall
							Biosciences Hyderabad site		
7	LEVETIRACETAM DR.REDDY'S	film-coated tablets	500 mg	levetiracetamum	Dr. Reddy's Laboratories	C404052	European Commission Decision no. C(2015)5100-final of 16.07.2015: suspension of MAs based on bioequivalence studies conducted at the GVK Biosciences Hyderabad site	Recall and destruction	30.07.2015
8	LEVETIRACETAM DR.REDDY'S	film-coated tablets	1000 mg	levetiracetamum	Dr. Reddy's Laboratories	C205749	European Commission Decision no. C(2015)5100-final of 16.07.2015: suspension of MAs based on bioequivalence studies conducted at the GVK Biosciences Hyderabad site	Recall and destruction	30.07.2015
9	ULTRAPROCT	ointment rectal		combinations	Intendis Man. SPA, ITALY/ Bayer Pharma AG, Romania	33155A, YY002V9	Expiry of product 1-year validity (as per Order of the Minister of Health no. 1810/2006) after NAMMD approval of transfer of marketing authorisation (MA) no. 1411/2009/02	Recall and destruction	05.08.2015
10	PARASINUS	tablets		combinations	GSK Consumer Healthcare/ Europharm Romania SRL	2307÷2310, 2312÷2348, 2350÷2399, 2400÷2499, 2500, 2592	Expiry of product 1-year validity (as per Order of the Minister of Health no. 1810/2006) after NAMMD approval of transfer of marketing authorisation (MA) no. 3193/2003/01	Recall and destruction	05.08.2015
11	ZAVEDOS	powder for solution for inj.	5 mg	idarubicinum	Actavis Italy SPA, ITALY/Pfizer Europe MA EEG, Great Britain	4YE0031	2 vials have been detected, each containing a glass particle	Recall and destruction	06.08.2015
12	COLDREX JUNIOR	tablets		combinations	Famar SA, GREECE/ GSK Healthcare, Great Britain	2064	Expiry of product 2-year validity (as per Order of the Minister of Health no. 279/2005) after NAMMD approval for amendment of MA no. 5687/2005/01-02 of 14.03.2013 (change of design of product packaging)	Recall and destruction	06.08.2015

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Proposed action	Date of recall
13	MYCOMAX ZENTIVA	capsules	150 mg	fluconazolum	Zentiva KS, the Czech Republic	All batches	Expiry of product 2-year validity (as per Order of the Minister of Health no. 279/2005) after NAMMD approval of the change of invented name to FLUCONAZOL ZENTIVA 150 mg capsules	Recall and destruction	14.08.2015
14	AZITROX	film-coated tablets	500 mg	azithromicinum	Zentiva KS, the Czech Republic	3580315	Failure to imprint the measure unit for strength (”*mg”*) and the pharmaceutical form *(”film-coated tablets”*) on the primary packaging	Recall and destruction	14.08.2015
15	PIROXICAM HELCOR	tablets	20 mg	piroxicamum	AC Helcor SRL	2680215	Imprint on certain blisters of the name of the product RAMPRIL	Recall and destruction	08.09.2015

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 2nd quarter of 2015

During the 2nd quarter of 2015, 184 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
A04 - ANTIEMETICS AND ANTINAUSEANTS
A05 – BILE AND LIVER THERAPY
A13 - TONICS
B01 – ANTITHROMBOTIC AGENTS
C01 – CARDIAC THERAPY
C04 – PERIPHERAL VASODILATORS
C07 – BETA BLOCKING AGENTS
C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
C10 - LIPID MODIFYING AGENTS
D01 - ANTIFUNGALS FOR DERMATOLOGICAL USE
D06 - ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE
D07 - CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS
G03 - SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM
G04 - UROLOGICALS
H01 - PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES
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
L03 - IMMUNOSTIMULANTS
L04 - IMMUNOSUPPRESSANTS
M01 - ANTI-INFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
M04 - ANTIGOUT PREPARATIONS
N02 - ANALGESICS
N03 - ANTIEPILEPTICS
N04 – ANTI-PARKINSON DRUGS
N05 - PSYCHOLEPTICS
N06 - PSYCHOANALEPTICS

Plants with traditional use
R01 – NASAL PREPARATIONS
R02 – THROAT PREPARATIONS
R03 - DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES
R05 - COUGH AND COLD PREPARATIONS
S01 - OPHTHALMOLOGICALS
V03 - ALL OTHER THERAPEUTIC PRODUCTS
V09 - DIAGNOSTIC RADIOPHARMACEUTICALS
XRN – HOMEOPATHIC MEDICINAL PRODUCTS

Medicinal products authorised for marketing during the 2nd quarter of 2015

INN	Invented name	Pharm. form	Strength	Manufacturer/MAH	Country	MA number		
ACETYLCYSTEINUM	FLUIMUCIL 20 mg/ml PEDIATRIC	oral solution	20mg/ml	ZAMBON S.P.A.	ITALY	7715	2015	01
ACETYLCYSTEINUM	FLUIMUCIL 300 mg/3 ml	solution for inj./nebuliser solution for inf./endo-tracheo-bronchial instillation	300mg/ 3ml	ZAMBON S.P.A.	ITALY	7716	2015	01
ACETYLCYSTEINUM	HIDONAC 5 g/25 ml	solution for inf.	200mg/ml	ZAMBON S.P.A.	ITALY	7728	2015	01
ACICLOVIRUM	ACICLOVIR 400 mg	tablets	400mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7732	2015	01
ACICLOVIRUM	ACICLOVIR 200 mg	tablets	200mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7731	2015	01
ACICLOVIRUM	ACICLOVIR 50mg/g	cream	50mg/g	EGIS PHARMACEUTICALS PLC	HUNGARY	7733	2015	02
ACIDUM ACETYLSALICYLICUM	ASPIMAX T 500mg	tablets	500mg	LAROPHARM SRL	ROMANIA	7781	2015	01
ACIDUM ACETYLSALICYLICUM	ALKA - SELTZER 324 mg	effervescent tablets	324mg	BAYER SRL	ROMANIA	7880	2015	01
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC 500 mg	tablets	500mg	SANOSAN SRL	ROMANIA	7600	2015	01
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC T 500 mg	tablets	500mg	SANTA S.A.	ROMANIA	7601	2015	01
ACIDUM ACETYLSALICYLICUM	PROTECARDIN 100 mg	tablets	100mg	BIOFARM S.A.	ROMANIA	7649	2015	01
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC T SANOSAN 500 mg	tablets	500mg	SANOSAN SRL	ROMANIA	7605	2015	01
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC SANTA 500 mg	tablets	500mg	SANTA S.A.	ROMANIA	7606	2015	01

ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC SANDOZ 75 mg	gastroresistant tablets	75mg	SANDOZ SRL	ROMANIA	7831	2015	01
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC SANDOZ 100 mg	gastroresistant tablets	100mg	SANDOZ SRL	ROMANIA	7832	2015	01
ACIDUM PAMIDRONICUM	PAMIDRONAT TORREX 15 mg/ml	concentrate for solution for inf.	15mg/ml	CHIESI PHARMACEUTICALS GMBH	AUSTRIA	7602	2015	01
ACIDUM PAMIDRONICUM	PAMIRED 60mg	powder for solution for inf.	60mg	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	7654	2015	01
ACIDUM PAMIDRONICUM	PAMIRED 30mg	powder for solution for inf.	30mg	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	7653	2015	01
ACIDUM TIOCTICUM (ALFA-LIPOICUM)	THIOCTACID 600T	solution for inj.	25mg/ml	MEDA PHARMA GMBH & CO. KG	GERMANY	7592	2015	01
ACIDUM URSODEOXYCHOLICUM	URSOCHOL 150 mg	tablets	150mg	ZAMBON S.P.A.	ITALY	7582	2015	01
ACIDUM URSODEOXYCHOLICUM	URSOCHOL 300 mg	tablets	300mg	ZAMBON S.P.A.	ITALY	7583	2015	01
HUMAN NANOCOLLOIDAL ALBUMIN	NANOSCAN 500 µgr	kit for radiopharmaceutical preparation	500 µgr	RADIOPHARMACY LABORATORY LTD.	HUNGARY	7665	2015	01
ALPRAZOLAMUM	XANAX 0.25 mg	tablets	0.25mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	7758	2015	01
ALPRAZOLAMUM	XANAX 0.5 mg	tablets	0.5mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	7759	2015	01
ALPRAZOLAMUM	XANAX 1 mg	tablets	1mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	7760	2015	01
ALPRAZOLAMUM	XANAX 2 mg	tablets	2mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	7761	2015	01
AMBROXOLUM	MUCOSOLVAN 30 mg	tablets	30mg	BOEHRINGER INGELHEIM INTERNATIONALGMBH	GERMANY	7694	2015	01
AMLODIPINUM	STAMLO M 5 mg	tablets	5mg	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	7651	2015	01
AMLODIPINUM	STAMLO M 10 mg	tablets	10mg	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	7652	2015	01

AMLODIPINUM	AMLODIPINA LPH 10 mg	tablets	10mg	LABORMED PHARMA S.A.	ROMANIA	7577	2015	01
AMLODIPINUM	AMLODIPINA LPH 5 mg	tablets	5mg	LABORMED PHARMA S.A	ROMANIA	7576	2015	01
AMLODIPINUM	AMLODIPINA AUROBINDO 5 mg	tablets	5mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7629	2015	01
AMLODIPINUM	AMLODIPINA AUROBINDO 10 mg	tablets	10mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7630	2015	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AUGMENTIN SR 1000 mg/62.5 mg	prolonged-release tablets	1000mg/ 62.5mg	BEECHAM GROUP PLC.	GREAT BRITAIN	7554	2015	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AUGMENTIN ES 600mg/42.9 mg/5 ml	powder for oral suspension	600 mg/ 42.9mg/5ml	SMITHKLINE BEECHAM LIMITED	GREAT BRITAIN	7850	2015	01
AMPICILLINUM	EPICOCILLIN 500 mg	powder for solution for inj./inf.	500mg	E.I.P.I.CO. MED SRL	ROMANIA	7707	2015	01
ANAGRELIDUM	THROMBO-REDUCTIN 0.5 mg	capsules	0.5mg	AOP ORPHAN PHARMACEUTICALS AG	AUSTRIA	7585	2015	01
ARIPIPRAZOLUM	ASTORET 10 mg	orodispersible tablets	10mg	TERAPIA S.A.	ROMANIA	7587	2015	01
ARIPIPRAZOLUM	ASTORET 15 mg	orodispersible tablets	15mg	TERAPIA S.A.	ROMANIA	7588	2015	01
ARIPIPRAZOLUM	ASTORET 30 mg	orodispersible tablets	30mg	TERAPIA S.A.	ROMANIA	7589	2015	01
ARIPIPRAZOLUM	ARIPIPRAZOL GLENMARK 5 mg	tablets	5mg	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	7843	2015	01
ARIPIPRAZOLUM	ARIPIPRAZOL GLENMARK 10 mg	tablets	10mg	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	7844	2015	01
ARIPIPRAZOLUM	ARIPIPRAZOL GLENMARK 15 mg	tablets	15mg	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	7845	2015	01
ARIPIPRAZOLUM	ARIPIPRAZOL GLENMARK 30 mg	tablets	30mg	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	7846	2015	01
ARIPIPRAZOLUM	ARIPIPRAZOL TEVA 10 mg	tablets	10mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7852	2015	01
ARIPIPRAZOLUM	ARIPIPRAZOL TEVA 15 mg	tablets	15mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7853	2015	01

ARIPIPRAZOLUM	ARIPIPRAZOL TEVA 20 mg	tablets	20mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7854	2015	01
ARIPIPRAZOLUM	ARIPIPRAZOL TEVA 30 mg	tablets	30mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7855	2015	01
ARIPIPRAZOLUM	ARIPIPRAZOL AUROBINDO 10 mg	tablets	10mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7886	2015	01
ARIPIPRAZOLUM	ARIPIPRAZOL AUROBINDO 15 mg	tablets	15mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7887	2015	01
ATORVASTATINUM	ATORVASTATINA BILLEV 10 mg	film-coated tablets	10mg	BILLEV PHARMA APS	DENMARK	7734	2015	01
ATORVASTATINUM	ATORVASTATINA BILLEV 20 mg	film-coated tablets	20mg	BILLEV PHARMA APS	DENMARK	7735	2015	01
ATORVASTATINUM	ATORVASTATINA BILLEV 40 mg	film-coated tablets	40mg	BILLEV PHARMA APS	DENMARK	7736	2015	01
ATORVASTATINUM	ATORIS 10 mg	film-coated tablets	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7766	2015	01
ATORVASTATINUM	ATORIS 20 mg	film-coated tablets	20mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7767	2015	01
ATORVASTATINUM	ATORIS 40 mg	film-coated tablets	40mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7768	2015	01
ATORVASTATINUM	TORVAZIN 10 mg	film-coated tablets	10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7819	2015	01
ATORVASTATINUM	TORVAZIN 20 mg	film-coated tablets	20mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7820	2015	01
ATORVASTATINUM	TORVAZIN 40 mg	film-coated tablets	40mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7821	2015	01
ATORVASTATINUM	ATORVASTATINA ZENTIVA 10 mg	film-coated tablets	10mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	7769	2015	01
ATORVASTATINUM	ATORVASTATINA ZENTIVA 20 mg	film-coated tablets	20mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	7770	2015	01
ATORVASTATINUM	ATORVASTATINA ZENTIVA 40 mg	film-coated tablets	40mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	7771	2015	01
ATORVASTATINUM	ATORVASTATINA ZENTIVA 80 mg	film-coated tablets	80mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	7772	2015	01
BENDAMUSTINUM	BENDAMUSTINA ACTAVIS 2.5 mg/ml	powder for concentrate for solution for inf.	2.5mg/ml	ACTAVIS GROUP PTC EHF	ICELAND	7532	2015	01

BENDAMUSTINUM	LEDUFAN 2.5 mg/ml	powder for concentrate for solution for inf.	2.5mg/ml	EGIS PHARMACEUTICALS PLC.	HUNGARY	7895	2015	01
BENZYDAMINUM	TANTUM VERDE FORTE 3 mg/ml	oromucosal spray	3mg/ml	CSC PHARMACEUTICALS HANDELS GMBH	AUSTRIA	7616	2015	01
BENZYDAMINUM	GARGANTA 1.5 mg/ml	oromucosal spray, solution	1.5mg/ml	PHARMASWISS CESKA REPUBLIKA S.R.O.	THE CZECH REPUBLIC	7530	2015	01
BENZYDAMINUM	GARGANTA 3 mg	orodispersible tablets	3mg	PHARMASWISS CESKA REPUBLIKA S.R.O.	THE CZECH REPUBLIC	7531	2015	01
BIMATOPROSTUM	BIMAGAN 0.1 mg/ml	eye drops, suspension	0.1mg/ml	ROMPHARM COMPANY SRL	ROMANIA	7714	2015	01
BIOLOGIC (LYSATUM BACTERIALE OM 85 CRYODESICATUM)	BRONCHO-VAXOM COPII 3.5 mg	powder for oral suspension	3.5mg	OM PHARMA S.A.	PORTUGAL	7822	2015	01
BORTEZOMIBUM	BORTEZOMIB GLENMARK 1 mg	powder for solution for inj.	1mg	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	7883	2015	01
BORTEZOMIBUM	BORTEZOMIB GLENMARK 3.5 mg	powder for solution for inj.	3.5mg	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	7884	2015	01
BRINZOLAMIDUM	OPTILAMID 10 mg/ml	eye drops, suspension	10mg/ml	MEDANA PHARMA SA	POLAND	7533	2015	01
BRINZOLAMIDUM	BRINZOLAMIDA TEVA 10 mg/ml	eye drops, suspension	10mg/ml	TEVA PHARMACEUTICALS SRL	ROMANIA	7774	2015	01
BUTAMIRATUM	PINEX ANTITUSIV 1.5 mg/ml	syrup	1.5mg/ml	ACTAVIS GROUP PTC EHF.	ICELAND	7632	2015	01
BUTYLSCOPOLAMMONII BROMIDUM	SCOBUSAL 10 mg	tablets	10mg	SLAVIA PHARM SRL	ROMANIA	7885	2015	01
CALCITRIOLUM	ROCALTROL 0.25 µgr	soft capsules	0.25µgr	ROCHE ROMANIA SRL	ROMANIA	7690	2015	01
CARBAMAZEPINUM	TIMONIL 100 mg/5 ml	oral suspension	100mg/5ml	DESITIN ARZNEIMITTEL GMBH	GERMANY	7575	2015	01
CARBOCISTEINUM	MUCOSIN 750 mg/15 ml SIROP EXPECTORANT PENTRU ADULTI	syrup	750mg/15 ml	SANOFI-AVENTIS OTC	FRANCE	7730	2015	01
CARBOCISTEINUM	TRECID 100 mg/5 ml	syrup	100mg/5ml	BIOFARM S.A.	ROMANIA	7677	2015	01
CARVEDILOLUM	DILATREND 25 mg	tablets	25mg	ROCHE ROMANIA SRL	ROMANIA	7689	2015	01
CARVEDILOLUM	DILATREND 12.5 mg	tablets	12.5mg	ROCHE ROMANIA SRL	ROMANIA	7688	2015	01

CARVEDILOLUM	DILATREND 6.25 mg	tablets	6.25mg	ROCHE ROMANIA SRL	ROMANIA	7687	2015	01
CEFTAZIDIMUM	CEFTAZIDIMA MIP 1g	powder for solution for inj./inf.	1g	MIP PHARMA GMBH	GERMANY	7748	2015	01
CEFTAZIDIMUM	CEFTAZIDIMA MIP 2 g	powder for solution for inj./inf.	2g	MIP PHARMA GMBH	GERMANY	7749	2015	01
CINNARIZINUM	CINARIZINA ARENA 25 mg	capsules	25mg	ARENA GROUP S.A.	ROMANIA	7596	2015	01
CISPLATINUM	CISPLATINA CIPLA 1 mg/ml	concentrate for solution for inf.	1mg/ml	CIPLA EUROPE NV	BELGIUM	7863	2015	01
CLINDAMYCINUM	CLINDAMYCIN - MIP 300 mg	film-coated tablets	300mg	MIP PHARMA GMBH	GERMANY	7785	2015	01
CLOBETASOLUM	CLOBETAZOL ATB 0.5 mg/g	ointment	0.5mg/g	ANTIBIOTICE SA	ROMANIA	7725	2015	01
CLOTRIMAZOLUM	CANESTEN 10 mg/g	cream	10mg/g	BAYER SRL	ROMANIA	7607	2015	01
COLECALCIFEROLUM	VIGANTOLETTEN 500	tablets	500IU	MERCK KGAA	GERMANY	7902	2015	01
COLECALCIFEROLUM	VIGANTOLETTEN 1000	tablets	1000IU	MERCK KGAA	GERMANY	7903	2015	01
COMBINATIONS	SCANDONEST 2% SPECIAL	solution for inj.	2%	SEPTODONT	FRANCE	7705	2015	01
COMBINATIONS	NEOPREOL 2.5 mg/5 mg/g	ointment	2.5mg/5mg/g	ANTIBIOTICE SA	ROMANIA	7825	2015	01
COMBINATIONS	ASPATOFORT	concentrate for solution for inf.		TERAPIA S.A.	ROMANIA	7656	2015	01
COMBINATIONS	MULTIBIC POTASSIUM-FREE	hemofiltration solution		FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	GERMANY	7823	2015	01
COMBINATIONS	OROFAR 1 mg/1 mg	orodispersible tablets	1mg/1mg	NOVARTIS CONSUMER HEALTH GMBH	GERMANY	7709	2015	01
COMBINATIONS	ROWATINEX	oral drops, solution		ROWA WAGNER GMBH&CO. KG	GERMANY	7597	2015	01
COMBINATIONS	NEOCONES 15400 IU + 5 mg	dental pencils	15400 UI+5mg	LABORATOIRES SEPTODONT	FRANCE	7706	2015	01
COMBINATIONS	COLDREX LEMON	powder for oral suspension		GLAXOSMITHKLINE CONSUMER HEALTHCARE	GREAT BRITAIN	7547	2015	01
COMBINATIONS	DRILL FARA ZAHAR 3 mg+0.2 mg	pills	3mg+0.2mg	PIERRE FABRE MEDICAMENT	FRANCE	7698	2015	01
COMBINATIONS	DRILL 3 mg+0.2 mg	pills	3mg+0.2mg	PIERRE FABRE MEDICAMENT	FRANCE	7697	2015	01

COMBINATIONS	DRILL MIERE CU AROMA DE TRANDAFIR 3 mg+0.2 mg	pills	3mg+0.2mg	PIERRE FABRE MEDICAMENT	FRANCE	7699	2015	01
COMBINATIONS	REPARIL N	gel		MADAUS GMBH	GERMANY	7710	2015	01
COMBINATIONS	FASCONAL PRO	film-coated tablets		GEDEON RICHTER ROMANIA S.A.	ROMANIA	7561	2015	01
COMBINATIONS	HEMOSOL B0	haemodialysis/haemo-filtration solution		GAMBRO LUNDIA AB	SWEDEN	7743	2015	01
COMBINATIONS	NUTRINEAL PD4 CLEARFLEX 1.1% CU AMINOACIZI	solution for peritoneal dialysis		BAXTER HEALTHCARE SRL	ROMANIA	7773	2015	01
COMBINATIONS (ETINILESTRADIOLUM + DROSPIRENONUM)	MIDIANA 0.03 mg/ 3mg	film-coated tablets	0.03mg/3mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	7834	2015	01
COMBINATIONS (ETINILESTRADIOLUM + DROSPIRENONUM)	VARENA 0.02 mg/ 3 mg 28	film-coated tablets	0.02mg/3mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7803	2015	01
COMBINATIONS (ETINILESTRADIOLUM + DROSPIRENONUM)	VARENA 0.03 mg/ 3 mg 28	film-coated tablets	0.03mg/3mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7804	2015	01
COMBINATIONS (BETAMETHASONUM+ TETRYZOLINUM)	BIORINIL 0.5mg/1 mg/ ml	nasal spray, suspension	0.5mg/1mg/ ml	THEA FARMA S.P.A.	ITALY	7569	2015	01
COMBINATIONS (CANDESARTANUM CILEXETIL+HCT)	CANDESARTAN HIDROCLOROTIAZIDA AUROBINDO 8 mg/12.5 mg	tablets	8mg/12.5mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7786	2015	01
COMBINATIONS (CANDESARTANUM CILEXETIL+HCT)	CANDESARTAN HIDROCLOROTIAZIDA AUROBINDO 16 mg/12.5 mg	tablets	16mg/12.5mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7787	2015	01
COMBINATIONS (CANDESARTANUM CILEXETIL+HCT)	CANDESARTAN HIDROCLOROTIAZIDA AUROBINDO 32 mg/12.5 mg	tablets	32mg/12.5mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7788	2015	01
COMBINATIONS (CANDESARTANUM CILEXETIL+HCT)	CANDESARTAN HIDROCLOROTIAZIDA AUROBINDO 32 mg/25 mg	tablets	32mg/25mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7789	2015	01

COMBINATIONS (ENALAPRILUM+HYDRO-CHLOROTHIAZIDUM)	ENAP-HL 20 mg/12.5 mg	tablets	20 mg/ 12.5mg	KRKA D.D. NOVO MESTO	SLOVENIA	7906	2015	01
COMBINATIONS (ENALAPRILUM+HYDRO-CHLOROTHIAZIDUM)	ENAP H 10 mg/25 mg	tablets	10mg/25mg	KRKA D.D. NOVO MESTO	SLOVENIA	7904	2015	01
COMBINATIONS (ENALAPRILUM+HYDRO-CHLOROTHIAZIDUM)	ENAP-HL 10 mg/12.5 mg	tablets	10mg+ 12.5mg	KRKA D.D. NOVO MESTO	SLOVENIA	7905	2015	01
COMBINATIONS (COAGULATION FACTORS)	PRONATIV 500 IU	powder and solvent for solution for inf.	500IU	OCTAPHARMA (IP) LTD.	GREAT BRITAIN	7802	2015	01
COMBINATIONS (FENAZONUM+LIDOCAINUM)	OTIPAX	ear drops, solution		BIOCODEX	FRANCE	7879	2015	01
COMBINATIONS (LEVONORGESTRELUM+ETINILESTRADIOLUM)	SEASONIQUE 150/30 µgr+10 µgr	film-coated tablets	150/30 µgr +10 µgr	TEVA PHARMACEUTICALS SRL	ROMANIA	7793	2015	01
COMBINATIONS (LIPIDE)	OMEGAVEN	emulsion for inf.		FRESENIUS KABI AB	SWEDEN	7901	2015	01
COMBINATIONS (LISINOPRILUM+ AMLODIPINUM)	LISONORM 10mg/5mg	tablets	10mg/5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	7635	2015	01
COMBINATIONS (LISINOPRILUM+ AMLODIPINUM)	LISONORM 20 mg/10 mg	tablets	20mg/ 10mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	7636	2015	01
COMBINATIONS (LISINOPRILUM+ AMLODIPINUM)	LISONORM 20 mg/ 5 mg	tablets	20mg/5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	7637	2015	01
COMBINATIONS (PARACETAMOLUM+ IBUPROFENUM)	VALCOMB 500 mg/ 150 mg	film-coated tablets	500mg/ 150mg	PHARMASWISS CESKA REPUBLIKA S.R.O.	THE CZECH REPUBLIC	7628	2015	01
COMBINATIONS (TIOTROPIUM+ OLODATEROLUM)	SPIOLTO RESPIMAT 2.5 µgr/2.5 µgr	solution for inhalation	2.5 µgr/ 2.5 µgr	BOEHRINGER INGELHEIM INTERNATIONALGMBH	GERMANY	7868	2015	01
COMBINATIONS (TIOTROPIUM+ OLODATEROLUM)	YANIMO RESPIMAT 2.5 µgr/2.5 µgr	solution for inhalation	2.5 µgr/ 2.5µgr	BOEHRINGER INGELHEIM INTERNATIONALGMBH	GERMANY	7867	2015	01
COMBINATIONS (TRAMADOLUM+ PARACETAMOLUM)	MARATIA 37.5 mg/325 mg	tablets	37.5mg/ 325mg	G.L. PHARMA GMBH	AUSTRIA	7776	2015	01
COMBINATIONS (TRAMADOLUM+ PARACETAMOLUM)	LINEROL 37.5 mg/325 mg	film-coated tablets	37.5mg/ 325mg	PHARMACEUTICAL WORKS POLPHARMA SA	POLAND	7807	2015	01

CYPROTERONUM	ANDROCUR 50 mg	tablets	50mg	BAYER PHARMA AG	GERMANY	7565	2015	01
DEXTROMETHORPHANUM	TUSSIN 6.5mg/5ml	syrup	6.5mg/5ml	ROPHARMA S.A.	ROMANIA	7876	2015	01
DICLOFENACUM	DICLOFENAC SINTOFARM 100 mg	suppositories	100mg	SINTOFARM S.A.	ROMANIA	7563	2015	01
DICLOFENACUM	DICLOSAL 50 mg/g	gel	50mg/g	SLAVIA PHARM SRL	ROMANIA	7726	2015	01
DICLOFENACUM	DICLOFENAC MCC 10 mg/g	cream	10mg/g	MAGISTRA C&C SRL	ROMANIA	7678	2015	01
DIFENHIDRAMINUM	DERMODRIN 20 mg/g	ointment	20mg/g	PHARMAZEUTISCHE FABRIK MONTAVIT GES.M.B.H.	AUSTRIA	7644	2015	01
DOCETAXELUM	DOCETAXEL DR. REDDY"S 160mg/8 ml	concentrate for solution for inf.	160mg/ 8ml	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	7775	2015	01
DONEPEZILUM	ARICEPT EVESS	orodispersible tablets	5mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	7571	2015	01
DONEPEZILUM	ARICEPT EVESS	orodispersible tablets	10mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	7572	2015	01
DONEPEZILUM	PRIDIA 5 mg	orodispersible tablets	5mg	LABORMED PHARMA S.A.	ROMANIA	7779	2015	01
DONEPEZILUM	PRIDIA 10 mg	orodispersible tablets	10mg	LABORMED PHARMA S.A.	ROMANIA	7780	2015	01
DOXAZOSINUM	KAMIREN (see G04CAN1)	tablets	1mg	KRKA D.D. NOVO MESTO	SLOVENIA	7763	2015	01
DOXAZOSINUM	KAMIREN (see C02CA04)	tablets	1mg	KRKA D.D. NOVO MESTO	SLOVENIA	7763	2015	01
DOXAZOSINUM	KAMIREN (see G04CAN1)	tablets	2mg	KRKA D.D. NOVO MESTO	SLOVENIA	7764	2015	01
DOXAZOSINUM	KAMIREN (see C02CA04)	tablets	2mg	KRKA D.D. NOVO MESTO	SLOVENIA	7764	2015	01
DOXAZOSINUM	KAMIREN (see G04CAN1)	tablets	4mg	KRKA D.D. NOVO MESTO	SLOVENIA	7765	2015	01
DOXAZOSINUM	KAMIREN (see C02CA04)	tablets	4mg	KRKA D.D. NOVO MESTO	SLOVENIA	7765	2015	01
DOXORUBICINUM	DOXORUBICINA AGILA SPECIALTIES 2 mg/ml	powder for concentrate for solution for inf.	2mg/ml	AGILA SPECIALTIES UK LIMITED	GREAT BRITAIN	7801	2015	01
DOXORUBICINUM	DOXORUBICINA AGILA SPECIALTIES 2 mg/ml	concentrate for solution for inf.	2mg/ml	AGILA SPECIALTIES UK LIMITED	GREAT BRITAIN	7800	2015	01

DULOXETINUM	DULSEVIA 30 mg	gastroresistant capsules	30mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7712	2015	01
DULOXETINUM	DULSEVIA 60 mg	gastroresistant capsules	60mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7713	2015	01
DULOXETINUM	DUTILOX 30 mg	gastroresistant capsules	30mg	OPTIMAL REGULATORY SOLUTIONS, SL	SPAIN	7893	2015	01
DULOXETINUM	DUTILOX 60 mg	gastroresistant capsules	60mg	OPTIMAL REGULATORY SOLUTIONS, SL	SPAIN	7894	2015	01
ENALAPRILUM	ENAP 20 mg	tablets	20mg	KRKA D.D. NOVO MESTO	SLOVENIA	7900	2015	01
ENALAPRILUM	ENAP 10 mg	tablets	10mg	KRKA D.D. NOVO MESTO	SLOVENIA	7899	2015	01
ENALAPRILUM	ENAP 5 mg	tablets	5mg	KRKA D.D. NOVO MESTO	SLOVENIA	7898	2015	01
ENALAPRILUM	ENAP 2.5 mg	tablets	2.5mg	KRKA D.D. NOVO MESTO	SLOVENIA	7897	2015	01
ERYTHROMYCINUM	ERITROMICINA SANDOZ 200mg/5ml	powder for oral suspension	200mg/ 5ml	SANDOZ SRL	ROMANIA	7782	2015	01
ESCITALOPRAMUM	LENUXIN 10 mg	film-coated tablets	10mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	7896	2015	01
ESOMEPRAZOLUM	DIGEN 20 mg	gastroresistant tablets	20mg	ALVOGEN IPCO S.A.R.L.	LUXEMBOURG	7555	2015	01
ESOMEPRAZOLUM	ALMAGEL UNO 20 mg	gastroresistant tablets	20mg	ACTAVIS GROUP PTC EHF.	ICELAND	7631	2015	01
ESTRADIOLUM	CLIMARA 50 µgr/24 hrs	transdermal patch	50µgr/24hrs	BAYER PHARMA AG	GERMANY	7541	2015	01
ETORICOXIBUM	ARCOXIA 30 mg	film-coated tablets	30mg	MERCK SHARP & DOHME ROMANIA SRL	ROMANIA	7877	2015	01
ETORICOXIBUM	ETORICOXIB SANDOZ 30 mg	film-coated tablets	30mg	SANDOZ SRL	ROMANIA	7794	2015	01
ETORICOXIBUM	ETORICOXIB SANDOZ 60 mg	film-coated tablets	60mg	SANDOZ SRL	ROMANIA	7795	2015	01
ETORICOXIBUM	ETORICOXIB SANDOZ 90 mg	film-coated tablets	90mg	SANDOZ SRL	ROMANIA	7796	2015	01
ETORICOXIBUM	ETORICOXIB SANDOZ 120 mg	film-coated tablets	120mg	SANDOZ SRL	ROMANIA	7797	2015	01
STANDARDISED ALLERGEN EXTRACT	ALUSTAL 0.1 IR/ml	suspension for inj.	0.1IR/ml	STALLERGENES S.A.	FRANCE	7579	2015	01
STANDARDISED ALLERGEN EXTRACT	ALUSTAL 1 IR/ml	suspension for inj.	1IR/ml	STALLERGENES S.A.	FRANCE	7580	2015	01

STANDARDISED ALLERGEN EXTRACT	ALUSTAL 10 IR/ml	suspension for inj.	10IR/ml	STALLERGENES S.A.	FRANCE	7581	2015	01
STANDARDISED ALLERGEN EXTRACT	ALUSTAL 0.01 IR/ml	suspension for inj.	0.01IR/ml	STALLERGENES S.A.	FRANCE	7578	2015	01
COAGULATION FACTOR VIII	BERIATE 250	powder and solvent for solution for inj./inf.	250IU	CSL BEHRING GMBH	GERMANY	7557	2015	01
COAGULATION FACTOR VIII	BERIATE 500	powder and solvent for solution for inj./inf.	500IU	CSL BEHRING GMBH	GERMANY	7558	2015	01
COAGULATION FACTOR VIII	BERIATE 1000	powder and solvent for solution for inj./inf.	1000IU	CSL BEHRING GMBH	GERMANY	7559	2015	01
COAGULATION FACTOR VIII	BERIATE 2000	powder and solvent for solution for inj./inf.	2000IU	CSL BEHRING GMBH	GERMANY	7560	2015	01
COAGULATION FACTOR VIII AND VON WILLEBRAND FACTOR	HAEMATE P 250 UI	powder and solvent for solution for inj./inf.	250IU	CSL BEHRING GMBH	GERMANY	7638	2015	01
COAGULATION FACTOR VIII AND VON WILLEBRAND FACTOR	HAEMATE P 500 UI	powder and solvent for solution for inj./inf.	500IU	CSL BEHRING GMBH	GERMANY	7639	2015	01
COAGULATION FACTOR VIII AND VON WILLEBRAND FACTOR	HAEMATE P 1000 UI	powder and solvent for solution for inj./inf.	1000IU	CSL BEHRING GMBH	GERMANY	7640	2015	01
FENOFIBRATUM	FENOLIP 160 mg	capsules	160mg	PHARMASWISS CESKA REPUBLIKA S.R.O.	THE CZECH REPUBLIC	7672	2015	01
FENSPIRIDUM	INFRES 2 mg/ml	syrup	2mg/ml	MEDANA PHARMA SA	POLAND	7866	2015	01
FENTICONAZOLUM	LOMEXIN 200 mg	soft vaginal capsules	200mg	RECORDATI S.P.A.	ITALY	7593	2015	01
FENTICONAZOLUM	LOMEXIN 600 mg	soft vaginal capsules	600mg	RECORDATI S.P.A.	ITALY	7594	2015	01
FENTICONAZOLUM	LOMEXIN 1000 mg	soft vaginal capsules	1000mg	RECORDATI S.P.A.	ITALY	7595	2015	01
FIBRINOGEN UMAN	HAEMOCOMPLETTAN P 1 g	powder for solution for inj./inf.	1g	CSL BEHRING GMBH	GERMANY	7708	2015	01
FLUCONAZOLUM	FLUCONAZOL ARENA 2mg/ml	solution for inf.	2mg/ml	ARENA GROUP S.A.	ROMANIA	7724	2015	01
FLUDARABINUM	FLUDARA 50 mg	powder for solution for inj./inf.	50mg	GENZYME EUROPE B.V.	THE NETHERLANDS	7693	2015	01
FLUTICASONUM PROPIONAT	FLONASE 50 µgr/dose	nasal spray, suspension	50micro grams/dose	GLAXOSMITHKLINE CONSUMER HEALTHCARE SRL	ROMANIA	7856	2015	01
FLUTICASONUM PROPIONAT	TRUFLO 125 µgr	pressurised suspension for inhalation	125µgr	MOMAJA S.R.O.	THE CZECH REPUBLIC	7864	2015	01
FLUTICASONUM PROPIONAT	TRUFLO 250 µgr	pressurised suspension for	250µgr	MOMAJA S.R.O.	THE CZECH	7865	2015	01

		inhalation			REPUBLIC			
GEMCITABINUM	DAPLAX 200 mg	powder for solution for inf.	200mg	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	7873	2015	01
GEMCITABINUM	DAPLAX 1 g	powder for solution for inf.	1g	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	7874	2015	01
GLICLAZIDUM	DIAPREL MR 30 mg	modified-release tablets	30mg	LES LABORATOIRES SERVIER	FRANCE	7648	2015	01
GLICLAZIDUM	GLICLAZIDA ACTAVIS 30 mg	modified-release tablets	30mg	ACTAVIS GROUP PTC EHF.	ICELAND	7835	2015	01
GLICLAZIDUM	GLICLAZIDA ACTAVIS 60 mg	modified-release tablets	60mg	ACTAVIS GROUP PTC EHF.	ICELAND	7836	2015	01
GLUCOSAMINUM	PROBEVEN 1500 mg	film-coated tablets	1500mg	PROENZI S.R.O.	THE CZECH REPUBLIC	7553	2015	01
GONADOTROPHINUM CHORIONICUM	PREGNYL 5000 UI	powder and solvent for solution for inj.	5000IU/ml	N.V ORGANON	THE NETHERLANDS	7695	2015	01
HEPARINUM	HEPARINA SODICA PANPHARMA 5000 UI/ml	solution for inj.	5000IU/ml	PANPHARMA	FRANCE	7534	2015	01
HOMEOPATE	CORYZALIA	lozenges		BOIRON	FRANCE	7664	2015	01
HOMEOPATE	SEDATIF PC	tablets		BOIRON	FRANCE	7663	2015	01
HOMEOPATE	PARAGRIPPE	tablets		BOIRON	FRANCE	7662	2015	01
HOMEOPATE	COCCULINE	tablets		BOIRON	FRANCE	7722	2015	01
HOMEOPATE	CEFAGIL	tablets		CEFAK KG	GERMANY	7784	2015	01
HOMEOPATE	HOMEOGENE 9	tablets		BOIRON	FRANCE	7727	2015	01
HOMEOPATE	OSTEOCYNESINE	tablets		BOIRON	FRANCE	7723	2015	01
IBUPROFENUM	FASPIC 400 mg	film-coated tablets	400mg	ZAMBON S.P.A.	ITALY	7655	2015	01
IBUPROFENUM	IBUTOP GEL 50 mg/g	gel	50mg/g	DOLORGIET GMBH & CO. KG	GERMANY	7878	2015	01
IBUPROFENUM	NUROFEN PENTRU COPII 125 mg	suppositories	125mg	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD.	GREAT BRITAIN	7718	2015	01
IBUPROFENUM	IBUPROFEN SANDOZ 20 mg/ml	oral suspension	20mg/ml	SANDOZ SRL	ROMANIA	7523	2015	01
IBUPROFENUM	IBUPROFEN SANDOZ 40 mg/ml	oral suspension	40mg/ml	SANDOZ SRL	ROMANIA	7524	2015	01

IBUPROFENUM	MIG PEDIATRIC 20 mg/ml	oral suspension	20mg/ml	BERLIN-CHEMIE AG	GERMANY	7529	2015	01
IBUPROFENUM	IBUPROFEN SANDOZ 200 mg	soft capsules	200mg	SANDOZ SRL	ROMANIA	7633	2015	01
IBUPROFENUM	IBUPROFEN SANDOZ 400 mg	soft capsules	400mg	SANDOZ SRL	ROMANIA	7634	2015	01
IBUPROFENUM	IBUVALEN 200 mg	capsules	200mg	POLISANO PHARMACEUTICALS SRL	ROMANIA	7808	2015	01
IBUPROFENUM	IBUVALEN 400 mg	capsules	400mg	POLISANO PHARMACEUTICALS SRL	ROMANIA	7809	2015	01
ANTI-LYMPHOCYTE IMMUNOGLOBULIN	GRAFALON	concentrate for solution for inf.	20mg/ml	NEOVII BIOTECH GMBH	GERMANY	7711	2015	01
ANTI-LYMPHOCYTE IMMUNOGLOBULIN	THYMOGLOBULINE 5 mg/ml	powder for solution for inf.	5mg/ml	GENZYME EUROPE B.V.	THE NETHERLANDS	7562	2015	01
NORMAL HUMAN IMMUNOGLOBULIN	GAMMANORM 165 mg/ml	solution for inj.	165mg/ml	OCTAPHARMA (IP) LIMITED	GREAT BRITAIN	7670	2015	01
HUMAN C1 ESTERASE INHIBITOR	BERINERT 1500 UI	powder and solvent for solution for inj.	1500IU	CSL BEHRING GMBH	GERMANY	7556	2015	01
IRINOTECANUM	IRINOTECAN STADA 20 mg/ml	concentrate for solution for inf.	20mg/ml	STADA ARZNEIMITTEL AG	GERMANY	7777	2015	01
ISOTRETINOINUM	ROACCUTANE 10 mg	soft capsules	10mg	ROCHE ROMANIA SRL	ROMANIA	7661	2015	01
IVERMECTINUM	SOOLANTRA 10 mg/g	cream	10mg/g	GALDERMA INTERNATIONAL	FRANCE	7674	2015	01
KANAMYCINUM	KANAMICINA PANPHARMA 1 g	powder for solution for inj./inf.	1g	PANPHARMA	FRANCE	7535	2015	01
KETOPROFENUM	RUBIFEN 100 mg	film-coated tablets	100 mg	ANTIBIOTICE SA	ROMANIA	7719	2015	01
KETOPROFENUM	KETOPROFEN SLAVIA 25 mg/g	gel	25mg/g	SLAVIA PHARM SRL	ROMANIA	7702	2015	01
KETOROLACUM TROMETHAMIN	KETOROL 30 mg/ml	solution for inj.	30mg/ml	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	7609	2015	01
KETOROLACUM TROMETHAMIN	KETOROL 10 mg	film-coated tablets	10mg	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	7608	2015	01
LERCANIDIPINUM	PEGFEL 10 mg	film-coated tablets	10mg	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	7518	2015	01

LERCANIDIPINUM	PEGFEL 20 mg	film-coated tablets	20mg	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	7519	2015	01
LERCANIDIPINUM	LERCANIDIPINA SANDOZ 10 mg	film-coated tablets	10mg	SANDOZ SRL	ROMANIA	7798	2015	01
LERCANIDIPINUM	LERCANIDIPINA SANDOZ 20 mg	film-coated tablets	20mg	SANDOZ SRL	ROMANIA	7799	2015	01
LERCANIDIPINUM	LERCANIDIPINA STADA 10 mg	film-coated tablets	10mg	STADA HEMOFARM SRL	ROMANIA	7891	2015	01
LERCANIDIPINUM	LERCANIDIPINA STADA 20 mg	film-coated tablets	20mg	STADA HEMOFARM SRL	ROMANIA	7892	2015	01
LETROZOLUM	ELOZORA 2.5 mg	film-coated tablets	2.5mg	TEVA PHARMACEUTICALS SRL	ROMANIA	778	2015	01
LEVOCETIRIZINUM	LEVOCETIRIZINA CIPLA 5 mg	film-coated tablets	5mg	CIPLA EUROPE NV	BELGIUM	7525	2015	01
LEVONORGESTRELUM	MIRENA 20 µgr/24hrs	intrauterine-releasing system	20µgr/24hrs	BAYER OY	FINLAND	7842	2015	01
LEVOSULPIRIDUM	LEVIDE 25 mg	tablets	25mg	MEDOCHEMIE LTD.	CYPRUS	7827	2015	01
LEVOSULPIRIDUM	LEVIDE 50 mg	tablets	50mg	MEDOCHEMIE LTD.	CYPRUS	7828	2015	01
LEVOSULPIRIDUM	LEVIDE 100 mg	tablets	100mg	MEDOCHEMIE LTD.	CYPRUS	7829	2015	01
LEVOTHYROXINUM	EUTHYROX 200µg	tablets	200µg	MERCK KGAA	GERMANY	7546	2015	01
LEVOTHYROXINUM	EUTHYROX 25µg	tablets	25µg	MERCK KGAA	GERMANY	7542	2015	01
LEVOTHYROXINUM	EUTHYROX 100µg	tablets	100µg	MERCK KGAA	GERMANY	7544	2015	01
LEVOTHYROXINUM	EUTHYROX 50µg	tablets	50µg	MERCK KGAA	GERMANY	7543	2015	01
LEVOTHYROXINUM	EUTHYROX 150µg	tablets	150µg	MERCK KGAA	GERMANY	7545	2015	01
LINEZOLIDUM	LINEZOLID INFOMED 2 mg/ml	solution for inf.	2mg/ml	INFOMED FLUIDS SRL	ROMANIA	7669	2015	01
LOPERAMIDUM	IMODIUM 2 mg	orodispersible tablets	2mg	MCNEIL PRODUCTS LTD	GREAT BRITAIN	7810	2015	01
LOPINAVIRUM+ RITONAVIRUM	LOPINAVIR/RITONAVIR SANDOZ 200 mg/50 mg	film-coated tablets	200mg/50 mg	SANDOZ SRL	ROMANIA	7890	2015	01
MECLOZINUM	EMETOSTOP 30 mg	tablets	30mg	SPECIFAR S.A.	GREECE	7611	2015	01
MENOTROPINUM	MENOTROPHIN LG 75 UI	powder for solution for inj.	75UI	LABORATOIRES GENEVRIER SA	FRANCE	7527	2015	01
MENOTROPINUM	MENOTROPHIN LG 150 UI	powder for solution for inj.	150IU	LABORATOIRES GENEVRIER SA	FRANCE	7528	2015	01

MESNUM	UROMITEXAN 400mg/4ml	solution for inj.	400mg/4ml	BAXTER ONCOLOGY GMBH	GERMANY	7623	2015	01
METAMIZOLUM NATRIUM	ALGIOTOP 500 mg	tablets	500mg	SANTA S.A.	ROMANIA	7824	2015	01
METFORMINUM	GLUCOPHAGE 500 mg	film-coated tablets	500mg	MERCK SANTE S.A.S	FRANCE	7536	2015	01
METFORMINUM	GLUCOPHAGE 850 mg	film-coated tablets	850mg	MERCK SANTE S.A.S	FRANCE	7537	2015	01
METFORMINUM	GLUCOPHAGE 1000 mg	film-coated tablets	1000mg	MERCK SANTE S.A.S	FRANCE	7538	2015	01
METHYLPREDNISOLONUM	MEDROL A 16 mg	tablets	16mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	7622	2015	01
METOPROLOLUM	METOSUCCINAT SANDOZ 47.5 mg	modified-release tablets	47.5mg	HEXAL AG	GERMANY	7566	2015	01
METOPROLOLUM	METOSUCCINAT SANDOZ 95 mg	modified-release tablets	95mg	HEXAL AG	GERMANY	7567	2015	01
METOPROLOLUM	METOSUCCINAT SANDOZ 190 mg	modified-release tablets	190mg	HEXAL AG	GERMANY	7568	2015	01
METOPROLOLUM	METOPROLOL ZENTIVA 50 mg	tablets	50mg	ZENTIVA S.A.	ROMANIA	7619	2015	01
METOPROLOLUM	METOPROLOL ZENTIVA 100 mg	tablets	100mg	ZENTIVA S.A.	ROMANIA	7620	2015	01
METOPROLOLUM	METOPROLOL SUCCINAT TEVA 23.75 mg	prolonged-release tablets	23.75mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7744	2015	01
METOPROLOLUM	METOPROLOL SUCCINAT TEVA 47.5 mg	prolonged-release tablets	47.5mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7745	2015	01
METOPROLOLUM	METOPROLOL SUCCINAT TEVA 95 mg	prolonged-release tablets	95mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7746	2015	01
METOPROLOLUM	METOPROLOL SUCCINAT TEVA 190 mg	prolonged-release tablets	190mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7747	2015	01
METRONIDAZOLUM	FLAGYL 250 mg (see J01XD01)	film-coated tablets	250mg	LABORATOIRE AVENTIS	FRANCE	7610	2015	01
METRONIDAZOLUM	FLAGYL 250 mg (see P01AB01)	film-coated tablets	250mg	LABORATOIRE AVENTIS	FRANCE	7610	2015	01
MIDAZOLAMUM	MIDAZOLAM TORREX 1 mg/ml	solution for inj.	1mg/ml	CHIESI PHARMACEUTICALS GMBH	AUSTRIA	7626	2015	01

MIDAZOLAMUM	MIDAZOLAM TORREX 5 mg/ml	solution for inj.	5mg/ml	CHIESI PHARMACEUTICALS GMBH	AUSTRIA	7627	2015	01
MONTELUKASTUM	MONTELUKAST SYNTHON 10 mg	film-coated tablets	10mg	SYNTHON B.V.	THE NETHERLANDS	7750	2015	01
MONTELUKASTUM	MONTELUKAST SYNTHON 4 mg	chewable tablets	4mg	SYNTHON B.V.	THE NETHERLANDS	7751	2015	01
MONTELUKASTUM	MONTELUKAST SYNTHON 5 mg	chewable tablets	5mg	SYNTHON B.V.	THE NETHERLANDS	7752	2015	01
MOXIFLOXACINUM	MOXIFLOXACINA SANDOZ 400 mg	film-coated tablets	400mg	SANDOZ SRL	ROMANIA	7833	2015	01
MYCOPHENOLATUM MOFETILUM	MICOFENOLAT MOFETIL STADA 250 mg	capsules	250 mg	STADA HEMOFARM SRL	ROMANIA	7888	2015	01
MYCOPHENOLATUM MOFETILUM	MICOFENOLAT MOFETIL STADA 500 mg	film-coated tablets	500 mg	STADA HEMOFARM SRL	ROMANIA	7889	2015	01
NATRII FLUORIDUM	ZYMAFLUOR 0.25 mg	tablets	0.25mg	ROTTAPHARM S.p.A.	ITALY	7881	2015	01
NATRII FLUORIDUM	ZYMAFLUOR 1 mg	tablets	1mg	ROTTAPHARM S.p.A.	ITALY	7882	2015	01
NATRII HYDROGENI CARBONAS	BICARBONAT DE SODIU 84 mg/ml	solution for inf.	84mg/ml	B. BRAUN MELSUNGEN A.G.	GERMANY	7641	2015	01
NICOTINUM	NIQUITIN MENTOL 2 mg	medicinal chewing gum	2mg	GLAXOSMITHKLINE CONSUMER HEALTHCARESRL	ROMANIA	7857	2015	01
NICOTINUM	NIQUITIN MENTOL 4 mg	medicinal chewing gum	4mg	GLAXOSMITHKLINE CONSUMER HEALTHCARESRL	ROMANIA	7858	2015	01
NICOTINUM	NIQUITIN FRESH MINT 2 mg	medicinal chewing gum	2mg	GLAXOSMITHKLINE CONSUMER HEALTHCARESRL	ROMANIA	7859	2015	01
NICOTINUM	NIQUITIN FRESH MINT 4 mg	medicinal chewing gum	4mg	GLAXOSMITHKLINE CONSUMER HEALTHCARESRL	ROMANIA	7860	2015	01
NIMESULIDUM	APONIL 100 mg	tablets	100mg	MEDOCHEMIE LTD.	CYPRUS	7762	2015	01
NORFLOXACINUM	NOLICIN 400 mg	film-coated tablets	400mg	KRKA D.D. NOVO MESTO	SLOVENIA	7701	2015	01
OLMESARTANUM MEDOXOMILUM	OLIMESTRA 10 mg	film-coated tablets	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7790	2015	01

OLMESARTANUM MEDOXOMILUM	OLIMESTRA 20 mg	film-coated tablets	20mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7791	2015	01
OLMESARTANUM MEDOXOMILUM	OLIMESTRA 40 mg	film-coated tablets	40mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7792	2015	01
OMEPRAZOLUM	ULTOP 20 mg	gastroresistant capsules	20mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7907	2015	01
OMEPRAZOLUM	OMERAN 20 mg	gastroresistant capsules	20mg	GLAXOSMITHKLINE (GSK) SRL	ROMANIA	7584	2015	01
OMEPRAZOLUM	ULTOP 40 mg	gastroresistant capsules	40mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7908	2015	01
ONDANSETRONUM	EMESET 8 mg/4 ml	solution for inj./inf.	8mg/4ml	CIPLA (UK) LIMITED	GREAT BRITAIN	7647	2015	01
ONDANSETRONUM	EMESET 4 mg/2 ml	solution for inj./inf.	4mg/2ml	CIPLA (UK) LIMITED	GREAT BRITAIN	7646	2015	01
PANCREATINUM	PANGROL 10000	capsules containing mini-gastroresistant tablets	153.5mg	BERLIN-CHEMIE AG (MENARINI GROUP)	GERMANY	7841	2015	01
PANTOPRAZOLUM	REDACIB 20 mg	gastroresistant tablets	20mg	SANDOZ SRL	ROMANIA	7671	2015	01
PANTOPRAZOLUM	PANTOPRAZOL MYLAN 20 mg	gastroresistant tablets	20mg	GENERICS (UK) LIMITED	GREAT BRITAIN	7861	2015	01
PANTOPRAZOLUM	PANTOPRAZOL MYLAN 40mg	gastroresistant tablets	40mg	GENERICS (UK) LIMITED	GREAT BRITAIN	7862	2015	01
PANTOPRAZOLUM	ULPRIX 20 mg	gastroresistant tablets	20mg	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	7830	2015	01
PANTOPRAZOLUM	PANTOPRAZOL SUN 40 mg	powder for solution for inj.	40mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	THE NETHERLANDS	7526	2015	01
PARACETAMOLUM	PARACETAMOL FARMEX 500mg	tablets	500mg	FARMEX COMPANY SRL	ROMANIA	7783	2015	01
PERINDOPRILUM	PRICORON 4 mg	tablets	4 mg	ZENTIVA K.S.	THE CZECH REPUBLIC	7675	2015	01
PERINDOPRILUM	PRICORON 8 mg	tablets	8 mg	ZENTIVA K.S.	THE CZECH REPUBLIC	7676	2015	01
PERINDOPRILUM	MYDEN 2 mg	tablets	2mg	ALKALOID-INT D.O.O.	SLOVENIA	7520	2015	01
PERINDOPRILUM	MYDEN 4 mg	tablets	4mg	ALKALOID-INT D.O.O.	SLOVENIA	7521	2015	01
PERINDOPRILUM	MYDEN 8 mg	tablets	8mg	ALKALOID-INT D.O.O.	SLOVENIA	7522	2015	01
PERINDOPRILUM	ERNYOM 4 mg	tablets	4mg	VIM SPECTRUM SRL	ROMANIA	7603	2015	01

PERINDOPRILUM	ERNYOM 8 mg	tablets	8mg	VIM SPECTRUM SRL	ROMANIA	7604	2015	01
PLANTE	PROSPAN 65 mg	effervescent tablets	65mg	ENGELHARD ARZNEIMITTEL GMBH & CO. KG	GERMANY	7540	2015	01
PODOPHYLLOTOXINUM	WARTEC 1.5 mg/g	cream	1.5mg/g	GLAXOSMITHKLINE (GSK) SRL	ROMANIA	7729	2015	01
PRAMIPEXOLUM	PRAMIPEXOL MYLAN 0.088 mg	tablets	0.088mg	GENERICS (UK) LTD.	GREAT BRITAIN	7753	2015	01
PRAMIPEXOLUM	PRAMIPEXOL MYLAN 0.18 mg	tablets	0.18mg	GENERICS (UK) LTD.	GREAT BRITAIN	7754	2015	01
PRAMIPEXOLUM	PRAMIPEXOL MYLAN 0.35 mg	tablets	0.35mg	GENERICS (UK) LTD.	GREAT BRITAIN	7755	2015	01
PRAMIPEXOLUM	PRAMIPEXOL MYLAN 0.7 mg	tablets	0.7mg	GENERICS (UK) LTD.	GREAT BRITAIN	7756	2015	01
PRAMIPEXOLUM	PRAMIPEXOL MYLAN 1.1 mg	tablets	1.1mg	GENERICS (UK) LTD.	GREAT BRITAIN	7757	2015	01
PREGABALINUM	PRAGIOLA 25 mg	capsules	25mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7679	2015	01
PREGABALINUM	PRAGIOLA 50 mg	capsules	50mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7680	2015	01
PREGABALINUM	PRAGIOLA 75 mg	capsules	75mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7681	2015	01
PREGABALINUM	PRAGIOLA 100 mg	capsules	100mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7682	2015	01
PREGABALINUM	PRAGIOLA 150 mg	capsules	150mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7683	2015	01
PREGABALINUM	PRAGIOLA 200 mg	capsules	200mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7684	2015	01
PREGABALINUM	PRAGIOLA 225 mg	capsules	225mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7685	2015	01
PREGABALINUM	PRAGIOLA 300 mg	capsules	300mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7686	2015	01
PROGESTERONUM	CRINONE 80 mg/g	vaginal gel	80mg/g	MERCK ROMANIA SRL	ROMANIA	7805	2015	01
QUETIAPINUM	KETILEPT EP 50 mg	prolonged-release tablets	50mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7513	2015	01
QUETIAPINUM	KETILEPT EP 150 mg	prolonged-release tablets	150mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7514	2015	01

QUETIAPINUM	KETILEPT EP 200 mg	prolonged-release tablets	200mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7515	2015	01
QUETIAPINUM	KETILEPT EP 300 mg	prolonged-release tablets	300mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7516	2015	01
QUETIAPINUM	KETILEPT EP 400 mg	prolonged-release tablets	400mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7517	2015	01
QUETIAPINUM	BIQUETAN 50 mg	prolonged-release tablets	50mg	PHARMATHEN S.A.	GREECE	7548	2015	01
QUETIAPINUM	BIQUETAN 150 mg	prolonged-release tablets	150mg	PHARMATHEN S.A.	GREECE	7549	2015	01
QUETIAPINUM	BIQUETAN 200 mg	prolonged-release tablets	200mg	PHARMATHEN S.A.	GREECE	7550	2015	01
QUETIAPINUM	BIQUETAN 300 mg	prolonged-release tablets	300mg	PHARMATHEN S.A.	GREECE	7551	2015	01
QUETIAPINUM	BIQUETAN 400 mg	prolonged-release tablets	400mg	PHARMATHEN S.A.	GREECE	7552	2015	01
QUETIAPINUM	QUETIAPINA INTAS 50 mg	prolonged-release tablets	50mg	INTAS PHARMACEUTICALS LIMITED	GREAT BRITAIN	7739	2015	01
QUETIAPINUM	QUETIAPINA INTAS 200 mg	prolonged-release tablets	200mg	INTAS PHARMACEUTICALS LIMITED	GREAT BRITAIN	7740	2015	01
QUETIAPINUM	QUETIAPINA INTAS 300 mg	prolonged-release tablets	300mg	INTAS PHARMACEUTICALS LIMITED	GREAT BRITAIN	7741	2015	01
QUETIAPINUM	QUETIAPINA INTAS 400 mg	prolonged-release tablets	400mg	INTAS PHARMACEUTICALS LIMITED	GREAT BRITAIN	7742	2015	01
QUETIAPINUM	QUETIAPINA PHARMATHEN 50 mg	prolonged-release tablets	50mg	PHARMATHEN S.A.	GREECE	7811	2015	01
QUETIAPINUM	QUETIAPINA PHARMATHEN 150 mg	prolonged-release tablets	150mg	PHARMATHEN S.A.	GREECE	7812	2015	01
QUETIAPINUM	QUETIAPINA PHARMATHEN 200 mg	prolonged-release tablets	200mg	PHARMATHEN S.A.	GREECE	7813	2015	01
QUETIAPINUM	QUETIAPINA PHARMATHEN 300 mg	prolonged-release tablets	300mg	PHARMATHEN S.A.	GREECE	7814	2015	01
QUETIAPINUM	QUETIAPINA PHARMATHEN 400 mg	prolonged-release tablets	400mg	PHARMATHEN S.A.	GREECE	7815	2015	01

QUININE SULPHATE	CINKONA 300mg	tablets	300 mg	CN UNIFARM S.A.	ROMANIA	142	2015	01
ROSUVASTATINUM	ROSUCARD 10 mg	film-coated tablets	10mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	7847	2015	01
ROSUVASTATINUM	ROSUCARD 20 mg	film-coated tablets	20mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	7848	2015	01
ROSUVASTATINUM	ROSUCARD 40 mg	film-coated tablets	40mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	7849	2015	01
ROSUVASTATINUM	ROSUVASTATINA STADA 10 mg	film-coated tablets	10mg	STADA ARZNEIMITTEL AG	GERMANY	7737	2015	01
ROSUVASTATINUM	ROSUVASTATINA STADA 20 mg	film-coated tablets	20mg	STADA ARZNEIMITTEL AG	GERMANY	7738	2015	01
ROSUVASTATINUM	ROSUVASTATINA TCHAIKAPHARMA 10 mg	film-coated tablets	10mg	TCHAIKAPHARMA HIGH QUALITY MEDICINES INC.	BULGARIA	7870	2015	01
ROSUVASTATINUM	ROSUVASTATINA TCHAIKAPHARMA 20 mg	film-coated tablets	20mg	TCHAIKAPHARMA HIGH QUALITY MEDICINES INC.	BULGARIA	7871	2015	01
ROSUVASTATINUM	ROSUVASTATINA TCHAIKAPHARMA 40 mg	film-coated tablets	40mg	TCHAIKAPHARMA HIGH QUALITY MEDICINES INC.	BULGARIA	7872	2015	01
SALBUTAMOLUM	VENTOLIN 0.5 mg/ml	solution for inj.	0.5mg/ml	GLAXO WELLCOME UK LIMITED	GREAT BRITAIN	7826	2015	01
SALBUTAMOLUM	ASTHALIN INHALER 100µg/dose	pressurised suspension for inhalation	100µg/dose	CIPLA (UK) LIMITED	GREAT BRITAIN	7696	2015	01
SALMETEROLUM+FLUTICASONUM	AIRFLUSAL FORSPIRO 50 µgr/ 250 µgr/dose	single dose powder for inhalation	50µgr/ 250µgr/dose	SANDOZ SRL	ROMANIA	7673	2015	01
SERTINDOL	SERDOLECT 4 mg	film-coated tablets	4mg	H. LUNDBECK A/S	DENMARK	7720	2015	01
SERTINDOL	SERDOLECT 16 mg	film-coated tablets	16mg	H. LUNDBECK A/S	DENMARK	7721	2015	01
SEVOFLURANUM	SEVORANE 250 mg	volatile liquid for inhalation	250mg	ABBVIE LTD.	GREAT BRITAIN	7586	2015	01
SILIBINUM	LEGALON 70	capsules	70mg	MADAUS GMBH	GERMANY	7691	2015	01
SILIBINUM	LEGALON 140	capsules	140mg	MADAUS GMBH	GERMANY	7692	2015	01
STREPTOKINASUM	STREPTASE 1500000 IU	powder for solution for inj./inf.	1500000IU	CSL BEHRING GMBH	GERMANY	7614	2015	01
STREPTOKINASUM	STREPTASE 250000 IU	powder for solution for inj./inf.	250000IU	CSL BEHRING GMBH	GERMANY	7612	2015	01
STREPTOKINASUM	STREPTASE 750000 IU	powder for solution for inj./inf.	750000IU	CSL BEHRING GMBH	GERMANY	7613	2015	01

SULBUTIAMINUM	ENERION 200 mg	lozenges	200mg	LES LABORATOIRES SERVIER	FRANCE	7700	2015	01
SULFAMETHOXAZOLUM + TRIMETHOPRIMUM	SUMETROLIM 400 mg/80 mg	tablets	400mg/80mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7658	2015	01
SULFAMETHOXAZOLUM + TRIMETHOPRIMUM	SUMETROLIM 25mg/ml+5mg/ml	oral suspension	25mg/ml+ 5mg/ml	EGIS PHARMACEUTICALS PLC	HUNGARY	7657	2015	01
SUXAMETHONII CHLORIDUM	LYSTHENON 0.1 g/5 ml	solution for inj.	0.1g/5ml	TAKEDA AUSTRIA GMBH	AUSTRIA	7621	2015	01
TAMSULOSINUM	TANYZ 0.4 mg	prolonged-release capsules	0.4mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7717	2015	01
TC 99 M - ALBUMINA UMANA	NANOCOLL 500 µgr	kit for radiopharmaceutical preparation	500µgr	GE HEALTHCARE SRL	ITALY	7564	2015	01
TEICOPLANINUM	TARGOCID 400 mg	powder and solvent for solution for inj./inf. or oral solution	400mg	AVENTIS PHARMA LTD.	GREAT BRITAIN	7869	2015	01
TERBINAFINUM	TERBINAFINA SLAVIA 250mg	tablets	250mg	SLAVIA PHARM SRL	ROMANIA	7645	2015	01
TERBINAFINUM	TERBINAFINA SLAVIA 10 mg/g	cream	10mg/g	SLAVIA PHARMA SRL	ROMANIA	7840	2015	01
TESTOSTERONUM	NEBIDO 1000 mg/4 ml	solution for inj.	1000mg/4ml	BAYER PHARMA AG	GERMANY	7615	2015	01
TETRABENAZINUM	XENAZINE 25 mg	tablets	25mg	PHARMASWISS CESKA REPUBLIKA S.R.O.	THE CZECH REPUBLIC	7851	2015	01
THIOPENTALUM	THIOPENTAL SODIUM EIPICO 1 g	powder for solution for inj.	1g	E.I.P.I.CO. MED SRL	ROMANIA	7704	2015	01
THIOPENTALUM	THIOPENTAL SODIUM EIPICO 500 mg	powder for solution for inj.	500mg	E.I.P.I.CO. MED SRL	ROMANIA	7703	2015	01
TIAPRIDUM	TIAPRIDAL 100 mg	tablets	100mg	SANOFI-SYNTHELABO FRANCE	FRANCE	7570	2015	01
TIMOLOLUM	TIMOLOL ROMPHARM 5 mg/ml	eye drops, solution	5mg/ml	ROMPHARM COMPANY SRL	ROMANIA	7599	2015	01
TIMOLOLUM	TIMOLOL ROMPHARM 2.5 mg/ml	eye drops, solution	2.5mg/ ml	ROMPHARM COMPANY SRL	ROMANIA	7598	2015	01
TIOGUANINUM	LANVIS 40 mg	tablets	40mg	ASPEN PHARMA TRADING LIMITED	IRELAND	7909	2015	01
TOLPERISONUM	MYDOCALM 150 mg	film-coated tablets	150mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	7643	2015	02

TOLPERISONUM	MYDOCALM 50 mg	film-coated tablets	50mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	7642	2015	01
TRAMADOLUM	TRAMADOL LPH 50 mg	capsules	50mg	LABORMED PHARMA S.A.	ROMANIA	7875	2015	01
TRIMEBUTINUM	COLPERIN 100 mg	tablets	100mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	7650	2015	01
TROSPIUM	INKONTAN 15 mg	film-coated tablets	15mg	PHARMAZEUTISCHE FABRIK MONTAVIT GES.M.B.H.	AUSTRIA	7659	2015	01
TROSPIUM	INKONTAN 30 mg	film-coated tablets	30mg	PHARMAZEUTISCHE FABRIK MONTAVIT GES.M.B.H.	AUSTRIA	7660	2015	01
VALSARTANUM	WENZELL 40 mg	film-coated tablets	40mg	NEOLA PHARMA SRL	ROMANIA	7837	2015	01
VALSARTANUM	WENZELL 80 mg	film-coated tablets	80mg	NEOLA PHARMA SRL	ROMANIA	7838	2015	01
VALSARTANUM	WENZELL 160 mg	film-coated tablets	160mg	NEOLA PHARMA SRL	ROMANIA	7839	2015	01
VALSARTANUM	VALSARTAN MYLAN 40 mg	capsules	40mg	MYLAN S.A.S	FRANCE	7666	2015	01
VALSARTANUM	VALSARTAN MYLAN 80 mg	capsules	80mg	MYLAN S.A.S	FRANCE	7667	2015	01
VALSARTANUM	VALSARTAN MYLAN 160 mg	capsules	160mg	MYLAN S.A.S	FRANCE	7668	2015	01
VANCOMYCINUM	VANCOMICINA HOSPIRA 500 mg	powder for concentrate for solution for inf.	500mg	HOSPIRA UK LIMITED	GREAT BRITAIN	7590	2015	01
VANCOMYCINUM	VANCOMICINA HOSPIRA 1000 mg	powder for concentrate for solution for inf.	1000mg	HOSPIRA UK LIMITED	GREAT BRITAIN	7591	2015	01
VARDENAFILUM	STAREXON 5 mg	film-coated tablets	5mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	7816	2015	01
VARDENAFILUM	STAREXON 10 mg	film-coated tablets	10mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	7817	2015	01
VARDENAFILUM	STAREXON 20 mg	film-coated tablets	20mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	7818	2015	01
VORICONAZOLUM	VORAMOL 200 mg	powder for solution for inf.	200mg	ALVOGEN IPCO S.AR.L.	LUXEMBOURG	7539	2015	01
VORICONAZOLUM	VORICONAZOL TEVA 20 mg	powder for solution for inf.	200mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7806	2015	01
ZOLPIDEMUM	ZOLSANA 5 mg	film-coated tablets	5mg	KRKA D.D. NOVO MESTO	SLOVENIA	7617	2015	01
ZOLPIDEMUM	ZOLSANA 10 mg	film-coated tablets	10mg	KRKA D.D. NOVO MESTO	SLOVENIA	7618	2015	01

Medicinal products authorised through centralised procedure by the EMA notified for marketing in Romania during the 2nd quarter of 2015

INN	Invented name	Pharmaceutical form	Strength	Manufacturer	Country	MA number		
INSULINUM GLARGINE	TOUJEO 300 units/ml	SOLUTION FOR INJ. IN PRE-FILLED INJ. PEN	300 units/ml	SANOFI - AVENTIS DEUTSCHLAND GMBH	GERMANY	133	2015	33
NIVOLUMABUM	OPDIVO 10 mg/ml	CONCENTRATE FOR SOLUTION FOR INF.	10 mg/ml	BRISTOL-MYERS SQUIBB PHARMA EEIG	GREAT BRITAIN	1014	2015	01
VACCIN PAPILOMAVIRUS	GARDASIL 9	SUSPENSION FOR INJ.	0.5 ml	SANOFI PASTEUR MSD SNC	FRANCE	1007	2015	01
VACCIN PAPILOMAVIRUS	GARDASIL 9	SUSPENSION FOR INJ. IN PRE-FILLED SYRINGE	0.5 ml	SANOFI PASTEUR MSD SNC	FRANCE	1007	2015	02