ROMANIA

Informative Bulletin

Year 14, No. 3 (55), 3rd quarter of 2012

National Agency for Medicines and Medical Devices

Decisions of the NAMMD Scientific Council

Orders of the Minister of Health

Medicinal product batches recalled during the 3rd quarter of 2012

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 2nd quarter of 2012

Medicinal products authorised for marketing by the NAMMD during the 2nd quarter of 2012

EMA centrally authorised medicinal products for which the European Commission issued decisions during the 2nd quarter of 2012

- All data herein represent official information and are under direct authority of the National Agency for Medicines and Medical Devices.

- The entire content of the present publication lies under complete legislative protection of the National Agency for Medicines and Medical Devices.

- Any use of present publication content for revenue purposes or its marketing without express consent of the National Agency for Medicines and Medical Devices is forbidden and punishable by law.

- The National Agency for Medicines and Medical Devices reserves exclusive publishing rights.

ISSN 1583-347X

TABLE OF CONTENTS

DECISIONS OF THE NAMMD ADMINISTRATIVE COUNCIL

ORDERS OF THE MINISTER OF HEALTH

DECISION
No. 21/06.12.2011

on approval of tariffs for various activities performed by the departments of the National Agency for Medicines and Medical Devices

The Administration Council of the National Agency for Medicines and Medical Devices (hereinafter called the NAMMD), summoned through Order of the Minister of Health No. 1567/2011, convened in the meeting of 6 December 2011;

On seeing the report of the **National Procedures Department** under No. 6925/2011, stating proposals for the tariff for approval of the variation for medicinal products authorised through the procedure for parallel import;

On seeing the report of the **National Procedures Department** under No. 6924/2011, stating proposals for tariffs for various activities performed by third parties;

On seeing the report of the **European Procedures Department** under No. 3890/2011, stating proposals for tariffs for various activities performed by third parties;

Based on Art. 10 (d) of Government Decision No. 734/2010 related to the organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Art. 1 – Approval of tariffs for the variations to the parallel import authorisations amounting to 250 Euros.

Art. 2 – Approval of tariffs for the activities performed by the **National Procedures Department – The Variations Service** according to the proposed quantums, in accordance with Annex 1 to this Decision.

Art. 3 – Approval of the tariff for renewal of the marketing authorisations for medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State performed by the European Procedures Department – the European procedures administration service, amounting to 4.305 Euros.

Art. 4 – Approves the proposal concerning the tariffs for the activities conducted by the **European Procedures Department – Variation service** according to the proposed quantums, in accordance with Annex 2 to this Decision.

Art. 5 – The calculation of tariffs has been performed in accordance with the Methodology approved by the Ministry of Public Health through direction No. 13.893/19.12.2002.

Art. 6 - This Decision shall be communicated to the Minister of Health, for information and release of the approval order.

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

Dr. Petru DOMOCOŞ

ANNEX 1

to ACD No. 21/06.12.2011

TARIFFS

for the performances undertaken by the National Procedures Department – the Variations Service

NO. CRT.	PERFORMANCE	TARIFF EURO
1.	Approval of Type IA variations defining the group for medicinal products authorised through national procedure	**300**
2.	Approval of Type IB variations defining the group for medicinal products authorised through national procedure	**500**
3.	Approval of Type II variations defining the group for medicinal products authorised through national procedure	**1600**
4.	Approval of grouped Type IA variations for medicinal products authorised through national procedure	**200**
5.	Approval of grouped Type IB variations for medicinal products authorised through national procedure	**340**
6.	Approval of grouped Type II variations for medicinal products authorised through national procedure	**1070**

ANNEX 2

to ACD No. 21/06.12.2011

TARIFFS

for the activities performed by the European Procedures Department – the Variations Service

CRT. NO.	PERFORMANCE	TARIFF EURO
1.	Approval of the Type IA variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	**375**
2.	Approval of the Type IB variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	**750**
3.	Approval of the Type II variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	**2400**
4.	Approval of the Type IA variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	**165**
5.	Approval of the Type IB variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	**225**
6.	Approval of the Type II variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	**825**

Note:

1. As far as grouped variations are concerned, the tariff will be calculated for each marketing authorisation, by summing up the tariff for the variation defining the group and the tariff for the grouped variations which apply to each variation in the group, other than the variation defining the group.
2. The tariff for the variation defining the group is the one for the variation to the marketing authorisation.

DECISION
No. 22/06.12.2011
on approval of tariffs for the inspection of readability testing providers

The Administration Council of the National Agency for Medicines and Medical Devices (henceforth NAMMD), established through Order of the Minister of Health No. 1567/2011, convened in the meeting of 6 December 2011;

On seeing the report of the National Procedures Department under No. 14718/22.11.2011, informing about the proposals concerning tariffs for the inspection of readability testing providers;

Based on Article 10 (d) of Government Ordinance No. 734/21.07.2010 related to the set up, organisation and functioning of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Art. 1 – Approves the proposal concerning tariffs for the inspection of readability testing providers amounting to 750 Euros.

Art. 2 – The calculation of the tariffs has been performed in accordance with the Methodology approved by the Ministry of Public Health approved through Direction No. 13.893/19.12.2002.

Art. 3 - This Decision shall be communicated to the Minister of Health, for information and release of the approval order.

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

Dr. Petru DOMOCOŞ

MINISTRY OF HEALTH

ORDER
on amendment of Order of the Minister of Health No. 716/2009 on approval of tariffs and amount of marketing authorisation maintenance fee required by the National Medicines Agency

(Published in the Official Gazette of Romania, Part I, No. 667 of 24/09/2012)

On seeing the Approval report of the Pharmaceutical and Medical Devices Direction No. C.V. 3.786/7 September 2012,

taking into account provisions of Art. 10 (d) of Government Decision No. 734/2010 on the set up, organisation and operation of the National Agency for Medicines and Medical Devices, as amended,

based on Art. 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:

Art. I. – The Order of the Minister of Health No. 716/2009 on approval of tariffs and amount of marketing authorisation maintenance fee required by the National Medicines Agency, published in the Official Gazette of Romania, Part I, No. 422 of 19 June 2009, is amended as follows:

1. "National Medicines Agency" (NMA) shall be replaced by "National Agency for Medicines and Medical Devices" (NAMMD).

2. Under Annex 2, "Tariffs due for various inspections and related activities", a new item is inserted after item 25, namely 26, which reads as follows:

Crt. No.	Performance	Tariff - euro - ***	Fixed component*	Variable component**
"26.	Inspection for accreditation of readability testing providers	750	750	-"

3. Under Annex 3 "Tariffs for assessment of documentation in view of marketing authorisation/marketing authorisation renewal of medicinal products for human use and development of marketing authorisation related activities", section B "Assessment of documentation in view of marketing authorisation/marketing authorisation renewal through European procedures", a new item is inserted, namely item 27.a), which reads as follows:

Crt. No.	Performance	Tariff - euro -
"27.a)	Marketing authorisation renewal of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	4.305"

4. Under Annex 3, section D, "Approval of variations" is amended and shall read as follows:

Crt. No.	Performance	Tariff - euro -
D.	Approval of variations	
35.	Approval of Type IA variations and Type IA variations defining the group for medicinal products authorised through national procedure	300
36.	Approval of Type IB variations and Type IB variations defining the group for medicinal products authorised through national procedure	500
37.	Approval of Type II variations and Type II variations defining the group for medicinal products authorised through national procedure	1.600
38.	Approval of Type IA variations included in the group for medicinal products authorised through national procedure	200
39.	Approval of Type IB variations included in the group for medicinal products authorised through national procedure	340
40.	Approval of Type II variations included in the group for medicinal products authorised through national procedure	1.070
41.	Approval of Type IA variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	460
43.	Approval of Type II variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	2.400

44.	Approval of Type IA variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	300
45.	Approval of Type IB variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	500
46.	Approval of Type II variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	1.600
47.	Approval of Type IA variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	375
47.a)	Approval of Type IB variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	750
47.b)	Approval of Type II variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	2.400
48.	Approval of Type IA variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	165
48.a)	Approval of Type IB variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	225
48.b)	Approval of Type II variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	825

NOTE: 1. As far as grouped variations are concerned, the tariff will be calculated for each marketing authorisation, by summing up the tariff for the variation defining the group and the tariff for the grouped variation which applies to each variation in the group, other than the variation defining the group.

2. The tariff for the variation defining the group is the one for the variation to the marketing authorisation.

5. Under Annex 3, section E "Other marketing authorisation related activities", a new item in inserted, which reads as follows:

Crt. No.	Performance	Tariff - euro -
"54.	Approval of parallel import authorisations	250"

Art. II. - The present order is to be published in the Official Gazette of Romania, Part I.

Minister of health,

Vasile Cepoi

Bucharest, 7 September 2012.
No. 868.

Medicinal product batches recalled during the 3rd quarter of 2012

Crt. No.	Product recalled	Pharmaceu-tical form	Strength	INN	Manufacturer/MAH	Batch	Grounds for withdrawal	Action proposed	Date of withdrawal
1	BARIUM SULFATE	powder for oral suspension	88.9g/ 100 g	barii sulfas	S.C. Meduman S.A.	1087 (expiry date: 11.2014)	Inadequate smell and taste	Voluntary withdrawal and destruction	05.07.2012
2	CALPOL INFANT SUSPENSION	oral suspension	120 mg/ 5 ml	paracetamolum	Aspen Bad Oldesloe GmbH, Germany/ MC NEIL Products Ltd. C/O Johnson & Johnson, Great Britain	all batches	End of the one-year period after the approval of the transfer of the Marketing Authorisation Holder	Voluntary withdrawal and destruction	11.07.2012
3	CALPOL ŞASE PLUS	oral suspension	250 mg/ 5 ml	paracetamolum	The Wellcome Foundation Ltd., Great Britain/ Mc Neil Products Ltd. C/O Johnson & Johnson, Great Britain	all batches	End of the one-year period after the approval of the transfer of the Marketing Authorisation Holder	Voluntary withdrawal and destruction	11.07.2012
4	SUDAFED	film-coated tablets	60 mg	pseudoefedrinum	GSK POLAND/ MCNEIL Products Ltd. C/O Johnson & Johnson, Great Britain	all batches	End of the one-year period after the approval of the transfer of the Marketing Authorisation Holder	Voluntary withdrawal and destruction	11.07.2012
5	OMNITROPE®	solution for injection	5mg/ 1.5 ml	somatropinum	Sandoz GmbH, Austria	CG6993 (expiry date: 12.2013)	The leaflet contains an error in the text imprinted in Hungarian („you should start treatment with 0.15-0.3 mg/kg body weight/day'' instead of „you should start treatment with 0.15-0.3 mg/day'')	Withdrawal and destruction	19.07.2012
6	OMNITROPE®	solution for injection	10mg/ 1.5 ml	somatropinum	Sandoz GmbH, Austria	CG9394 (expiry date: 06.2013)	The leaflet contains an error in the text imprinted in Hungarian („you should start treatment with 0.15-0.3 mg/kg body weight/day" instead of „you should start treatment with 0.15-0.3 mg/day'')	Withdrawal and destruction	19.07.2012
7	ZOLOFT	concentrate for oral solution	20 mg/ml	sertalinum	Pfizer Manufacturing Deutschland GmbH, Germany	0BBXF (expiry date: 06.2013), 0BCUO (expiry date: 02.2013)	Voluntary withdrawal by the MAH in accordance with the Order of the Minister of Health No. 279/30.03.2005	Voluntary withdrawal and destruction	23.07.2012

Crt. No.	Product recalled	Pharmaceu-tical form	Strength	INN	Manufacturer/MAH	Batch	Grounds for withdrawal	Action proposed	Date of withdrawal
8	ADRENOSTAZIN	solution for injection/ infusion	1.5 mg	carbazochromi salicylas	Terapia S.A.	All batches manufactured during 11.2011-02.2012: 07108254, 02118436, 02118438, 03118479, 06118542, 01123214, 07108253, 07108255, 09108290, 09108291, 11108337, 11108338, 12108385, 12108386, 02118437, 02118439, 03118478, 05118498, 05118499, 06118540, 06118541, 06118596, 06118597, 06118598, 10112402, 10112403, 11112705, 11112706, 11112707, 11112834, 11112835, 01123215, 01123117, 02123385, 02123384	Result outside the specification to parameter ,,Dosage''	Withdrawal and destruction	24.08.2012
9	THYMOGLOBULINE	powder for solution for infusion	5 mg/ml	Antilymphocyte immunoglobulin	Genzyme Polyclonals S.A.S., France/ Genzyme Japan KK	C0074H17 (expiry date: 02.2013)	Result outside the specification to parameter ,,Molar mass distribution'' (of polymers, aggregates and fragments) of Thymoglobuline for batch C0072 (exp. date: 02.2013)	Voluntary withdrawal and destruction	24.08.2012

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 2nd quarter of 2012

During the 2nd quarter of 2012, 410 marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

A02 – Drugs for acid related disorders
A03 – Drugs for functional gastrointestinal disorders
A07 – Antidiarrheals, intestinal anti-inflammatory – anti-infective agents
A08 – Antiobesity preparations (excl. diet products)
A10 – Drugs used in diabetes
A11 - Vitamins
C01 – Cardiac therapy
C02 - Antihypertensives
C03 – Diuretics
C04 – Peripheral vasodilators
C05 – Vasoprotectives
C07 – Beta blocking agents
C08 – Calcium channel blockers
C09 – Agents acting on the renin-angiotensin system
C10 – Lipid modifying agents
D01 – Antifungals for dermatological use
D03 – Preparations for treatment of wounds and ulcers
G01 – Gynecological antiinfectives and antiseptics
G03 – Sex hormones and modulators of the genital system
G04 - Urologicals
H02 – Corticosteroids for systemic use
H03 – Thyroid therapy
J01 – Antibacterials for systemic use
J02 – Antimycotics for systemic use
J04 - Antimycobacterials
J05 – Antivirals for systemic use
L01 – Antineoplastic agents
L02 – Endocrine therapy
L03 – Immunostimulants
L04 - Immunosuppressants
M01 – Anti-inflammatory and antirheumatic products
M02 – Topical products for joint and muscular pain
M05 – Drugs for treatment of bone diseases

N02 - Analgezics
N03 - Antiepileptics
N04 – Anti-parkinsonian drugs
N05 - Psycholeptics
N06 - Psychoanaleptics
R01 – Nasal preparations
R03 – Drugs for obstructive airway diseases
R05 – Cough and cold preparations
R06 – Antihistamines for systemic use
S01 - Ophthalmologicals
S03 – Ophthalmological and otological preparations
V01 - Allergens
V03 – All other therapeutic products

Medicinal products authorised for marketing by the NAMMD during the 2nd quarter of 2012

INN	Invented name	Pharmaceutical form	Strength	Manufacturer	Country	MA Number		
ACIDUM ALENDRONICUM	STEOVESS 70 mg	effervescent tablets	70 mg	NYCOMED GMBH	GERMANY	4563	2012	3
ACIDUM IBANDRONICUM	ACID IBANDRONIC ALVOGEN 6 mg	concentrate for solution for infusion	6 mg	ALVOGEN IPCO S.AR.L.	LUXEMBOURG	4748	2012	3
ACIDUM IBANDRONICUM	ACID IBANDRONIC ALVOGEN 3 mg	solution for injection in pre-filled syringe	3 mg	ALVOGEN IPCO S.AR.L	LUXEMBOURG	4747	2012	3
ACIDUM URSODEOXYCHOLICUM	URSOFALK 500 mg	film-coated tablets	500mg	DR. FALK PHARMA GMBH	CZECH REPUBLIC	4646	2012	2
ACIDUM ZOLEDRONICUM	FAYTON 4 mg/5 ml	concentrate for solution for infusion	4mg/5ml	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	4708	2012	3
ACIDUM ZOLEDRONICUM	DESINOBON 4 mg/5 ml	concentrate for solution for infusion	4mg/5ml	ALVOGEN IPCO S.A.R.L	LUXEMBOURG	4763	2012	3
AMBROXOLUM	MUCOSIN 30 mg COMPRIMATE	tablets	30 mg	ZENTIVA A.S.	SLOVAK REPUBLIC	4562	2012	2
AMBROXOLUM	NEO-BRONCHOL 15 mg	lozenges	15mg	FARMACEUTICA REMEDIA S.A.	ROMANIA	4692	2012	1
AMLODIPINUM	ALOZUR 5 mg	tablets	5mg	OZONE LABORATORIES PHARMA S.A.	ROMANIA	4510	2012	1
AMLODIPINUM	ALOZUR 10 mg	tablets	10mg	OZONE LABORATORIES PHARMA S.A.	ROMANIA	4511	2012	1
AMLODIPINUM	AMLODIPINA TEVA 5 mg	tablets	5 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4733	2012	15
AMLODIPINUM	AMLODIPINA TEVA 10 mg	tablets	10 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4734	2012	15
AMOXICILLINUM	AMOXICILINA CNP PHARMA 500 mg	tablets	500 mg	CNP PHARMA GMBH	GERMANY	4614	2012	2
AMOXICILLINUM	AMOXICILINA CNP PHARMA 750 mg	tablets	750 mg	CNP PHARMA GMBH	GERMANY	4615	2012	2
AMOXICILLINUM	AMOXICILINA CNP PHARMA 1000 mg	tablets	1000 mg	CNP PHARMA GMBH	GERMANY	4616	2012	2
AMOXICILLINUM	AMOXICILINA MIP PHARMA 50 mg/ml	powder for oral suspension	50mg/ml	MIP PHARMA GMBH	GERMANY	4713	2012	1
AMOXICILLINUM + ACIDUM CLAVULANICUM	AUGMENTIN® ES	powder for oral suspension	600mg/ 42.9mg/5ml	SMITHKLINE BEECHAM LIMITED	GREAT BRITAIN	4629	2012	4
ATOMOXETINUM	ATOMOXETINA TEVA 10 mg	capsules	10 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4564	2012	2
ATOMOXETINUM	ATOMOXETINA TEVA 18 mg	capsules	18 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4565	2012	2

ATOMOXETINUM	ATOMOXETINA TEVA 60 mg	capsules	60 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4568	2012	3
ATOMOXETINUM	ATOMOXETINA TEVA 25 mg	capsules	25 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4566	2012	3
ATOMOXETINUM	ATOMOXETINA TEVA 80 mg	capsules	80 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4569	2012	3
ATOMOXETINUM	ATOMOXETINA TEVA 100 mg	capsules	100 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4570	2012	3
ATORVASTATINUM	ATORVASTATINA BILLEV 10 mg	film-coated tablets	10mg	BILLEV PHARMA APS	DENMARK	4678	2012	14
ATORVASTATINUM	ATORVASTATINA BILLEV 20 mg	film-coated tablets	20mg	BILLEV PHARMA APS	DENMARK	4679	2012	14
ATORVASTATINUM	ATORVASTATINA BILLEV 40 mg	film-coated tablets	40mg	BILLEV PHARMA APS	DENMARK	4680	2012	14
BICALUTAMIDUM	BICALUTAMIDA RANBAXY 50 mg	film-coated tablets	50 mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	4698	2012	16
BISOPROLOLUM	BOREZ 5 mg	film-coated tablets	5 mg	ALKALOID-INT D.O.O.	SLOVENIA	4729	2012	1
BISOPROLOLUM	BOREZ 10 mg	film-coated tablets	10 mg	ALKALOID-INT D.O.O.	SLOVENIA	4730	2012	1
BISOPROLOLUM	BOREZ 2.5 mg	film-coated tablets	2.5 mg	ALKALOID-INT D.O.O.	SLOVENIA	4728	2012	1
BUDESONIDUM	RHINOCORT AQUA 32 micrograms/dose	nasal spray, suspension	32 micrograms/ dose	ASTRAZENECA AB	SWEDEN	4552	2012	1
CANDESARTANUM CILEXETIL	CLASTINOL 4 mg	tablets	4 mg	EGIS PHARMACEUTICALS PLC	HUNGARY	4576	2012	13
CANDESARTANUM CILEXETIL	CLASTINOL 4 mg	tablets	4mg	EGIS PHARMACEUTICALS PLC	HUNGARY	4576	2012	13
CANDESARTANUM CILEXETIL	CLASTINOL 8 mg	tablets	8mg	EGIS PHARMACEUTICALS PLC	HUNGARY	4577	2012	13
CANDESARTANUM CILEXETIL	CLASTINOL 16 mg	tablets	16mg	EGIS PHARMACEUTICALS PLC	HUNGARY	4578	2012	13
CANDESARTANUM CILEXETIL	CLASTINOL 32 mg	tablets	32mg	EGIS PHARMACEUTICALS PLC	HUNGARY	4579	2012	13
CANDESARTANUM CILEXETIL	CANDEZEK 4 mg	tablets	4mg	ADAMED SP. Z.O.O.	POLAND	4538	2012	2
CANDESARTANUM CILEXETIL	CANDEZEK 8 mg	tablets	8mg	ADAMED SP. Z.O.O.	POLAND	4539	2012	2
CANDESARTANUM CILEXETIL	CANDEZEK 16 mg	tablets	16mg	ADAMED SP. Z.O.O.	POLAND	4540	2012	2
CANDESARTANUM CILEXETIL	CANDEZEK 32 mg	tablets	32mg	ADAMED SP. Z.O.O.	POLAND	4541	2012	2
CANDESARTANUM CILEXETIL	CANDESARTAN GSK 8 mg	tablets	8mg	GLAXOSMITHKLINE (GSK) S.R.L.	ROMANIA	4640	2012	1
CANDESARTANUM CILEXETIL	CANDESARTAN GSK 16 mg	tablets	16mg	GLAXOSMITHKLINE (GSK) S.R.L.	ROMANIA	4641	2012	1
CANDESARTANUM CILEXETIL	CANDESARTAN GSK 32 mg	tablets	32mg	GLAXOSMITHKLINE (GSK) S.R.L.	ROMANIA	4642	2012	1
CARBAMAZEPINUM	TIMONIL RETARD 50 mg	prolonged-release tablets	150mg	DESITIN ARZNEIMITTEL GMBH	GERMANY	4590	2012	2
CARBAMAZEPINUM	TIMONIL RETARD 300 mg	prolonged-release tablets	300mg	DESITIN ARZNEIMITTEL GMBH	GERMANY	4591	2012	2

CARBAMAZEPINUM	TIMONIL RETARD 600 mg	prolonged-release tablets	600mg	DESITIN ARZNEIMITTEL GMBH	GERMANY	4592	2012	2
CARBOPLATINUM	CARBOPLATIN KABI 10mg/ml	concentrate for solution for infusion	10mg/ml	FRESENIUS KABI ONCOLOGY PLC.	GREAT BRITAIN	4711	2012	4
CLOPIDOGRELUM	CLOPEZ 75 mg	film-coated tablets	75 mg	ALKALOID-INT D.O.O.	SLOVENIA	4715	2012	1
COMBINATIONS	KALCIPOS - D FORTE 500 mg/800 UI	chewable tablets	500mg/800IU	MEDA AB	SWEDEN	4559	2012	8
COMBINATIONS	CALCIVID CITRAT 300 mg/200 UI	film-coated tablets	300mg/200IU	BIO EEL S.R.L.	ROMANIA	4694	2012	3
COMBINATIONS (PARACETAMOLUM+ CODEINUM)	ULTRACOD 500 mg/30 mg	tablets	500mg/30mg	ZENIVA K.S.	CZECH REPUBLIC	4561	2012	5
COMBINATIONS (AMINOACIDS)	NUTRIFLEX OMEGA PLUS	emulsion for infusion		B. BRAUN MELSUNGEN AG	GERMANY	4509	2012	3
COMBINATIONS (AMINOACIDS)	NUTRIFLEX OMEGA SPECIAL	emulsion for infusion		B. BRAUN MELSUNGEN AG	GERMANY	4509	2012	4
COMBINATIONS (CANDESARTANUM CILEXETIL+HCT)	CLASTINOL HCT 8 mg/12.5 mg	tablets	8mg/12.5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	4580	2012	13
COMBINATIONS (CANDESARTANUM CILEXETIL+HCT)	CLASTINOL HCT 16 mg/12.5 mg	tablets	16mg/12.5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	4581	2012	13
COMBINATIONS (DIENOGESTUM+ ETINILESTRADIOLUM)	SIBILLA 2 mg/0,03 mg	film-coated tablets	2mg/0.03mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	4736	2012	3
COMBINATIONS (GESTODENE+ ETINILESTRADIOL)	ZULFIJA 75 micrograms/30 micrograms	pills	75micrograms/ 30micrograms	GEDEON RICHTER ROMANIA S.A.	ROMANIA	4717	2012	3
COMBINATIONS (GESTODENE+ ETINILESTRADIOL)	KOSTYA 75 micrograms/20 micrograms	pill	75micrograms/ 20micrograms	GEDEON RICHTER ROMANIA S.A.	ROMANIA	4716	2012	3
COMBINATIONS (LATANOPROSTUM+ TIMOLOLUM)	LATANOPROST/ TIMOLOL TEVA 0.05 mg/ml + 5 mg/ml	eye drops, solution	0.05mg/ml+ 5mg/ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4525	2012	3
COMBINATIONS (LATANOPROSTUM+ TIMOLOLUM)	ARUCOM 50 micrograms/ml+5 mg/ml	eye drops, solution	50micrograms/ ml+5mg/ml	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	GERMANY	4608	2012	3
COMBINATIONS (LISINOPRILUM+ AMLODIPINUM)	LISONORM 20 mg/5 mg	tablets	20mg/5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	4764	2012	2
COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM)	BEATIL 4 mg/ 5 mg	tablets	4mg/5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	4719	2012	1
COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM)	BEATIL 8 mg/ 5 mg	tablets	8mg/5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	4720	2012	1

COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM)	BEATIL 4 mg/ 10 mg	tablets	4mg/10 mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	4721	2012	1
COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM)	BEATIL 8 mg/ 10 mg	tablets	8mg/10mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	4722	2012	1
COMBINATIONS (SPIRONOLACTONUM+ FUROSEMIDUM)	DIUROCARD 50 mg/20 mg	tablets	50mg/20 mg	LABORMED PHARMA S.A.	ROMANIA	4704	2012	1
COMBINATIONS (TRAMADOLUM+ PARACETAMOLUM	DORETA 75 mg/650 mg	film-coated tablets	75 mg/650 mg	KRKA, D.D., NOVO MESTO	SLOVENIA	4586	2012	10
DACARBAZINUM	DACARBAZINA LIPOMED 200 mg	powder for sol. for injection/infusion	200 mg	LIPOMED GMBH	GERMANY	4749	2012	1
DESLORATADINUM	DELOPES 5 mg	film-coated tablets	5mg	SPECIFAR S.A.	GREECE	4503	2012	10
DESLORATADINUM	DESLORATADINA ALVOGEN 0.5 mg/ml	oral solution	0.5mg/ml	ALVOGEN IPCO S.A.R.L	LUXEMBOURG	4535	2012	8
DESLORATADINUM	DESLORATADINA ALVOGEN 5 mg	film-coated tablets	5mg	ALVOGEN IPCO S.A.R.L	LUXEMBOURG	4534	2012	28
DESLORATADINUM	RODISPES 5 mg	film-coated tablets	5mg	SPECIFAR S.A.	GREECE	4516	2012	10
DESLORATADINUM	VASLOSPERAN 5 mg	film-coated tablets	5mg	SPECIFAR S.A.	GREECE	4521	2012	10
DESLORATADINUM	DESLORATADINA LABORMED 5 mg	orodispersible tablets	5mg	LABORMED PHARMA SA	ROMANIA	4537	2012	2
DESLORATADINUM	DESLORATADINA LABORMED 2.5 mg	orodispersible tablets	2.5mg	LABORMED PHARMA SA	ROMANIA	4536	2012	2
DESLORATADINUM	DESLORATADINA TEVA 5 mg	orodispersible tablets	5mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4575	2012	9
DESLORATADINUM	DYNID 5 mg	tablets	5mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	4684	2012	10
DESLORATADINUM	DESLORATADINA SANDOZ 0.5 mg/ml	oral solution	0.5 mg/ml	SANDOZ S.R.L.	ROMANIA	4660	2012	5
DESLORATADINUM	DESLORATADINA SANDOZ 5 mg	film-coated tablets	5 mg	SANDOZ S.R.L.	ROMANIA	4659	2012	56
DESLORATADINUM	YOSQIERO 5 mg	film-coated tablets	5 mg	SANDOZ S.R.L.	ROMANIA	4712	2012	64
DESLORATADINUM	PYLODES 5 mg	tablets	5mg	PHARMASWISS CESKA REPUBLIKA S.R.O.	CZECH REPUBLIC	4762	2012	9
DEXAMETHASONUM	DEXAMETAZONA ROMPHARM 4 mg/ml	solution for injection	4mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	4647	2012	6
DEXTROMETHORPHANUM	TUSSIN FORTE	tablets	20mg	EUROPHARM SA	ROMANIA	4754	2012	1
OTHERS	URO - VAXOM	capsules	6mg	OM PHARMA S.A.	PORTUGAL	4628	2012	2
OTHERS	LUIVAC®	tablets	3mg	DAIICHI SANKYO EUROPE GMBH	GERMANY	4595	2012	2
DOBUTAMINUM	DOBUTAMINA CLARIS 12.5 mg/ml	concentrate for solution for infusion	12.5mg/ml	CLARIS LIFESCIENCES (UK) LTD.	GREAT BRITAIN	4522	2012	2
DONEPEZILUM	DONEPEZIL STADA HEMOFARM 5 mg	orodispersible tablets	5mg	STADA HEMOFARM SRL	ROMANIA	4529	2012	18
DONEPEZILUM	DONEPEZIL STADA HEMOFARM 10 mg	orodispersible tablets	10mg	STADA HEMOFARM SRL	ROMANIA	4530	2012	18

ESOMEPRAZOLUM	HELIDES 20 mg	gastroresistant tablets	20mg	ZENTIVA, K.S.	CZECH REPUBLIC	4709	2012	10
ESOMEPRAZOLUM	HELIDES 40 mg	gastroresistant tablets	40mg	ZENTIVA, K.S.	CZECH REPUBLIC	4710	2012	10
OMEGA-3-ACID ETHYL ESTERS 90	TEVOCOR 1000 mg	soft capsules	1000 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4735	2012	16
COAGULATION FACTOR IX	BETAFACT 50 IU/ml	powder and solvent for solution for injection	50 IU/ml	LFB - BIOMEDICAMENTS	FRANCE	4622	2012	3
FLUCONAZOLUM	DIFLAZON 200 mg	capsules	200mg	KRKA D.D., NOVO MESTO	SLOVENIA	4550	2012	2
FLUCONAZOLUM	DIFLAZON 150 mg	capsules	150mg	KRKA D.D., NOVO MESTO	SLOVENIA	4549	2012	1
FLUCONAZOLUM	DIFLAZON 100 mg	capsules	100mg	KRKA D.D., NOVO MESTO	SLOVENIA	4548	2012	1
FLUCONAZOLUM	DIFLAZON 50 mg	capsules	50mg	KRKA D.D., NOVO MESTO	SLOVENIA	4547	2012	1
FLUDEOXIGLUCOZA (18F)	POZITRONSCAN-FDG	solution for injection	37-7400MBq	POZITRON DIANOSZTIKA LTD.	HUNGARY	4731	2012	1
GLUCOSAMINUM	CARTIFAST 625 mg	capsules	625 mg	BIOIBERICA S.A.	SPAIN	4732	2012	2
HYDROCORTISONUM	HIDROCORTIZON HF 100 mg	powder and solvent for solution for injection/infusion	100mg	STADA HEMOFARM S.R.L.	ROMANIA	4597	2012	1
HYDROCORTISONUM	HIDROCORTIZON HF 500 mg	powder and solvent for solution for injection/infusion	500mg	STADA HEMOFARM S.R.L.	ROMANIA	4598	2012	1
IBUPROFENUM	MARCOFEN 200 mg	capsules	200mg	EUROPHARM S.A.	ROMANIA	4513	2012	1
IBUPROFENUM	NUROFEN EXPRESS FORTE 400 mg	soft capsules	400mg	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD.	GREAT BRITAIN	4515	2012	6
IMIPENEMUM + CILASTATINUM	IMIPENEM/CILASTAN SANDOZ 250 mg/250mg	powder for solution for infusion	250 mg/250 mg	SANDOZ SRL	ROMANIA	4602	2012	5
IMIPENEMUM + CILASTATINUM	IMIPENEM/CILASTAN SANDOZ 500 mg/500mg	powder for solution for infusion	500 mg/500 mg	SANDOZ SRL	ROMANIA	4603	2012	10
IRBESARTANUM	ATOKKEN 75 mg	film-coated tablets	75mg	ROMASTRU TRADING SRL	ROMANIA	4648	2012	1
IRBESARTANUM	ATOKKEN 150 mg	film-coated tablets	150mg	ROMASTRU TRADING SRL	ROMANIA	4649	2012	1
IRBESARTANUM	ATOKKEN 300 mg	film-coated tablets	300mg	ROMASTRU TRADING SRL	ROMANIA	4650	2012	1
ISONIAZIDUM	IZONIAZIDA ATB 100 mg	tablets	100mg	ANTIBIOTICE S.A.	ROMANIA	4553	2012	2
KETOTIFENUM	KETOTIFEN LPH® 1 mg	tablets	1mg	LABORMED PHARMA SA	ROMANIA	4752	2012	1
KETOTIFENUM	ZABAK 0.25 mg/ml	eye drops, solution	0.25mg/ml	LABORATORIES THEA	FRANCE	4610	2012	1
LANREOTIDUM	SOMATULINE AUTOGEL 120 mg	solution for injection in pre-filled syringe	120mg	IPSEN PHARMA	FRANCE	4589	2012	1
LANREOTIDUM	SOMATULINE AUTOGEL 90 mg	solution for injection in pre-filled syringe	90mg	IPSEN PHARMA	FRANCE	4588	2012	1
LANREOTIDUM	SOMATULINE AUTOGEL 60mg	solution for injection in pre-filled syringe	60mg	IPSEN PHARMA	FRANCE	4587	2012	1
LEVETIRACETAMUM	VETIRA 250 mg	film-coated tablets	250mg	ADAMED SP. Z.O.O.	POLAND	4517	2012	6
LEVETIRACETAMUM	VETIRA 500 mg	film-coated tablets	500mg	ADAMED SP. Z.O.O.	POLAND	4518	2012	8
LEVETIRACETAMUM	VETIRA 750 mg	film-coated tablets	750mg	ADAMED SP. Z.O.O.	POLAND	4519	2012	7
LEVETIRACETAMUM	VETIRA 1000 mg	film-coated tablets	1000mg	ADAMED SP. Z.O.O.	POLAND	4520	2012	7

LEVETIRACETAMUM	LEVETIRACETAM EWOPHARMA 250 mg	film-coated tablets	250mg	EWOPHARMA INTERNATIONAL S.R.O.	SLOVAKIA	4542	2012	6
LEVETIRACETAMUM	LEVETIRACETAM EWOPHARMA 500 mg	film-coated tablets	500mg	EWOPHARMA INTERNATIONAL S.R.O.	SLOVAKIA	4543	2012	8
LEVETIRACETAMUM	LEVETIRACETAM EWOPHARMA 750 mg	film-coated tablets	750mg	EWOPHARMA INTERNATIONAL S.R.O.	SLOVAKIA	4544	2012	7
LEVETIRACETAMUM	LEVETIRACETAM EWOPHARMA 1000 mg	film-coated tablets	1000mg	EWOPHARMA INTERNATIONAL S.R.O.	SLOVAKIA	4545	2012	7
LEVETIRACETAMUM	LEVETIRACETAM GSK 100mg/ml	oral solution	100 mg/ml	GLAXOSMITHKLINE (GSK) S.R.L.	ROMANIA	4558	2012	3
LEVETIRACETAMUM	LEVETIRACETAM GSK 250mg	film-coated tablets	250 mg	GLAXOSMITHKLINE (GSK) S.R.L.	ROMANIA	4554	2012	8
LEVETIRACETAMUM	LEVETIRACETAM GSK 500mg	film-coated tablets	500 mg	GLAXOSMITHKLINE (GSK) S.R.L.	ROMANIA	4555	2012	8
LEVETIRACETAMUM	LEVETIRACETAM GSK 1000 mg	film-coated tablets	1000 mg	GLAXOSMITHKLINE (GSK) S.R.L.	ROMANIA	4557	2012	8
LEVETIRACETAMUM	LEVETIRACETAM TERAPIA 250 mg	film-coated tablets	250 mg	TERAPIA S.A.	ROMANIA	4617	2012	8
LEVETIRACETAMUM	LEVETIRACETAM TERAPIA 500 mg	film-coated tablets	500 mg	TERAPIA S.A.	ROMANIA	4618	2012	8
LEVETIRACETAMUM	LEVETIRACETAM TERAPIA 1000 mg	film-coated tablets	1000 mg	TERAPIA S.A.	ROMANIA	4619	2012	5
LEVETIRACETAMUM	NORMEG 250 mg	film-coated tablets	250mg	ZENTIVA, K.S.	CZECH REPUBLIC	4699	2012	9
LEVETIRACETAMUM	NORMEG 500 mg	film-coated tablets	500mg	ZENTIVA, K.S.	CZECH REPUBLIC	4700	2012	9
LEVETIRACETAMUM	NORMEG 750 mg	film-coated tablets	750mg	ZENTIVA, K.S.	CZECH REPUBLIC	4701	2012	9
LEVETIRACETAMUM	NORMEG 1000 mg	film-coated tablets	1000mg	ZENTIVA, K.S.	CZECH REPUBLIC	4702	2012	9
LEVETIRACETAMUM	LEVETIRACETAM GSK 750mg	film-coated tablets	750 mg	GLAXOSMITHKLINE (GSK) S.R.L.	ROMANIA	4556	2012	8
LEVETIRACETAMUM	DRETACEN 250 mg	film-coated tablets	250mg	SANDOZ S.R.L.	ROMANIA	4604	2012	9
LEVETIRACETAMUM	DRETACEN 500 mg	film-coated tablets	500mg	SANDOZ S.R.L.	ROMANIA	4605	2012	9
LEVETIRACETAMUM	DRETACEN 750 mg	film-coated tablets	750mg	SANDOZ S.R.L.	ROMANIA	4606	2012	7
LEVETIRACETAMUM	DRETACEN 500 mg	film-coated tablets	500mg	SANDOZ S.R.L.	ROMANIA	4605	2012	10
LEVETIRACETAMUM	EPRILEXAN 250 mg	film-coated tablets	250 mg	PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	AUSTRIA	4655	2012	6
LEVETIRACETAMUM	EPRILEXAN 500 mg	film-coated tablets	500 mg	PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	AUSTRIA	4656	2012	8
LEVETIRACETAMUM	EPRILEXAN 1000 mg	film-coated tablets	1000 mg	PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	AUSTRIA	4657	2012	7
LEVETIRACETAMUM	VETIRA 100 mg/ml	oral solution	100mg/ml	ADAMED SP. Z.O.O.	POLAND	4697	2012	3
LEVETIRACETAMUM	LEVETIRACETAM G.L. PHARMA 250 mg	film-coated tablets	250 mg	G.L. PHARMA GMBH	AUSTRIA	4685	2012	27
LEVETIRACETAMUM	LEVETIRACETAM G.L. PHARMA 500 mg	film-coated tablets	500 mg	G.L. PHARMA GMBH	AUSTRIA	4686	2012	27

LEVETIRACETAMUM	LEVETIRACETAM G.L. PHARMA 1000 mg	film-coated tablets	1000 mg	G.L. PHARMA GMBH	AUSTRIA	4687	2012	27
LEVETIRACETAMUM	LEVETIRACETAM MYLAN 250 mg	film-coated tablets	250 mg	GENERICS (UK) LTD	GREAT BRITAIN	4688	2012	20
LEVETIRACETAMUM	LEVETIRACETAM MYLAN 500 mg	film-coated tablets	500 mg	GENERICS (UK) LTD	GREAT BRITAIN	4689	2012	20
LEVETIRACETAMUM	LEVETIRACETAM MYLAN 750 mg	film-coated tablets	750 mg	GENERICS (UK) LTD	GREAT BRITAIN	4690	2012	20
LEVETIRACETAMUM	LEVETIRACETAM MYLAN 1000 mg	film-coated tablets	1000 mg	GENERICS (UK) LTD	GREAT BRITAIN	4691	2012	20
LEVOFLOXACINUM	OFTAQUIX 5 mg/ml	eye drops, solution	5mg/ml	SANTEN OY	FINLAND	4609	2012	1
LEVONORGESTRELUM	RAMONNA 1500 micrograms	tablets	1500 micrograms	GEDEON RICHTER ROMANIA S.A.	ROMANIA	4737	2012	1
LOPERAMIDUM	LOPERAMID BIOEEL 2 mg	tablets	2mg	BIO EEL S.R.L.	ROMANIA	4644	2012	2
LOPERAMIDUM	LOPERAMID SLAVIA 2 mg	capsules	2mg	SLAVIA PHARM S.R.L.	ROMANIA	4693	2012	1
HUMAN ALBUMIN MACROAGGREGATES	MAASOL 1.75 mg/vial	radiopharmaceutical kit for preparation for suspension for injection	1.75 mg/flacon	GE HEALTHCARE SRL	ITALY	4753	2012	1
MAGNESII SULFAS	CORMAGNESIN 204.7 mg/ml	solution for injection	204.7mg/ml	BIOMEDIAL PHARMA S.R.L.	ROMANIA	4670	2012	2
MAGNESII SULFAS	CORMAGNESIN 409.5 mg/ml	solution for injection	409.5mg/ml	BIOMEDIAL PHARMA S.R.L.	ROMANIA	4671	2012	2
MEPIVACAINUM	MEPIVASTESIN 30 mg/ml	solution for injection	30mg/ml	3M DEUTSCHLAND GMBH	GERMANY	4662	2012	1
METOCLOPRAMIDUM	METOCLOPRAMID ACCORD 10 mg	tablets	10 mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	4653	2012	1
MOMETASONUM	SINGULAIR 4 mg	chewable tablets	4mg	MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	4718	2012	15
MYCOPHENOLATUM MOFETILUM	SUPREPHEN 250 mg	film-coated tablets	250mg	ROMASTRU TRADING S.R.L.	ROMANIA	4651	2012	1
MYCOPHENOLATUM MOFETILUM	SUPREPHEN 500 mg	film-coated tablets	500mg	ROMASTRU TRADING S.R.L.	ROMANIA	4652	2012	1
NAPROXENUM	REUXEN 200 mg	tablets	200mg	HELCOR S.R.L.	ROMANIA	4512	2012	2
NATRII IODIDUM (131I)	MONIYOT-131 CAPSULE T	capsules	37-7400MBq	MONROL EUROPE S.R.L.	ROMANIA	4669	2012	1
NATRII IODIDUM (131I)	MONIYOT-131 CAPSULE D	capsules	0.37-36MBq	MONROL EUROPE S.R.L.	ROMANIA	4668	2012	2
NATRII IODIDUM (131I)	MONIYOT-131	oral solution	14.8-3700MBq	MONROL EUROPE S.R.L.	ROMANIA	4667	2012	2
OCTREOTIDUM	SANDOSTATIN®	solution for injection	0.1mg/ml	NOVARTIS PHARMA GMBH	GERMANY	4756	2012	1
OLMESARTANUM MEDOXOMILUM	OLMETEC 10 mg	film-coated tablets	10mg	DAIICHI SANKYO EUROPE GMBH	GERMANY	4672	2012	4
OLMESARTANUM MEDOXOMILUM	OLMETEC 20 mg	film-coated tablets	20mg	DAIICHI SANKYO EUROPE GMBH	GERMANY	4673	2012	4
OLMESARTANUM MEDOXOMILUM	OLMETEC 40 mg	film-coated tablets	40mg	DAIICHI SANKYO EUROPE GMBH	GERMANY	4674	2012	4

OMEPRAZOLUM	XANTRAZOL 20 mg	gastroresistant tablets	20 mg	BAYER S.R.L.	ROMANIA	4658	2012	2
OMEPRAZOLUM	OMEPRAZOL SANDOZ 20 mg	gastroresistant capsules	20 mg	SANDOZ SRL	ROMANIA	4724	2012	5
OMEPRAZOLUM	OMEPRAZOL SANDOZ 10 mg	gastroresistant capsules	10 mg	SANDOZ SRL	ROMANIA	4723	2012	9
ORLISTATUM	ORLISTAT TEVA 120 mg	capsules	120mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4572	2012	3
ORLISTATUM	ORLISTAT TEVA 60 mg	capsules	60mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4571	2012	16
OXALIPLATINUM	OXALIPLATIN ATTIC 5 mg/ml	concentrate for solution for infusion	5mg/ml	ATTIC PHARMA EHF.	ICELAND	4744	2012	3
OXIGENUM	OXIGEN MEDICINAL LICHID AIR LIQUIDE	medicinal gas for inhalation		AIR LIQUIDE ROMANIA SRL	ROMANIA	4746	2012	1
OXYCODONUM	CLORHIDRAT DE OXICODONA ACCORD 5 mg	prolonged-release tablets	5mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	4757	2012	14
OXYCODONUM	CLORHIDRAT DE OXICODONA ACCORD 10 mg	prolonged-release tablets	10mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	4758	2012	14
OXYCODONUM	CLORHIDRAT DE OXICODONA ACCORD 20 mg	prolonged-release tablets	20mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	4759	2012	14
OXYCODONUM	CLORHIDRAT DE OXICODONA ACCORD 40 mg	prolonged-release tablets	40mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	4760	2012	14
OXYCODONUM	CLORHIDRAT DE OXICODONA ACCORD 80 mg	prolonged-release tablets	80mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	4761	2012	14
PANCREATINUM	KREON 10000	gastroresistant capsules	150mg	ABBOTT PRODUCTS GMBH	GERMANY	4626	2012	4
PANCREATINUM	KREON 25000	gastroresistant capsules	300mg	ABBOTT PRODUCTS GMBH	GERMANY	4627	2012	4
PANTOPRAZOLUM	CONTROLOC 20 mg	gastroresistant tablets	20mg	NYCOMED GMBH	GERMANY	4630	2012	83
PANTOPRAZOLUM	CONTROLOC 40mg	gastroresistant tablets	40mg	NYCOMED GMBH	GERMANY	4631	2012	71
PAPAVERINI HYDROCHLORIDUM	PAPAVERINA FARMACOM 200 mg	tablets	200 mg	FARMACOM S.A.	ROMANIA	4645	2012	1
PARACETAMOLUM	PARACETAMOL B.BRAUN 10 mg/ml	solution for infusion	10 mg/ml	B. BRAUN MELSUNGEN AG	GERMANY	4714	2012	2
PARACETAMOLUM	PARACETAMOL INFANT 160 mg	tablets	160mg	LMN CONSULTANTA S.R.L.	ROMANIA	4745	2012	2
PARACETAMOLUM	ACOMOL 10 mg/ml	solution for infusion	10 mg/ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4750	2012	8
PIOGLITAZONUM	ZIPION 15 mg	tablets	15 mg	ZENTIVA K.S.	CZECH REPUBLIC	4623	2012	13
PIOGLITAZONUM	ZIPION 30 mg	tablets	30 mg	ZENTIVA K.S.	CZECH REPUBLIC	4624	2012	13
PIOGLITAZONUM	ZIPION 45 mg	tablets	45 mg	ZENTIVA K.S.	CZECH REPUBLIC	4625	2012	13
PIOGLITAZONUM	PIOGLITAZONA AUROBINDO 15 mg	tablets	15mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	4637	2012	12
PIOGLITAZONUM	PIOGLITAZONA AUROBINDO 30 mg	tablets	30mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	4638	2012	12

PIOGLITAZONUM	PIOGLITAZONA AUROBINDO 45 mg	tablets	45mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	4639	2012	13
PIOGLITAZONUM	PIOGLITAZONA MYLAN 15 mg	tablets	15mg	GENERICS (UK) LTD	GREAT BRITAIN	4632	2012	9
PIOGLITAZONUM	PIOGLITAZONA MYLAN 30 mg	tablets	30mg	GENERICS (UK) LTD	GREAT BRITAIN	4633	2012	9
PIOGLITAZONUM	PIOGLITAZONA MYLAN 45 mg	tablets	45mg	GENERICS (UK) LTD	GREAT BRITAIN	4634	2012	9
PIOGLITAZONUM	PIOGLITAZONA TERAPIA 15 mg	tablets	15mg	TERAPIA S.A.	ROMANIA	4675	2012	16
PIOGLITAZONUM	PIOGLITAZONA TERAPIA 30 mg	tablets	30mg	TERAPIA S.A.	ROMANIA	4676	2012	16
PIOGLITAZONUM	PIOGLITAZONA TERAPIA 45 mg	tablets	45mg	TERAPIA S.A.	ROMANIA	4677	2012	16
PIOGLITAZONUM	MELIZON 15 mg	tablets	15mg	SPECIFAR S.A.	GREECE	4705	2012	7
PIOGLITAZONUM	MELIZON 30 mg	tablets	30mg	SPECIFAR S.A.	GREECE	4706	2012	7
PIOGLITAZONUM	MELIZON 45 mg	tablets	45mg	SPECIFAR S.A.	GREECE	4707	2012	7
DEHYDRATED SODIUM PYROPHOSPHATE	TECHNESCAN® PYP (V09GAN1)	kit for radiopharmaceutical preparations		MALLINCK RODT MEDIC. BV	HOLLAND	4755	2012	1
PROPOFOLUM	PROFAST 20 mg/ml	emulsion for injection/infusion	20 mg/ml	UAB NORAMEDA	LITHUANIA	4613	2012	2
PROPOFOLUM	PROFAST 10 mg/ml	emulsion for injection/infusion	10 mg/ml	UAB NORAMEDA	LITHUANIA	4612	2012	7
QUETIAPINUM	QUETIAPINA TEVA 50 mg	prolonged-release tablets	50mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4663	2012	11
QUETIAPINUM	QUETIAPINA TEVA 200 mg	prolonged-release tablets	200mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4664	2012	11
QUETIAPINUM	QUETIAPINA TEVA 300 mg	prolonged-release tablets	300mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4665	2012	11
QUETIAPINUM	QUETIAPINA TEVA 400 mg	prolonged-release tablets	400mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4666	2012	11
RILUZOLUM	RILUZOL PMCS 50 mg	film-coated tablets	50 mg	PRO. MED. CS PRAHA A.S.	CZECH REPUBLIC	4611	2012	7
RIVASTIGMINUM	RIVASTIGMINA TEVA PHARMA 2 mg/ml	oral solution	2mg/ml	TEVA PHARMA B.V.	HOLLAND	4523	2012	1
ROCURONIUM BROMIDE	ROCURONIUM KABI 10mg/ml	solution for injection/infusion	10mg/ml	FRESENIUS KABI ROMANIA SRL	ROMANIA	4560	2012	6
ROPINIROLUM	ROPINIROL POLPHARMA 2 mg	prolonged-release tablets	2 mg	PHARMACEUTICAL WORKS POLPHARMA SA	POLAND	4599	2012	16
ROPINIROLUM	ROPINIROL POLPHARMA 4 mg	prolonged-release tablets	4 mg	PHARMACEUTICAL WORKS POLPHARMA SA	POLAND	4600	2012	16
ROPINIROLUM	ROPINIROL POLPHARMA 8 mg	prolonged-release tablets	8 mg	PHARMACEUTICAL WORKS POLPHARMA SA	POLAND	4601	2012	16
ROPINIROLUM	ROPINIROL LPH 2 mg	prolonged-release tablets	2mg	LABORMED PHARMA S.A.	ROMANIA	4681	2012	1
ROPINIROLUM	ROPINIROL LPH 4 mg	prolonged-release tablets	4mg	LABORMED PHARMA S.A.	ROMANIA	4682	2012	1

ROPINIROLUM	ROPINIROL LPH 8 mg	prolonged-release tablets	8mg	LABORMED PHARMA S.A.	ROMANIA	4683	2012	1
ROPINIROLUM	ROPINIROL PHARMASWISS 2 mg	prolonged-release tablets	2mg	PHARMASWISS D.O.O.	SLOVENIA	4738	2012	10
ROPINIROLUM	ROPINIROL PHARMASWISS 4 mg	prolonged-release tablets	4mg	PHARMASWISS D.O.O.	SLOVENIA	4739	2012	10
ROPINIROLUM	ROPINIROL PHARMASWISS 8 mg	prolonged-release tablets	8mg	PHARMASWISS D.O.O.	SLOVENIA	4740	2012	10
ROSUVASTATINUM	STARCREST 5 mg	film-coated tablets	5mg	ALVOGEN IPCO S.A.R.L.	LUXEMBOURG	4531	2012	4
ROSUVASTATINUM	STARCREST 10 mg	film-coated tablets	10mg	ALVOGEN IPCO S.A.R.L.	LUXEMBOURG	4532	2012	4
ROSUVASTATINUM	STARCREST 20 mg	film-coated tablets	20mg	ALVOGEN IPCO S.A.R.L.	LUXEMBOURG	4533	2012	4
ROSUVASTATINUM	EXCELTIN 5 mg	film-coated tablets	5 mg	ACTAVIS GROUP PTC EHF	ICELAND	4582	2012	17
ROSUVASTATINUM	EXCELTIN 10 mg	film-coated tablets	10 mg	ACTAVIS GROUP PTC EHF	ICELAND	4583	2012	17
ROSUVASTATINUM	EXCELTIN 20 mg	film-coated tablets	20 mg	ACTAVIS GROUP PTC EHF	ICELAND	4584	2012	17
ROSUVASTATINUM	EXCELTIN 40 mg	film-coated tablets	40 mg	ACTAVIS GROUP PTC EHF	ICELAND	4585	2012	17
SALMETEROLUM+ FLUTICASONUM	FLUSAMER 50 micrograms/ 250 micrograms/dose	inhalation powder, pre-established doses	50 micrograms/ 250micrograms/ dose	PHAROS-PHARMACEUTICAL ORIENTED SERVICES LTD.	GREECE	4501	2012	1
SILDENAFILUM	SILDENAFIL TERAPIA 25 mg	film-coated tablets	25mg	TERAPIA SA	ROMANIA	4526	2012	7
SILDENAFILUM	SILDENAFIL TERAPIA 50 mg	film-coated tablets	50mg	TERAPIA SA	ROMANIA	4527	2012	7
SILDENAFILUM	SILDENAFIL TERAPIA 100 mg	film-coated tablets	100mg	TERAPIA SA	ROMANIA	4528	2012	7
SIMVASTATINUM	SIMVASTATIN SINTOFARM 10 mg	film-coated tablets	10mg	SINTOFARM S.A.	ROMANIA	4741	2012	1
SIMVASTATINUM	SIMVASTATIN SINTOFARM 20 mg	film-coated tablets	20mg	SINTOFARM S.A.	ROMANIA	4742	2012	1
SIMVASTATINUM	SIMVASTATIN SINTOFARM 40 mg	film-coated tablets	40mg	SINTOFARM S.A.	ROMANIA	4743	2012	1
TERBINAFINUM	TERBINAFINA ROMPHARM 10.1 mg/ml	cutaneous spray, solution	10.1mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	4514	2012	1
TERBINAFINUM	LAMISIL SPRAY 1%	cutaneous spray, solution	1%	NOVARTIS CONSUMER HEALTH GMBH	GERMANY	4524	2012	2
TIOTROPIUM	SPIRIVA RESPIMAT 2.5 micrograms	inhalation solution	2.5micrograms	BOEHRINGER INGELHEIM PHARMA GMBH & CO. K.G.	GERMANY	4546	2012	4
TOPIRAMATUM	TOPAMAX 25 mg	film-coated tablets	25mg	JOHNSON & JOHNSON D.O.O.	SLOVENIA	4504	2012	15
TOPIRAMATUM	TOPAMAX 50 mg	film-coated tablets	50mg	JOHNSON & JOHNSON D.O.O.	SLOVENIA	4505	2012	15
TOPIRAMATUM	TOPAMAX 100 mg	film-coated tablets	100mg	JOHNSON & JOHNSON D.O.O.	SLOVENIA	4506	2012	15
TRIFLUSALUM	PLATROX 300 mg	capsules	300 mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	4654	2012	4
DIPHTHERIA, TETANUS, AND ACELLULAR PERTUSSIS BOOSTER VACCINE	INFANRIX®	suspension for injection	0.5 ml/dose	GLAXOSMITHKLINE BIOLOGICALS S.A.	BELGIUM	4751	2012	15

TYPE B (HIB) INFLUENZA VACCINE	HIBERIX VACCIN HAEMOPHILUS INFLUENZAE TIP B	powder and solvent for solution for injection		GLAXOSMITHKLINE BIOLOGICALS S.A.	BELGIUM	4551	2012	8
TRIVALENT INACTIVATED POLIO VACCINE	IMOVAX POLIO	suspension for injection		SANOFI PASTEUR SA	FRANCE	4596	2012	2
TRIVALENT INACTIVATED POLIO VACCINE	IMOVAX POLIO	suspension for injection		SANOFI PASTEUR SA	FRANCE	4596	2012	8
MEASLES, MUMPS, RUBELLA AND VARICELLA VACCINE (LIVE)	PRIORIX-TETRA	powder and solvent for solution for injection in pre-filled syringe		GLAXOSMITHKLINE (GSK) SRL	ROMANIA	4621	2012	6
MEASLES, MUMPS, RUBELLA AND VARICELLA VACCINE (LIVE)	PRIORIX-TETRA	powder and solvent for solution for injection		GLAXOSMITHKLINE (GSK) SRL	ROMANIA	4620	2012	6
TETANUS VACCINE (ADSORBED)	TETAVAX SUSP.INJ.	suspension for injection	0.5ml/dose	SANOFI PASTEUR S.A.	FRANCE	4593	2012	4
VALACYCLOVIRUM	VALTREX 500 mg	film-coated tablets	500 mg	THE WELLCOME FOUNDATION LIMITED	GREAT BRITAIN	4643	2012	6
VENLAFAXINUM	ELIFY EP 37,5 mg	prolonged-release capsules	37.5 mg	MEDOCHEMIE LTD.	CYPRUS	4725	2012	8
VENLAFAXINUM	ELIFY EP 75 mg	prolonged-release capsules	75 mg	MEDOCHEMIE LTD.	CYPRUS	4726	2012	8
VENLAFAXINUM	ELIFY EP 150 mg	prolonged-release capsules	150 mg	MEDOCHEMIE LTD.	CYPRUS	4727	2012	8
VINBLASTINUM	VINBLASTINA ARCHIE SAMUEL 1 mg/ml	solution for injection	1mg/ml	ARCHIE SAMUEL S.R.O.	CZECH REPUBLIC	4703	2012	1
VINORELBINUM	NAVELBINE 10 mg/ml	concentrate for solution for infusion	10mg/ml	PIERRE FABRE MEDICAMENT	FRANCE	4661	2012	3
VINPOCETINUM	VINPOCETINA VIM SPECTRUM 5 mg	capsules	5mg	VIM SPECTRUM SRL	ROMANIA	4594	2012	2
TBE VIRUS (TICK-BORNE ENCEPHALITIS VIRUS)	FSME-IMMUN 0.5 ml	suspension for injection in pre-filled syringe	0.5ml	BAXTER AG	AUSTRIA	4696	2012	4
TBE VIRUS (TICK-BORNE ENCEPHALITIS VIRUS)	FSME-IMMUN 0.25 ml JUNIOR	suspension for injection in pre-filled syringe	0.25ml	BAXTER AG	AUSTRIA	4695	2012	8
XYLOMETAZOLINUM	TEZOLINE 0.5 mg/ml	nasal spray, solution	0.5mg/ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4635	2012	2
XYLOMETAZOLINUM	TEZOLINE 1 mg/ml	nasal spray, solution	1mg/ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	4636	2012	3
ZOLPIDEMUM	ZADOBRA 5 mg	film-coated tablets	5 mg	ALKALOID-INT D.O.O.	SLOVENIA	4573	2012	2

EMA centrally authorised medicinal products for which the European Commission issued decisions during the 2nd quarter of 2012

INN	Invented name	Pharmaceutical form	Strength	Manufacturer	Country	MA Number		
PASIREOTIDUM	SIGNIFOR 0.3 mg	solution for injection	0.3 mg	NOVARTIS EUROPHARM LTD.	GREAT BRITAIN	753	24.04.2012	04
PASIREOTIDUM	SIGNIFOR 0.6 mg	solution for injection	0.6 mg	NOVARTIS EUROPHARM LTD.	GREAT BRITAIN	753	24.04.2012	04
PASIREOTIDUM	SIGNIFOR 0.9 mg	solution for injection	0.9 mg	NOVARTIS EUROPHARM LTD.	GREAT BRITAIN	753	24.04.2012	04