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MINISTRY OF HEALTH

ORDER
on approval of the Norms for implementation of provisions of Art. 699 (1) and (2) of Law No. 95/2006 on healthcare reform concerning medicinal products for special needs

On seeing the Approval report of the Pharmaceutical and Medical Devices Directorate No. E.N. 996/2013,

taking into account:

- provisions of Art. 699 (2) of Law 95/2006 on healthcare reform, as amended;

- provisions of Art. 12 (9) 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. 1. – The Norms for implementation of provisions of Art. 699 (1) and (2) of Law 95/2006 on healthcare reform concerning medicinal products for special needs are approved, as provided in the Annex which is integral part of this Order.

Art. 2. – On this Order coming into force, Order of the Minister of Public Health No. 962/2006 on approval of the Norms for implementation of provisions of Art. 699 (1) of Law 95/2006 on healthcare reform, concerning medicinal products for special needs, published in the Official Gazette of Romania, Part I, No. 701 of 16 August 2006, is repealed.

Art. 3. – This Order is to be published in the Official Gazette of Romania, Part I.

Minister of health,
Gheorghe-Eugen Nicolăescu

Bucharest, 7 February 2013.
No. 85.

(Published in the Official Gazette of Romania, Part I, No. 93/14/II/2013)

ANNEX

NORMS
for implementation of provisions of Art. 699 (1) and (2) of Law 95/2006 on healthcare reform concerning medicinal products for special needs

CHAPTER I
Norms for implementation of provisions of Art. 699 (1) of Law 95/2006 on healthcare reform concerning medicinal products for special needs

Art. 1. - (1) These Norms refer to medicinal products for special needs without valid marketing authorisation in Romania in accordance with Art. 700 of Law 95/2006, as amended, required for special needs in accordance with Art. 699 of the same Law (1).

(2) Medicinal products subject to a clinical trial performed in Romania and off-label prescription of a medicinal product without are not subject to these Norms.

Art. 2. - (1) The decision on whether or not a patient has special needs which cannot be met by medicinal products authorised for marketing lies with the respective patient's physician; prescription of the medicinal product for special needs must comply with the therapeutic indications for which the product has been authorised; the medical prescription must be accompanied by a explanatory document.

(2) As an interim solution, a medicinal product authorised for marketing may be considered for special needs in case it cannot be obtained via the regular distribution chains in reasonable time; this does not justify long-term supply; supply under such circumstances must be discontinued as soon as availability of the authorised medicinal product in the regular distribution chains is re-established.

(3) Medicinal products for special needs have to be authorised in at least one EEA Member State or in a third country.

(4) A medicinal product which is the pharmaceutical equivalent of an already authorised product shall not be considered a medicinal product for special needs; in line with this paragraph, a medicinal product is considered a pharmaceutical equivalent if it meets all the following requirements:

a) it contains the same active substance(s);

b) it contains the same amount of active substance(s) or the same strength, for liquid pharmaceutical forms;

c) it has the same pharmaceutical form;

d) it meets the same/equivalent standards as regards the patient's clinical needs at the moment of product administration.

Art. 3. – The National Agency for Medicines and Medical Devices grants the authorisation for supply of medicinal products for special needs, in accordance with Art. 699 (1) of Law 95/2006, as amended, if the following requirements are met:

a) there is a bona fide unsolicited order (on behalf of the supplier, initiated by the physician, with the patient's consent);

b) the product is prescribed by a physician, who provides justification for the respective request;

c) the product is meant for one/several patient(s) under the respective physician's direct responsibility.

Art. 4. – In accordance with Art. 699 (1) of Law 95/2006, as amended, the wholesale distributor, holder of an authorisation for supply of medicinal products for special needs, must inform everyone involved in the supply circuit that the respective product does not have a valid marketing authorisation in Romania.

Art. 5. – The authorisation for supply of medicinal products for special needs can only be granted to wholesale distributors authorised by the National Agency for Medicines and Medical Devices, in accordance with Annex 3.

Art. 6. - (1) The applicant submits to the National Agency for Medicines and Medical Devices a dossier containing:

a) a standard application form, in accordance with Annex 1;

b) a medical explanatory document signed by the prescribing physician;

c) the product quality specifications, quality/compliance/Good Manufacturing Practice certificates, as required;

d) a marketing authorisation in one of the EEA states or in the third country where the product has been authorised;

e) The Summary of Product Characteristics and package leaflet in the language of the country where the product has been authorised, as well as the Romanian version thereof;

f) proof of the existence of pharmacovigilance responsible staff and the means required for notification of the National Agency for Medicines and Medical Devices about all suspected adverse reactions, reported in Romania or another Member State.

(2) The authorisation is granted for the amount specified in the prescription, without exceeding the necessary for 12 months use.

(3) The authorisation may be suspended or withdrawn when the conditions for its grant have not been met. The suspension remains in force until remedy of deficiencies found, without extending the period of the validity of the authorisation.

Art. 7. – The wholesale distributor of medicinal products for special needs has the following obligations:

a) to immediately inform the National Agency for Medicines and Medical Devices about safety/quality concerns, including those determined by a potential counterfeit, of which the distributor has been informed;

b) not to advertise the medicinal product;

c) to retain specific records about its supply, in accordance with Art. 8 provisions;

d) to notify the National Agency for Medicines and Medical Devices about the actual imported/marketed amount of the medicinal product for special needs as well as any other issue related to its supply.

Art. 8. – The records mentioned under Art. 7 c) are to be retained for at least 5 years from the date of the issuance of the authorisation and include the following information:

a) the external supplier of the medicinal product;

b) the date and beneficiary of the medicinal product;

c) the amount of each delivery;

d) the number of the product manufacturing batch;

e) the product storage/shipping conditions;

f) details about any adverse reaction as known to the supplier;

g) details about any potential report on counterfeiting of the medicinal product as known to the supplier.

Art. 9. – The National Agency for Medicines and Medical Devices may at any time require evidence from the wholesale distributor of records mentioned under Art. 8 and may impose any measure concerning the quality/safety/efficacy of the medicinal product authorised for special needs, in accordance with Art. 699 (1) of Law 95/2006, as amended, meant to reduce the potential risk for the patient's health.

CHAPTER II
Norms on implementation of provisions of Art. 699 (2) of Law 95/2006 on healthcare reform concerning medicinal products for special needs

Art. 10. - (1) These Norms refer to medicinal products without valid marketing authorisation in Romania in accordance with Art. 700 of Law 95/2006, as amended, required for special needs in accordance with Art. 699 of the same Law (1).

(2) Medicinal products subject to a clinical trial performed in Romania and off-label prescription of a medicinal product without are not subject to these Norms.

Art. 11. – (1) The National Agency for Medicines and Medical Devices grants the authorisation for supply of medicinal products for special needs, in accordance with Art. 699 (1) of Law 95/2006, as amended, if the following requirements are met:

a) there is an explanatory document in place on the respective medicinal product designation as special needs which cannot be met by medicinal products already authorised for marketing in Romania at the time of the request, as granted by specialised Ministry of Health commissions/directorates;

b) there is a bona fide unsolicited order (on behalf of the supplier, initiated by the specialised Ministry of Health commissions/directorates), for circumstances provided for in Art. 699 (2) of Law 95/2006, as amended;

c) the product is authorised in at least one EEA state a third country;

(2) As an interim solution, a medicinal product authorised for marketing may be considered for special needs in case it cannot be obtained via the regular distribution chains in reasonable time; this does not justify long-term supply; supply under such circumstances must be discontinued as soon as availability of the authorised medicinal product in the regular distribution chains is re-established.

(3) A medicinal product which is the pharmaceutical equivalent of an already authorised product shall not be considered a medicinal product for special needs; in line with this paragraph, a medicinal product is considered a pharmaceutical equivalent if it meets all the following requirements:

a) it contains the same active substance(s);

b) it contains the same amount of active substance(s) or the same strength, for liquid pharmaceutical forms;

c) it has the same pharmaceutical form;

d) it meets the same/equivalent standards as regards the patient's clinical needs at the moment of product administration.

Art. 12. - (1) In accordance with Art. 699 (2) of Law 95/2006, as amended, the wholesale distributor, holder of an authorisation for supply of medicinal products for special needs, must inform everyone involved in the supply circuit that the respective medicinal product does not have a valid marketing authorisation in Romania.

(2) In accordance with Art. 699 (2) of Law 95/2006, as amended, for each delivery to the beneficiary, the wholesale distributor, holder of an authorisation for supply of medicinal products for special needs, attaches the Summary of Product Characteristics and the leaflet, both translated into Romania.

Art. 13. – In accordance with Art. 699 (2) of Law 95/2006, as amended, the authorisation for supply of medicinal products for special needs can only be granted to wholesale distributors authorised by the National Agency for Medicines and Medical Devices, in accordance with Annex 4.

Art. 14. - (1) The applicant submits to the National Agency for Medicines and Medical Devices a dossier containing:

a) the standard application form, in accordance with Annex 2;

b) the medical explanatory document and quantity required by the specialised Ministry of Health commission/directorate;

c) the marketing authorisation in one of the EEA states or third country where it has been authorised;

d) the medicinal product quality specifications, summary of batch protocol, the quality/compliance certificate, GMP certificate, as required;

e) the Summary of Product Characteristics and the leaflet in the language of the country where it is authorised as well as the Romanian version thereof;

f) proof of the existence of pharmacovigilance responsible staff and the means required for notification of the National Agency for Medicines and Medical Devices about all suspected adverse reactions, reported in Romania or another Member State.

(2) The authorisation is granted for the amount established by the specialised Ministry of Health commission/directorate, without exceeding the necessary for 12 months use.

(3) The authorisation may be suspended or withdrawn when the conditions for its grant have not been met. The suspension remains in force until remedy of deficiencies found, without extending the period of the validity of the authorisation.

(4) After having obtained the authorisation for supply of medicinal products for special needs, in accordance with Art. 699 (2) of Law 95/2006, as amended, the wholesale distributor submits to the National Agency for Medicines and Medical Devices a request for exemption from legal provisions in force concerning the packaging/labelling of medicinal products authorised for marketing, other than those mentioned in the Norms on the procedure for grant of exemption of specific medicinal products labelling and package leaflet from the obligation that certain particulars should appear and that the leaflet are written in Romanian, when the product is not intended to be delivered to the patient for self-administration, approved through Order of the Minister of Public Health No. 872/2006.

Art. 15. – The wholesale distributor of medicinal products for special needs has the following obligations:

a) to immediately inform the National Agency for Medicines and Medical Devices about safety and quality concerns, including those determined by a potential counterfeit, of which the distributor has been informed;

b) to not advertise the medicinal product;

c) to retain specific records of its supply, in accordance with Art. 7 provisions;

d) to notify the National Agency for Medicines and Medical Devices on the actual imported/marketed quantity of the respective medicinal product for special needs at each supply/release as well as about any other issue related to its supply;

e) to ensure that the medicinal product for which a special needs authorisation has been granted is used on Romanian territory only.

Art. 16. – The records mentioned under Art. 15 c) are stored for at least 5 years from issuance of the authorisation and contain the following information:

a) the external supplier of the product;

b) the date and list of the product beneficiaries;

c) the quantity of each supply;

d) the product manufacturing batch;

e) the product storage/shipping conditions;

f) details about all adverse reactions known to the supplier;

g) details about any potential report of product counterfeiting known to the supplier.

Art.17. – The National Agency for Medicines and Medical Devices may at any time require evidence from the wholesale distributor of records mentioned

under Art. 16 and may impose any measure concerning the quality/safety/efficacy of the medicinal product authorised for special needs, in accordance with Art. 699 (1) of Law 95/2006, as amended, meant to reduce the potential risk for the patient's health.

Art. 18. – Annexes 1-4 are integral part of these Norms.

ANNEX 1
to the Norms

THE NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES

FORM
Application for authorisation of supply of medicinal products for special needs, in accordance with Art. 699 (1) of Law No. 95/2006 on healthcare reform

1. Prescriber information
Name and surname:
Number of the free practice document:
Stamp code:
Medical unit:
Address:
Telephone number:
Fax number:
Mobile phone number:
E-mail address:
I hereby declare that I take the responsibility for use of ....., in accordance with the attached medical explanatory document, full aware that this is not authorised for marketing in Romania, in accordance with the law.

Prescriber,
.....
(Signature and stamp)
Date .....

2. Patient information
Name and surname:
Identity document:
PIN:
Address:
Telephone number:
Fax number:
Mobile phone number:
E-mail address:
Date of birth:
Diagnosis:
I hereby declare that I have been informed that ..... does not have a marketing authorisation in Romania, in accordance with the law, and duly agree with the treatment.

I have been informed about the potential adverse reactions as well as the manner of their reporting and undertake the charges for the product.
Patient,
.....
(signature)
Date .....

3. Information about the medicinal product for special needs
Trade name:
Active substance (INN):
Strength:
Pharmaceutical form:
Manufacturer and country of origin:
Quantity required*)
Indications on administration (dosage):
Adverse reactions and cautions related to the administration:

_____
***)** Please specify quantity for one year at most

4. Information about the applicant:
Name of the wholesale distributor:
Address:
Number of the wholesale distribution authorisation:
Qualified person (contact data):
Telephone number:
Fax number:
E-mail address:
We hereby apply for grant of an authorisation for supply of the aforementioned product according to the quantity required.
We hereby declare compliance with legal provisions on supply of medicinal products for special needs without a marketing authorisation in Romania, in accordance with Art. 699 (1) of Law 95/2006 on healthcare reform, as amended.

Applicant,
.....
(signature and stamp)

Date .....

NOTE:
This application form is available only if accompanied by all documents mentioned under Art. 6 (1) of the Norms for implementation of provisions of Art. 699 points (1) and (2) of Law 95/2006 on healthcare reform concerning medicinal products for special needs, approved through Order of the Minister of Health No. 85/2013.

ANNEX 2
to Norms

THE NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES

APPLICATION FORM
concerning authorisation for supply of medicinal products for special needs, in accordance with Art. 699 (2) of Law 95/2006 on healthcare reform

1. Information about the medicinal product for special needs:
Trade name:
Active substance (INN):
Strength:
Pharmaceutical form:
Manufacturer and country of origin:
Quantity required*):
Indication for administration:
Adverse reactions and warning for administration:

_____
***)** Specify quantity for one year at most

2. Information about the applicant:
Name of the wholesale distributor:
Address:
Number of the wholesale distribution authorisation:
Qualified person (contact data):
Telephone number:
Fax number:
E-mail address:
We hereby require the supply of the aforementioned product in the specified quantity.
We hereby declare compliance with legal provisions on supply of medicinal products for special needs without a marketing authorisation in Romania, in accordance with Art. 699 (1) of Law 95/2006 on healthcare reform, as amended.

Applicant,

.....
(signature and stamp)

Date .....

NOTE:
This application form is available only if accompanied by all documents mentioned under Art. 14 (1) of the Norms for implementation of provisions of Art. 699 points (1) and (2) of Law 95/2006 on healthcare reform concerning medicinal products for special needs, approved through Order of the Minister of Health No. 85/2013.

ANNEX 3
to Norms

THE NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES

AUTHORISATION

for supply of medicinal products for special needs

in accordance with Art. 699 (1) of Law 95/2006 on healthcare reform

No. ..... of .....

Taking into account Application No. ..... of ....., submitted to the National Agency for Medicines and Medical Devices,..... ……..…….. is authorised to supply ….....,
(Trade name, pharmaceutical form and strength), containing.....
…….....
(International Non-proprietary Name)
quantity: ....., in response to the prescription issued by Dr. ..... for .....

This authorisation is valid for 1 year.

President,
.....
(Name and surname, signature and stamp of the institution)

ANNEX 4
to Norms

THE NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES

AUTHORISATION

for supply of medicinal products for special needs in accordance with Art. 699 (1) of Law 95/2006 on healthcare reform

No. ..... of .....

Taking into account Application No. ..... of ....., submitted to the National Agency for Medicines and Medical Devices, ……..…….. is authorised to supply …....,
(Trade name, pharmaceutical form and strength) containing …….....
(International Non-proprietary Name)
quantity: ....., in response to the application submitted by the commission ...../directorate ..... of the
(name of specialised commission/direction)
Ministry of Health.

This authorisation is valid for 1 year.
President,
.....
(Name and surname, signature and stamp of the institution)

Medicinal product batches recalled during the 1st quarter of 2013

Crt. No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for withdrawal	Action proposed	Date of withdrawal
1	BENGAY GREASELESS	cream		combinations	Janssen Cilag, FRANCE/McNeil Products Ltd. c/o Johnson & Johnson, Great Britain (MA No. 7025/2006/01-02)	0971V A.1, 1031V A.1, 1241V B.2, 1821V A.1, 3220V A.1, 3220V B.3, 3221V A.1, 3420V A.1	Product whose one-year period since MAH approval of transfer has expired	Voluntary withdrawal and destruction	17.01.2013
2	CALPOL ȘASE PLUS	oral suspension	250 mg/5 ml	paracetamol	McNeil Products Ltd., Great Britain (MA No. 7725/2006/01)	1M002, 1M003, 1M004	Product whose one-year period since MAH approval of transfer has expired	Voluntary withdrawal and destruction	17.01.2013
3	LIPANOR	capsules	100 mg	ciprofibrate	Sanofi Winthrop Industrie, FRANCE/Sanofi-Aventis Romania SRL	All batches	Voluntary withdrawal of the marketing authorisation	Voluntary withdrawal and destruction	17.01.2013
4	NICORETTE FRESHMINT 2 mg gum	medical chewing gum	2 mg	nicotine	McNeil AB, Sweden (MA No. 8101/2006/01)	NB902B, NB902E, NC988F, NC9881, NE818B, NE849E	Product whose one-year period since MAH approval of transfer has expired	Voluntary withdrawal and destruction	17.01.2013
5	NICORETTE FRESHMINT 4 mg gum	medical chewing gum	4 mg	nicotine	McNeil AB, Sweden (MA No. 8102/2006/01)	ND823E, ND881B, NE953B, NI940B	Product whose one-year period since MAH approval of transfer has expired	Voluntary withdrawal and destruction	17.01.2013
6	NICORETTE patch 10/16	transdermal patches	10 mg/16h	nicotine	McNeil AB, Sweden (MA No. 8105/2006/01-02-03)	MI023D, ML066B, ND049B, NF124B, NI135D	Product whose one-year period since MAH approval of transfer has expired	Voluntary withdrawal and destruction	17.01.2013
7	NICORETTE patch 15/16	transdermal patches	15 mg/16h	nicotine	McNeil AB, Sweden (MA No. 8106/2006/01-02-03)	MI144B, MK059B, ML096F, MM094F, NB032B, NC171D, ND136D, NE114B, NE161D, NE164L, NH110B, NI088B, NI137B, NM027D	Product whose one-year period since MAH approval of transfer has expired	Voluntary withdrawal and destruction	17.01.2013
8	NICORETTE patch 5/16	transdermal patches	5 mg/16h	nicotine	McNeil AB, Sweden (MA No. 8104/2006/01-02-03)	MI033B, ML033D, NE108B, NE138F, NL112D	Product whose one-year period since MAH approval of transfer has expired	Voluntary withdrawal and destruction	17.01.2013
9	NIZORAL SHAMPOO	shampoo	2 %	ketoconazole	McNeil AB, Sweden (MA No. 7624/2006/01-02)	AHB2R00, AIB4H00, AKB2V00, BAB7700, BBB4S00, BIB0Z02, BKB1A00	Product whose one-year period since MAH approval of transfer has expired	Voluntary withdrawal and destruction	17.01.2013

10	OLYNTH	nasal spray, solution	0.05 %	xylometazoline	McNeil Products Ltd. c/o Johnson & Johnson, Great Britain (MA No. 7299/2006/01)	A04202, A06514, A06668, A07891, C00849, C04090R, C04845R, C05939R, C06551R, C08127R, C08128R	Product whose one-year period since MAH approval of transfer has expired	Voluntary withdrawal and destruction	17.01.2013
11	OLYNTH	nasal spray, solution	0.1 %	xylometazoline	McNeil Products Ltd. c/o Johnson & Johnson, Great Britain (MA No. 7300/2006/01)	A04000, A04247, A06155, A07578, A07056, A08240, A08241, C00726, C00785, C03117, C03325, C03844R, C04491R, C04672R C04673R, C05186R, C08273R	Product whose one-year period since MAH approval of transfer has expired	Voluntary withdrawal and destruction	17.01.2013
12	OLYNTH HA	nasal spray, solution	0.1 %	xylometazoline	McNeil Products Ltd. c/o Johnson & Johnson, Great Britain (MA No. 8100/ 2006/01)	271939UP, 272287UP, 272288UP, 272370UP, 272754UP, 273085UP, 273614UP, 273925UP, 274174UP, 274332UP, 274493UP, 274945UP, 275297UP, 275298UP, 275558UP, 275571UP	Product whose one-year period since MAH approval of transfer has expired	Voluntary withdrawal and destruction	17.01.2013
13	OLYNTH HA	nasal spray, solution	0.05 %	xylometazoline	McNeil Products Ltd. c/o Johnson & Johnson, Great Britain (MA No. 8099/2006/01)	271204UP, 271998UP, 271999UP, 272001UP, 272352UP, 272380UP, 272789UP, 272790UP, 274922UP, 275650UP	Product whose one-year period since MAH approval of transfer has expired	Voluntary withdrawal and destruction	17.01.2013
14	SUDAFED	film-coated tablets	60 mg	pseudoephedrine	GSK Pharmaceuticals SA, POLAND/McNeil Products Ltd. c/o Johnson & Johnson, Great Britain (MA No. 7127/2006/01)	PK0655, RB0372, RB0373, RE1038	Product whose one-year period since MAH approval of transfer has expired	Voluntary withdrawal and destruction	17.01.2013
15	TICLID	film-coated tablets	250 mg	Ticlopidine HCl	Sanofi Winthrop Industrie, FRANCE/Sanofi-Aventis, Romania SRL	All batches	Voluntary withdrawal of the marketing authorisation	Voluntary withdrawal and destruction	17.01.2013
16	CLINDAMYCIN-MIP	solution for injection/infusion	150 mg/ml	clindamycin	Solupharm, GERMANY/Mip Pharma GmbH, Germany	2383809	A black visible particle discovered inside a vial	Voluntary withdrawal and destruction	24.01.2013

17	PROCTO-GLYVENOL	suppositories		tribenozide+ lidocaine	Novartis Consumer Health, GmbH, GERMANY/Recordati, Romania SRL	H5088, H5085, H5090, H5089, H5084, H5095, H5078, H5091, H5093, H5094, K02269A, H5087A	The listed batches manufactured prior to approval of MA transfer (6054/2005/01) from Novartis Consumer Health, GmbH, GERMANY to Artmed international SRL (currently called Recordati Romania SRL)	Voluntary withdrawal and destruction	07.02.2013
18	PROCTO-GLYVENOL	cream		tribenozide+ lidocaine	Novartis Consumer Health, GmbH, GERMANY/Recordati Romania SRL	K01738A, K02536A, L01245B, K02537A, K02560A, K02914A, K02561A, K02562A, K02953A, K00771A, K01737B, K01995A	The listed batches have been manufactured prior to the approval of MA transfer (6055/2005/01) from Novartis Consumer Health, GmbH, GERMANY to Artmed international SRL (currently called Recordati Romania SRL)	Voluntary withdrawal and destruction	07.02.2013
19	PANADOL	film-coated tablets	1 g	paracetamol	GSK Ltd., Ireland/ GSK Consumer Healthcare, Great Britain	90889	Expiry of the 2-year period specified in Order of the Minister of Health No. 279/2005 after approval, on 14.01.2011, of certain Type II variations amending the package leaflet and/or product information on the labelling	Voluntary withdrawal and destruction	11.02.2013
20	PANADOL	film-coated tablets	500 mg	paracetamol	GSK Dungarvan Ltd., Ireland/GSK Consumer Healthcare, Great Britain	090362, 090881, 090995, 090997, 091027, 091080, 091081, 100011, 100024, 100025, 100058, 100062, 100085, 100164, 100165, 100215, 013/2, 014/1, 016/1, 017/2, 018/01	Expiry of the 2-year period specified in Order of the Minister of Health No. 279/2005 after approval, on 14.01.2011, of certain Type II variations amending the package leaflet and/or product information on the labelling	Voluntary withdrawal and destruction	11.02.2013

21	PANADOL BABY	oral suspension	120 mg/5 ml	paracetamol	Farmaclair FRANCE/GSK Consumer Healthcare, Great Britain	H001, H002, H040, H041, H042, H043, H112, H113, H114, H115, H116, H118, H119, H131, H132, H141, H141, J011, H018, J019, J045, J046, J109, J110, J111	Expiry of the 2-year period specified in Order of the Minister of Health No. 279/2005 after approval, on 14.01.2011, of certain Type II variations amending the package leaflet and/or product information on the labelling	Voluntary withdrawal and destruction	11.02.2013
22	PANADOL RAPIDE	film-coated tablets	500 mg	paracetamol	GSK Dungarvan Ltd., Ireland/GSK Consumer Healthcare, Great Britain	110316, 110364	Expiry of the 2-year period specified in Order of the Minister of Health No. 279/2005 after approval, on 14.01.2011, of certain Type II variations amending the package leaflet and/or product information on the labelling	Voluntary withdrawal and destruction	11.02.2013
23	PANADOL EXTRA	film-coated tablets		paracetamol	GSK Dungarvan Ltd., Ireland/GSK Consumer Healthcare, Great Britain	90539, 90886, 90982, 110471	Expiry of the 2-year period specified in Order of the Minister of Health No. 279/2005 after approval, on 14.01.2011, of certain Type II variations amending the package leaflet and/or product information on the labelling	Voluntary withdrawal and destruction	11.02.2013
24	CETEBE	prolonged-release capsules	500 mg	ascorbic acid	GSK Consumer Healthcare, Great Britain	All batches	Expiry of the one-year period from cessation of MA validity (Art. 730 (9) of Law 95/2006)	Voluntary withdrawal and destruction	13.02.2013
25	DESLORATADINA RATIOPHARM	film-coated tablets	5 mg	desloratadine	Teva Pharmaceuticals, India/Ratiopharm GmbH, Germany	14074212, 14074312, 14074412, 14161712	Out-of-specification results obtained for related impurities and total impurity content during stability trials	Withdrawal and destruction	21.02.2013

26	OMERAN 20	gastroresistant capsules	20 mg	omeprazole	Europharm S.A.	LC05370, LC05636, LC05666, LC05775, LC05809, LC06601, LC06886, LC06995, LC07393, LC07394	In accordance with the provisions of Order of the Minister of Health No. 279/2005 on approval of the manner of implementation of amendments to marketing authorisations approved by the NAMMD	Voluntary withdrawal and destruction	14.03.2013

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 4th quarter of 2012

During the 4th quarter of 2012, 313 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
A05 – Bile and liver therapy
A07 – Antidiarrheals, intestinal anti-inflammatory/anti-infective agents
A10 – Drugs used in diabetes
A11 - Vitamins
A12 – Mineral supplements
B01 – Antithrombotic agents
B02 – Antihemorrhagics
C01 – Cardiac therapy
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
D05 – Antipsoriatics
D07 – Corticosteroids, dermatological preparations
D10 – Anti-acne preparations
D11 – Other dermatological preparations
G01 – Gynecological antiinfectives and antiseptics
G03 – Sex hormones and modulators of the genital system
G04 - Urologicals
H02 – Corticosteroids for systemic use
H05 – Calcium homeostasis
J01 – Antibacterials for systemic use
J02 – Antimycotics for systemic use
J05 – Antivirals for systemic use
L01 – Antineoplastic agents
L02 – Endocrine therapy
M01 – Anti-inflammatory and antirheumatic products
M05 – Drugs for treatment of bone diseases

N01 - Anesthetics
N02 - Analgezics
N03 - Antiepileptics
N04 – Anti-parkinson drugs
N05 - Psycholeptics
N06 - Psychoanaleptics
N07 – Other nervous system drugs
R01 – Nasal preparations
R03 – Drugs for obstructive airway diseases
R05 – Cough and cold preparations
R06 – Antihistamines for systemic use
S01 - Ophthalmologicals
V01 - Allergens
V09 – Diagnostic radiopharmaceuticals
XRN – Homeopathic medicinal products

Medicinal products authorised for marketing by the NAMMD during the 4th quarter of 2012

INN	Invented name	Pharmaceutical form	Strength	Manufacturer	Country	MA Number		
ACIDUM IBANDRONICUM	ACID IBANDRONIC SYNTHON 150 mg	film-coated tablets	150 mg	SYNTHON BV	HOLLAND	5131	2012	10
ACIDUM IBANDRONICUM	ACID IBANDRONIC SYNTHON 50 mg	film-coated tablets	50 mg	SYNTHON BV	HOLLAND	5130	2012	36
ACIDUM RISEDRONICUM	ACTONEL 75 mg	film-coated tablets	75 mg	SANOFI - AVENTIS ROMÂNIA S.R.L.	ROMANIA	5122	2012	04
ACIDUM RISEDRONICUM	RISEDRONAT AUROBINDO 35 mg	film-coated tablets	35 mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	5248	2012	06
ACIDUM ZOLEDRONICUM	ACID ZOLEDRONIC MEDISON PHARMA 4 mg/5 ml	concentrate for solution for infusion	4 mg/5 ml	MEDISON PHARMA S.R.L.	ROMANIA	5107	2012	06
ACIDUM ZOLEDRONICUM	ACID ZOLEDRONIC POLPHARMA 4 mg	powder + solvent for solution for infusion	4 mg	PHARMACEUTICAL WORKS POLPHARMA SA	POLAND	5039	2012	01
ACIDUM ZOLEDRONICUM	ACID ZOLEDRONIC POLPHARMA 4 mg/5 ml	concentrate for solution for infusion	4 mg/5 ml	PHARMACEUTICAL WORKS POLPHARMA SA	POLAND	5038	2012	01
ACIDUM ZOLEDRONICUM	ACID ZOLEDRONIC TERAPIA 4 mg/5 ml	concentrate for solution for infusion	4 mg/5 ml	TERAPIA SA	ROMANIA	5112	2012	06
ACIDUM ZOLEDRONICUM	ACID ZOLEDRONIC ZENTIVA 4 mg/5 ml	solution for infusion	4 mg/5 ml	ZENTIVA, K.S.	THE CZECH REPUBLIC	5161	2012	04
ACIDUM ZOLEDRONICUM	ACID ZOLEDRONIC ZENTIVA 5 mg/100 ml	solution for infusion	4 mg/5 ml	ZENTIVA, K.S.	THE CZECH REPUBLIC	5162	2012	01
ACIDUM ZOLEDRONICUM	OSOPRIL 4 mg/5 ml	concentrate for solution for infusion	4 mg/5 ml	EGIS PHARMACEUTICALS PLC	HUNGARY	5059	2012	02
ACIDUM ZOLEDRONICUM	ZOLACITOR 4 mg/5 ml	concentrate for solution for infusion	4 mg/5 ml	CHIESI PHARMACEUTICALS GMBH	AUSTRIA	5238	2012	02
AMBROXOLUM	AMBROXOL FONTANE 30 mg/5 ml	oral solution	30 mg/5 ml	FONTANE PHARMA GMBH	GERMANY	5054	2012	01
AMLODIPINUM	NORVASC 10 mg	tablets	10 mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	5164	2012	17
AMLODIPINUM	NORVASC 5 mg	tablets	5 mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	5163	2012	16
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOXICILINA/ACID CLAVULANIC AUROBINDO 400 mg/57 mg/5 ml	powder for oral suspension	400mg/57 mg/ 5ml	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	5051	2012	04
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOXICILINA/ACID CLAVULANIC BROWN & BURK 200mg/28.5 mg/5ml	powder for oral suspension	200mg/28.5mg/ 5 ml	BROWN & BURK UK LIMITED	GREAT BRITAIN	5105	2012	04
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOXICILINA/ACID CLAVULANIC BROWN & BURK 400mg/57 mg/5 ml	powder for oral suspension	400mg/57mg/ 5 ml	BROWN & BURK UK LIMITED	GREAT BRITAIN	5106	2012	04
AMPICILLINUM	AMPICILINA STRIDES ARCOLAB INTERNAȚIONAL 1g	powder for solution for injection/infusion	1 g	STRIDES ARCOLAB INTERNAȚIONAL LIMITED	GREAT BRITAIN	5101	2012	01

AMPICILLINUM	AMPICILINA STRIDES ARCOLAB INTERNAȚIONAL 250 mg	powder for solution for injection/infusion	250 mg	STRIDES ARCOLAB INTERNAȚIONAL LIMITED	GREAT BRITAIN	5099	2012	01
AMPICILLINUM	AMPICILINA STRIDES ARCOLAB INTERNAȚIONAL 2g	powder for solution for injection/infusion	2 g	STRIDES ARCOLAB INTERNAȚIONAL LIMITED	GREAT BRITAIN	5102	2012	01
AMPICILLINUM	AMPICILINA STRIDES ARCOLAB INTERNAȚIONAL 500 mg	powder for solution for injection/infusion	500 mg	STRIDES ARCOLAB INTERNAȚIONAL LIMITED	GREAT BRITAIN	5100	2012	01
ANASTROZOLUM	ANAROMAT 1 mg	film-coated tablets	1 mg	ACTAVIS GROUP PTC EHF.	ICELAND	5135	2012	20
ANTITROMBINA III	ANTITHROMBIN III IMMUNO 50 UI/ml	powder and solvent for solution for infusion	50 IU/ml	BAXTER AG	AUSTRIA	5063	2012	02
ATORVASTATINUM	AMICOR 10 mg	film-coated tablets	10 mg	MEDOCHEMIE LTD.	CIPRU	5179	2012	21
ATORVASTATINUM	AMICOR 20 mg	film-coated tablets	20 mg	MEDOCHEMIE LTD.	CIPRU	5180	2012	21
ATORVASTATINUM	AMICOR 40 mg	film-coated tablets	40 mg	MEDOCHEMIE LTD.	CIPRU	5181	2012	21
ATORVASTATINUM	ATORVASTATIN RANBAXY 10mg	film-coated tablets	10 mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	5150	2012	12
ATORVASTATINUM	ATORVASTATIN RANBAXY 20mg	film-coated tablets	20 mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	5151	2012	12
ATORVASTATINUM	ATORVASTATIN RANBAXY 40mg	film-coated tablets	40 mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	5152	2012	12
ATORVASTATINUM	ATORVASTATIN RANBAXY 80mg	film-coated tablets	80 mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	5153	2012	12
ATORVASTATINUM	ATORVASTATINA POLIPHARMA 10 mg	film-coated tablets	10 mg	POLIPHARMA INDUSTRIES S.R.L.	ROMANIA	5255	2012	02
ATORVASTATINUM	ATORVASTATINA POLIPHARMA 20 mg	film-coated tablets	20 mg	POLIPHARMA INDUSTRIES S.R.L.	ROMANIA	5256	2012	03
ATORVASTATINUM	ATORVASTATINA POLIPHARMA 40 mg	film-coated tablets	40 mg	POLIPHARMA INDUSTRIES S.R.L.	ROMANIA	5257	2012	03
ATORVASTATINUM	ATORVASTATINA POLIPHARMA 80 mg	film-coated tablets	80 mg	POLIPHARMA INDUSTRIES S.R.L.	ROMANIA	5258	2012	02
ATORVASTATINUM	STAVRA 10 mg	film-coated tablets	10 mg	ALKALOID-INT D.O.O.	SLOVENIA	5165	2012	01
ATORVASTATINUM	STAVRA 20 mg	film-coated tablets	20 mg	ALKALOID-INT D.O.O.	SLOVENIA	5166	2012	01
ATORVASTATINUM	STAVRA 40 mg	film-coated tablets	40 mg	ALKALOID-INT D.O.O.	SLOVENIA	5167	2012	01
ATORVASTATINUM	STAVRA 80 mg	film-coated tablets	80 mg	ALKALOID-INT D.O.O.	SLOVENIA	5168	2012	01
ATORVASTATINUM	TORVALIPIN 10 mg	film-coated tablets	10 mg	ACTAVIS GROUP PTC EHF.	ICELAND	5239	2012	11
ATORVASTATINUM	TORVALIPIN 20 mg	film-coated tablets	20 mg	ACTAVIS GROUP PTC EHF.	ICELAND	5240	2012	11
ATORVASTATINUM	TORVALIPIN 40 mg	film-coated tablets	40 mg	ACTAVIS GROUP PTC EHF.	ICELAND	5241	2012	11
AZITHROMYCINUM	AZITROMICINA ACTAVIS 250 mg	film-coated tablets	250 mg	ACTAVIS GROUP PTC EHF.	ICELAND	5215	2012	04
AZITHROMYCINUM	AZITROMICINA ACTAVIS 500 mg	film-coated tablets	500 mg	ACTAVIS GROUP PTC EHF.	ICELAND	5216	2012	04
AZITHROMYCINUM	AZITROMICINA SANDOZ 100 mg/5 ml	powder for oral suspension	100 mg/5ml	SANDOZ S.R.L.	ROMANIA	5097	2012	01
AZITHROMYCINUM	AZITROMICINA SANDOZ 200 mg/5 ml	powder for oral suspension	200 mg/5ml	SANDOZ S.R.L.	ROMANIA	5098	2012	05
BICALUTAMIDUM	BICALUTAMIDA SANDOZ 150 mg	film-coated tablets	150 mg	SANDOZ S.R.L.	ROMANIA	5148	2012	19
BROMHEXINUM	BROMHEXIN FARMACOM 8 mg	tablets	8 mg	FARMACOM S.A.	ROMANIA	5040	2012	01
BROMHEXINUM	BRONHOSOLV 10 mg/5 ml	oral solution	10 mg/5 ml	LAROPHARM SRL	ROMANIA	5121	2012	01
BUDESONIDUM	BUDENOFALK 2 mg/dose	rectal foam	2 mg/dose	DR. FALK PHARMA GMBH	GERMANY	5237	2012	03
BUTYLSCOPOLAMMONII BROMIDUM	BUSCOREM 10 mg	tablets	10 mg	REMEDIA S.R.L.	ROMANIA	5127	2012	01

CANDESARTANUM CILEXETIL	CANDEGAMMA 16 mg	tablets	16 mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	5092	2012	09
CANDESARTANUM CILEXETIL	CANDEGAMMA 2 mg	tablets	2 mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	5089	2012	09
CANDESARTANUM CILEXETIL	CANDEGAMMA 32 mg	tablets	32 mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	5093	2012	09
CANDESARTANUM CILEXETIL	CANDEGAMMA 4 mg	tablets	4 mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	5090	2012	09
CANDESARTANUM CILEXETIL	CANDEGAMMA 8 mg	tablets	8 mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	5091	2012	09
CAPECITABINUM	CAPECITABINA ACTAVIS 150 mg	film-coated tablets	150 mg	ACTAVIS GROUP PTC EHF.	ICELAND	5177	2012	01
CAPECITABINUM	CAPECITABINA ACTAVIS 500 mg	film-coated tablets	500 mg	ACTAVIS GROUP PTC EHF.	ICELAND	5178	2012	01
CAPECITABINUM	CAPECITABINA ZENTIVA 150 mg	film-coated tablets	150 mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	5219	2012	02
CAPECITABINUM	CAPECITABINA ZENTIVA 500 mg	film-coated tablets	500 mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	5220	2012	02
CAPECITABINUM	CEREX 150 mg	film-coated tablets	150 mg	TERAPIA SA	ROMANIA	5230	2012	02
CAPECITABINUM	CEREX 500 mg	film-coated tablets	500 mg	TERAPIA SA	ROMANIA	5231	2012	02
CAPECITABINUM	XALVOBIN 150 mg	film-coated tablets	150 mg	ALVOGEN IPCO S.AR.L.	LUXEMBURG	5087	2012	02
CAPECITABINUM	XALVOBIN 500 mg	film-coated tablets	500 mg	ALVOGEN IPCO S.AR.L.	LUXEMBURG	5088	2012	02
CAPECITABINUM	XELITABYN 150 mg	film-coated tablets	150 mg	ASTRAZENECA UK LIMITED	GREAT BRITAIN	5110	2012	06
CAPECITABINUM	XELITABYN 500 mg	film-coated tablets	500 mg	ASTRAZENECA UK LIMITED	GREAT BRITAIN	5111	2012	06
CEFPODOXIMUM	FOREXO 100 mg	film-coated tablets	100 mg	ALKALOID-INT D.O.O.	SLOVENIA	5211	2012	02
CEFPODOXIMUM	FOREXO 200 mg	film-coated tablets	200 mg	ALKALOID-INT D.O.O.	SLOVENIA	5212	2012	02
CEFPODOXIMUM	FOREXO 8 mg/ml	powder for oral suspension	8 mg/ml	ALKALOID-INT D.O.O.	SLOVENIA	5213	2012	02
CEFTRIAXONUM	CEFTRIAXONA-MIP 1 g	powder for solution for injection/infusion	1g	MIP PHARMA GMBH	GERMANY	5078	2012	02
CEFTRIAXONUM	CEFTRIAXONA-MIP 2 g	powder for solution for injection/infusion	2g	MIP PHARMA GMBH	GERMANY	5079	2012	02
CEFUROXIMUM	ZINNAT 125 mg/5 ml	granules for oral suspension	125 mg/5ml	GLAXO WELLCOME UK LIMITED	GREAT BRITAIN	5184	2012	01
CETIRIZINUM	ZYRTEC 10 mg/ml	oral drops, solution	10 mg/ml	UCB PHARMA GMBH	GERMANY	5076	2012	03
CISPLATINUM	CISPLATIN STRIDES ARCOLAB INTERNAŢIONAL 1 mg/ml	concentrate for sol. for infusion	1 mg/ml	STRIDES ARCOLAB INTERNAŢIONAL LTD.	GREAT BRITAIN	5050	2012	02
CLONIDINUM	CLONIDINA ARENA 0.15 mg	tablets	0.15 mg	ARENA GROUP S.A.	ROMANIA	5182	2012	02
CLOPIDOGRELUM	CLOPIDOGREL POLIPHARMA 75 mg	film-coated tablets	75 mg	POLIPHARMA INDUSTRIES S.R.L.	ROMANIA	5279	2012	02
COMBINATIONS	ANTINEVRALGIC FORTE	tablets		ZENTIVA, K.S.	THE CZECH REPUBLIC	5068	2012	04
COMBINATIONS	CALCIU D3 PLUS 1000 mg/800 IU	chewable tablets	1000 mg/800 UI	NYCOMED PHARMA AS	NORWAY	5070	2012	14
COMBINATIONS	CALCIU D3 PLUS 500 mg/400 IU	chewable tablets	500 mg/400 UI	NYCOMED PHARMA AS	NORWAY	5069	2012	19
COMBINATIONS	GEROVITAL H³ 100 mg/5 ml	solution for injection	100 mg/5ml	ZENTIVA SA	ROMANIA	5183	2012	3
COMBINATIONS (ETINILESTRADIOLUM + DROSPIRENONUM)	YAZ 0.02 mg/ 3mg	film-coated tablets		BAYER PHARMA AG	GERMANY	5060	2012	03

COMBINATIONS (CIPROFLOXACINUM+ FLUOCINOLONUM)	CEXIDAL 3 mg/ml/0.25 mg/ml	ear drops, solution	3 mg/ml/ 25 mg/ml	LABORATORIOS SALVAT, S.A.	SPAIN	5055	2012	01
COMBINATIONS (DROSPIRENONUM+ ETINILESTRADIOLUM)	MYWY 3 mg/0.02 mg	film-coated tablets	3 mg/0.02 mg	LABORATORIOS LEON FARMA S.A.	SPAIN	5175	2012	04
COMBINATIONS (DROSPIRENONUM+ ETINILESTRADIOLUM)	VELGYN 3 mg/0.02 mg	film-coated tablets	3 mg/0.02 mg	LADEE PHARMA KFT	SPAIN	5176	2012	04
COMBINATIONS (IRBERSARTANUM+ HYDROCHLOROTHIAZIDUM)	IRBESARTAN/ HIDROCLOROTIAZIDA DR. REDDY'S 150mg/12.5mg	film-coated tablets	150 mg/12.5 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	5243	2012	06
COMBINATIONS (IRBERSARTANUM+ HYDROCHLOROTHIAZIDUM)	IRBESARTAN/ HIDROCLOROTIAZIDA DR. REDDY'S 300 mg/12.5 mg	film-coated tablets	300 mg/12.5 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	5244	2012	06
COMBINATIONS (IRBERSARTANUM+ HYDROCHLOROTHIAZIDUM)	IRBESARTAN/ HIDROCLOROTIAZIDA DR. REDDY'S 300 mg/25 mg	film-coated tablets	300 mg/25 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	5245	2012	06
COMBINATIONS (MIFEPRISTONUM+ MISOPROSTOLUM)	MEDABON (see G02AD06)	tablets and vaginal tablets	200 mg+0.2 mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HOLLAND	5071	2012	01
COMBINATIONS (MIFEPRISTONUM+ MISOPROSTOLUM)	MEDABON (see G03XB01)	tablets and vaginal tablets	200 mg+0.2 mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HOLLAND	5071	2012	01
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	CO-PRENESSA 2mg/0.625mg	tablets	2 mg/0.625mg	KRKA POLSKA SP. Z O.O.	POLAND	5201	2012	18
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	CO-PRENESSA 4mg/1.25mg	tablets	4 mg/1.25mg	KRKA POLSKA SP. Z O.O.	POLAND	5202	2012	18
COMBINATIONS (TRAMADOLUM+ PARACETAMOLUM)	PYLADOX 37.5 mg/325 mg	film-coated tablets	37.5 mg/325 mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	5200	2012	01
COMBINATIONS (TRAMADOLUM+ PARACETAMOLUM)	TRAMCET 37.5 mg/325mg	tablets	37.5 mg/325 mg	ICN POLFA RZESZOW S.A.	POLAND	5053	2012	06
IRON (III) HYDROXIDE POLYMALTOSE COMPLEX	FER ROMPHARM 50 mg/ml	oral drops, solution	50 mg/ml	ROMPHARM COMPANY SRL	ROMANIA	5041	2012	01
DONEPEZILUM	ALDEMIZ 10 mg	film-coated tablets	10 mg	Dr. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	5170	2012	12
DONEPEZILUM	ALDEMIZ 5 mg	film-coated tablets	5 mg	Dr. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	5169	2012	12
DONEPEZILUM	COGNEZIL 10 mg	film-coated tablets	10 mg	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	5160	2012	11
DONEPEZILUM	COGNEZIL 5 mg	film-coated tablets	5 mg	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	5159	2012	11
DONEPEZILUM	DONEPEZIL HF 10mg	film-coated tablets	10 mg	STADA HEMOFARM S.R.L.	ROMANIA	5197	2012	07
DONEPEZILUM	DONEPEZIL HF 5mg	film-coated tablets	5 mg	STADA HEMOFARM S.R.L.	ROMANIA	5196	2012	07
DORZOLAMIDUM	DORZOLAMIDA POLPHARMA 20 mg/ml	eye drops, solution	20 mg/ml	PHARMACEUTICAL WORKS POLPHARMA SA	POLAND	5288	2012	03
ENALAPRILUM	ENALAPRIL RANBAXY 10 mg	tablets	10 mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	5115	2012	10

ENALAPRILUM	ENALAPRIL RANBAXY 2.5 mg	tablets	2.5 mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	5113	2012	10
ENALAPRILUM	ENALAPRIL RANBAXY 20 mg	tablets	20 mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	5116	2012	08
ENALAPRILUM	ENALAPRIL RANBAXY 5 mg	tablets	5 mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	5114	2012	05
ETOMIDATUM	ETOMIDAT-LIPURO 2 mg/ml	emulsion for injection	2 mg/ml	B. BRAUN MELSUNGEN AG	GERMANY	5185	2012	01
EXEMESTANUM	EXEMESTAN POLIPHARMA 25mg	film-coated tablets	25 mg	POLIPHARMA INDUSTRIES S.R.L.	ROMANIA	5278	2012	03
VALERIAN ROOT DRY EXTRACT	EXIGAN 210 mg	tablets	210 mg	GEDEON RICHTER ROMÂNIA SA	ROMANIA	5242	2012	01
FENTANYLUM	DOLFORIN 100 micrograms/hour	transdermal patch	100micrograms/ hour	GEDEON RICHTER ROMÂNIA S.A.	ROMANIA	5228	2012	03
FENTANYLUM	DOLFORIN 25 micrograms/hour	transdermal patch	25 micrograms/ hour	GEDEON RICHTER ROMÂNIA S.A.	ROMANIA	5225	2012	03
FENTANYLUM	DOLFORIN 50 micrograms/hour	transdermal patch	50 micrograms/ hour	GEDEON RICHTER ROMÂNIA S.A.	ROMANIA	5226	2012	03
FENTANYLUM	DOLFORIN 75 micrograms/hour	transdermal patch	75 micrograms/ hour	GEDEON RICHTER ROMÂNIA S.A.	ROMANIA	5227	2012	03
FENTANYLUM	FENTANYL ETHYPHARM 133 micrograms	sublingual tablets	133 micrograms	ETHYPHARM	FRANCE	5267	2012	08
FENTANYLUM	FENTANYL ETHYPHARM 267 micrograms	sublingual tablets	267 micrograms	ETHYPHARM	FRANCE	5268	2012	08
FENTANYLUM	FENTANYL ETHYPHARM 400 micrograms	sublingual tablets	400 micrograms	ETHYPHARM	FRANCE	5269	2012	08
FENTANYLUM	FENTANYL ETHYPHARM 533 micrograms	sublingual tablets	533 micrograms	ETHYPHARM	FRANCE	5270	2012	08
FENTANYLUM	FENTANYL ETHYPHARM 67 micrograms	sublingual tablets	67 micrograms	ETHYPHARM	FRANCE	5266	2012	08
FENTANYLUM	FENTANYL ETHYPHARM 800 micrograms	sublingual tablets	800 micrograms	ETHYPHARM	FRANCE	5271	2012	08
FERRI CARBOXYMALTOSUM	FERINJECT 50 mg fer/ml	solution for injection/infusion	50 mg/ml	VIFOR FRANCE SA	FRANCE	5232	2012	06
FLUCONAZOLUM	DIFLUCAN 150 mg	capsules	150 mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	5125	2012	01
FLUCONAZOLUM	DIFLUCAN 2mg/ml	solution for infusion	2 mg/ml	PFIZER EUROPE MA EEIG	GREAT BRITAIN	5263	2012	04
FLUCONAZOLUM	DIFLUCAN 50 mg	capsules	50 mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	5124	2012	01
FLUCONAZOLUM	FUNGOLON UNO 100 mg	capsules	100 mg	ACTAVIS GROUP PTC EHF.	ICELAND	5205	2012	16
FLUCONAZOLUM	FUNGOLON UNO 150 mg	capsules	150 mg	ACTAVIS GROUP PTC EHF.	ICELAND	5206	2012	16
FLUCONAZOLUM	FUNGOLON UNO 200 mg	capsules	200 mg	ACTAVIS GROUP PTC EHF.	ICELAND	5207	2012	16
FLUCONAZOLUM	FUNGOLON UNO 50 mg	capsules	50 mg	ACTAVIS GROUP PTC EHF.	ICELAND	5204	2012	16
GEMCITABINUM	GEMCITABINA STRIDES ARCOLAB INTERNATIONAL 38 mg/ml	powder for solution for infusion	38 mg/ml	STRIDES ARCOLAB INTERNATIONAL LIMITED	GREAT BRITAIN	5214	2012	02
GLUCOSAMINUM	PROENZI 750 mg	film-coated tablets	750 mg	WALMARK A.S.	THE CZECH REPUBLIC	5137	2012	30
GRANISETRONUM	KYTRIL	solution for injection	3 mg/3 ml	ROCHE ROMANIA S.R.L.	ROMANIA	5224	2012	03
GRANISETRONUM	SETROGEN 1 mg	film-coated tablets	1 mg	ALVOGEN IPCO S.A.R.L.	LUXEMBURG	5077	2012	01

GUAIFENESINUM	BENYLIN MIERE ŞI LĂMÂIE 20 mg/ml	syrup	20 mg/ml	MCNEIL PRODUCTS LIMITED	GREAT BRITAIN	5037	2012	01
HEPATITIS B IMMUNOGLOBULIN	IVHEBEX 5000 IU/100 ml	powder and solvent for solution for infusion	50 UI/ml	LFB - BIOMEDICAMENTS	FRANCE	5129	2012	01
IMMUNOGLOBULINS, NORMAL HUMAN, FOR INTRAVASCULAR ADMINISTRATION	IG VENA 10g/200ml	solution for infusion	10 g/200 ml	KEDRION S.P.A.	ITALY	5144	2012	01
IMMUNOGLOBULINS, NORMAL HUMAN, FOR INTRAVASCULAR ADMINISTRATION	IG VENA 5g/100ml	solution for infusion	5 g/100 ml	KEDRION S.P.A.	ITALY	5143	2012	01
IMMUNOGLOBULINS, NORMAL HUMAN, FOR INTRAVASCULAR ADMINISTRATION	IG VENA 1g/20ml	solution for infusion	1 g/20 ml	KEDRION S.P.A.	ITALY	5141	2012	01
IMMUNOGLOBULINS, NORMAL HUMAN, FOR INTRAVASCULAR ADMINISTRATION	IG VENA 2.5g/50ml	solution for infusion	2.5 g/50 ml	KEDRION S.P.A.	ITALY	5142	2012	01
INDAPAMIDUM	INDAPAGAMMA 1.5 mg	prolonged-release tablets	1.5 mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	5138	2012	07
IRBESARTANUM	IRBESARTAN AUROBINDO 150 mg	tablets	150 mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	5221	2012	14
IRBESARTANUM	IRBESARTAN AUROBINDO 300 mg	tablets	300 mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	5222	2012	14
IRBESARTANUM	IRBESARTAN BLEUFISH 150 mg	film-coated tablets	150 mg	BLUEFISH PHARMACEUTICALS AB	SWEDEN	5217	2012	16
IRBESARTANUM	IRBESARTAN BLEUFISH 300 mg	film-coated tablets	300 mg	BLUEFISH PHARMACEUTICALS AB	SWEDEN	5218	2012	16
KETOPROFENUM	KETOPROFEN SR TERAPIA 100 mg	prolonged-release capsules	100 mg	TERAPIA SA	ROMANIA	5061	2012	02
KETOPROFENUM	KETOPROFEN SR TERAPIA 200 mg	prolonged-release capsules	200 mg	TERAPIA SA	ROMANIA	5062	2012	02
LACTULOSUM	SIRULAX 670 mg/ml	oral solution	670 mg/ml	SANDOZ SRL	ROMANIA	5072	2012	30
LAMIVUDINUM	LAMIVUDINA AUROBINDO 150 mg	film-coated tablets	150 mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	5108	2012	07
LANTANUM	FOSRENOL 1000 mg	oral powder	1000 mg	SHIRE PHARMACEUTICAL CONTRACTS LTD.	GREAT BRITAIN	5199	2012	01
LANTANUM	FOSRENOL 750 mg	oral powder	750 mg	SHIRE PHARMACEUTICAL CONTRACTS LTD.	GREAT BRITAIN	5198	2012	01
LEFLUNOMIDUM	LEFLON 10 mg	film-coated tablets	10 mg	ROMASTRU TRADING S.R.L.	ROMANIA	5035	2012	04
LEFLUNOMIDUM	LEFLON 20 mg	film-coated tablets	20 mg	ROMASTRU TRADING S.R.L.	ROMANIA	5036	2012	10
LEUPRORELINUM	LUTRATE DEPOT 3.75 mg	prolonged-release powder and solvent for susp. for injection	3.75 mg	CSC PHARMACEUTICALS HANDELS GMBH	AUSTRIA	5123	2012	01
LEVETIRACETAMUM	LEVETIRAGAMMA 1000 mg	film-coated tablets	1000 mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	5195	2012	24
LEVETIRACETAMUM	LEVETIRAGAMMA 250 mg	film-coated tablets	250 mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	5192	2012	24

LEVETIRACETAMUM	LEVETIRAGAMMA 500 mg	film-coated tablets	500 mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	5193	2012	24
LEVETIRACETAMUM	LEVETIRAGAMMA 750 mg	film-coated tablets	750 mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	5194	2012	24
LEVOCETIRIZINUM	LEVOCETIRIZINA ACTAVIS 5 mg	film-coated tablets	5 mg	ACTAVIS GROUP PTC EHF.	ICELAND	5208	2012	44
LEVOTHYROXINUM	LEVOTIROXINA TEVA 100 micrograms	tablets	100 micrograms	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	5283	2012	21
LEVOTHYROXINUM	LEVOTIROXINA TEVA 125 micrograms	tablets	125 micrograms	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	5284	2012	21
LEVOTHYROXINUM	LEVOTIROXINA TEVA 150 micrograms	tablets	150 micrograms	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	5285	2012	21
LEVOTHYROXINUM	LEVOTIROXINA TEVA 175 micrograms	tablets	175 micrograms	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	5286	2012	21
LEVOTHYROXINUM	LEVOTIROXINA TEVA 200 micrograms	tablets	200 micrograms	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	5287	2012	21
LEVOTHYROXINUM	LEVOTIROXINA TEVA 25 micrograms	tablets	25 micrograms	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	5280	2012	21
LEVOTHYROXINUM	LEVOTIROXINA TEVA 50 micrograms	tablets	50 micrograms	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	5281	2012	21
LEVOTHYROXINUM	LEVOTIROXINA TEVA 75 micrograms	tablets	75 micrograms	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	5282	2012	21
LOPERAMIDUM	LOPEMIDOL 2 mg	tablets	2 mg	BIOFARM SA	ROMANIA	5253	2012	02
LOPERAMIDUM	LOPERAMID VIM SPECTRUM 2mg	tablets	2 mg	VIM SPECTRUM S.R.L.	ROMANIA	5265	2012	01
MELOXICAMUM	NOFLAMEN 15 mg	tablets	15 mg	EGIS PHARMACEUTICALS PLC	HUNGARY	5261	2012	02
MELOXICAMUM	NOFLAMEN 7.5 mg	tablets	7.5 mg	EGIS PHARMACEUTICALS PLC	HUNGARY	5260	2012	02
MILRINONUM	COROTROPE	solution for injection	10 mg/10 ml	SANOFI - AVENTIS ROMANIA S.R.L.		50	2012	01
MOMETASONUM	MOMETAZONA FUROAT SANDOZ 50 micrograms/dose	nasal spray, suspension	50 micrograms/ dose	SANDOZ S.R.L.	ROMANIA	5229	2012	02
MONTELUKASTUM	JEPAFEX 10 mg	film-coated tablets	10 mg	MERCK SHARP & DOHME ROMÂNIA S.R.L.	ROMANIA	5082	2012	17
MONTELUKASTUM	JEPAFEX 4 mg	chewable tablets	4 mg	MERCK SHARP & DOHME ROMÂNIA S.R.L.	ROMANIA	5080	2012	15
MONTELUKASTUM	JEPAFEX 4 mg	granules in single-dose sachet	4 mg	MERCK SHARP & DOHME ROMÂNIA S.R.L.	ROMANIA	5083	2012	04
MONTELUKASTUM	JEPAFEX 5 mg	chewable tablets	5 mg	MERCK SHARP & DOHME ROMÂNIA S.R.L.	ROMANIA	5081	2012	17
MOXIFLOXACINUM	MOXIFLOXACINA AUROBINDO 400 mg	film-coated tablets	400 mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	5136	2012	11
OCTREOTIDUM	OCTREOTIDE CSC 100 micrograms/ml	solution for injection	100micrograms/ ml	CSC PHARMACEUTICALS HANDELS GMBH	AUSTRIA	5133	2012	01
OCTREOTIDUM	OCTREOTIDE CSC 50 micrograms/ml	solution for injection	50micrograms/ ml	CSC PHARMACEUTICALS HANDELS GMBH	AUSTRIA	5132	2012	01
OCTREOTIDUM	OCTREOTIDE CSC 500 micrograms/ml	solution for injection	500micrograms/ ml	CSC PHARMACEUTICALS HANDELS GMBH	AUSTRIA	5134	08.12. 2012	01
OMEPRAZOLUM	LOSEC 40 mg	powder for solution for infusion	40 mg	ASTRAZENECA AB	SWEDEN	0	2012	03
OMEPRAZOLUM	LOSEC MUPS 10 mg	gastroresistant tablets	10 mg	ASTRAZENECA AB	SWEDEN	5171	2012	27

OMEPRAZOLUM	LOSEC MUPS 20 mg	gastroresistant tablets	20 mg	ASTRAZENECA AB	SWEDEN	5172	2012	31
OXALIPLATINUM	OXALIPLATIN CSC 5 mg/ml	powder for solution for infusion	5 mg/ml	CSC PHARMACEUTICALS HANDELS GMBH	AUSTRIA	5174	2012	02
OXALIPLATINUM	OXALIPLATINA STRIDES ARCOLAB INTERNAȚIONAL 5 mg/ml	concentrate for solution for infusion	5 mg/ml	STRIDES ARCOLAB INTERNAȚIONAL LTD.	GREAT BRITAIN	5139	2012	03
OXYCODONUM	OXICODONA SANDOZ 40 mg	prolonged-release tablets	40 mg	SANDOZ S.R.L.	ROMANIA	5047	2012	14
OXYCODONUM	OXICODONA SANDOZ 60 mg	prolonged-release tablets	60 mg	SANDOZ S.R.L.	ROMANIA	5048	2012	14
OXYCODONUM	OXICODONA SANDOZ 80 mg	prolonged-release tablets	80 mg	SANDOZ S.R.L.	ROMANIA	5049	2012	14
OXYMETAZOLINUM	NASIVIN 0.5 mg/ml	nasal drops, solution		MERCK SELBSTMEDIKATION	GERMANY	5128	2012	01
PANCREATINUM	TRIFERMENT 275 mg	gastroresistant tablets	275 mg	BIOFARM SA	ROMANIA	5264	2012	02
PANCREATINUM (COMBINED)	PANZCEBIL	gastroresistant lozenges		BIOFARM SA	ROMANIA	5223	2012	02
PANTOPRAZOLUM	PANTOPRAZOL MACLEODS 40 mg	gastroresistant tablets	40 mg	MACLEODS PHARMA UK LIMITED	GREAT BRITAIN	5109	2012	01
PIROXICAMUM	PIROXICAM HELCOR 20 mg	tablets	20 mg	AC HELCOR PHARMA S.R.L.	ROMANIA	5254	2012	01
QUETIAPINUM	QUETIAPINA NEVADAPHARMA 100 mg	film-coated tablets	100 mg	NEVADA PHARMA AB	SWEDEN	5188	2012	05
QUETIAPINUM	QUETIAPINA NEVADAPHARMA 200 mg	film-coated tablets	200 mg	NEVADA PHARMA AB	SWEDEN	5189	2012	04
QUETIAPINUM	QUETIAPINA NEVADAPHARMA 25 mg	film-coated tablets	25 mg	NEVADA PHARMA AB	SWEDEN	5187	2012	05
QUETIAPINUM	QUETIAPINA NEVADAPHARMA 300 mg	film-coated tablets	300 mg	NEVADA PHARMA AB	SWEDEN	5190	2012	04
QUETIAPINUM	QUETIAPINA SANDOZ 200 mg	prolonged-release tablets	200 mg	SANDOZ S.R.L.	ROMANIA	5145	2012	10
QUETIAPINUM	QUETIAPINA SANDOZ 300 mg	prolonged-release tablets	300 mg	SANDOZ S.R.L.	ROMANIA	5146	2012	10
QUETIAPINUM	QUETIAPINA SANDOZ 400 mg	prolonged-release tablets	400 mg	SANDOZ S.R.L.	ROMANIA	5147	2012	10
QUETIAPINUM	TREKSTA 100 mg	film-coated tablets	100 mg	STADA HEMOFARM S.R.L.	ROMANIA	5155	2012	10
QUETIAPINUM	TREKSTA 200 mg	film-coated tablets	200 mg	STADA HEMOFARM S.R.L.	ROMANIA	5156	2012	10
QUETIAPINUM	TREKSTA 25 mg	film-coated tablets	25 mg	STADA HEMOFARM S.R.L.	ROMANIA	5154	2012	07
QUETIAPINUM	TREKSTA 300 mg	film-coated tablets	300 mg	STADA HEMOFARM S.R.L.	ROMANIA	5157	2012	10
RADIOPHARMACEUTICALS (FLUOROCHOLINE CHLORIDE 18 F)	IASOCHOLINE 1 GBq/ml	solution for injection	1 GBq/ml	IASON GMBH	AUSTRIA	5052	2012	01
RAMIPRILUM	AMPRIGEN 1.25mg	tablets	1.25mg	ALVOGEN IPCO S.A.R.L,	LUXEMBURG	5117	2012	02
RAMIPRILUM	AMPRIGEN 10 mg	tablets	10 mg	ALVOGEN IPCO S.A.R.L,	LUXEMBURG	5120	2012	01
RAMIPRILUM	AMPRIGEN 2.5 mg	tablets	2.5 mg	ALVOGEN IPCO S.A.R.L,	LUXEMBURG	5118	2012	02
RAMIPRILUM	AMPRIGEN 5 mg	tablets	5 mg	ALVOGEN IPCO S.A.R.L,	LUXEMBURG	5119	2012	02
RISPERIDONUM	RISPERIDONA CIPLA 1 mg	film-coated tablets	1 mg	CIPLA UK LTD.	GREAT BRITAIN	5249	2012	02
RISPERIDONUM	RISPERIDONA CIPLA 2 mg	film-coated tablets	2 mg	CIPLA UK LTD.	GREAT BRITAIN	5250	2012	02

RISPERIDONUM	RISPERIDONA CIPLA 3 mg	film-coated tablets	3 mg	CIPLA UK LTD.	GREAT BRITAIN	5251	2012	02
RISPERIDONUM	RISPERIDONA CIPLA 4 mg	film-coated tablets	4 mg	CIPLA UK LTD.	GREAT BRITAIN	5252	2012	02
SALBUTAMOLUM	VENTILASTIN NOVOLIZER 100micrograms/dose	inhalation powder	100micrograms/ dose	MEDA PHARMA GMBH & CO. KG	GERMANY	5262	2012	05
SILDENAFILUM	SILDENAFIL LABORMED 100 mg	chewable tablets	100 mg	LABORMED PHARMA S.A.	ROMANIA	5086	2012	04
SILDENAFILUM	SILDENAFIL LABORMED 25 mg	chewable tablets	25 mg	LABORMED PHARMA S.A.	ROMANIA	5084	2012	04
SILDENAFILUM	SILDENAFIL LABORMED 50 mg	chewable tablets	50 mg	LABORMED PHARMA S.A.	ROMANIA	5085	2012	04
SILDENAFILUM	SILDENAFIL MACLEODS 100 mg	film-coated tablets	100 mg	MACLEODS PHARMA UK LIMITED	GREAT BRITAIN	5046	2012	01
SILDENAFILUM	SILDENAFIL MACLEODS 25 mg	film-coated tablets	25 mg	MACLEODS PHARMA UK LIMITED	GREAT BRITAIN	5044	2012	01
SILDENAFILUM	SILDENAFIL MACLEODS 50 mg	film-coated tablets	50 mg	MACLEODS PHARMA UK LIMITED	GREAT BRITAIN	5045	2012	01
SILDENAFILUM	SILDENAFIL TEVA 100 mg	chewable tablets	100 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	5067	2012	04
SILDENAFILUM	SILDENAFIL TEVA 25 mg	chewable tablets	25 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	5065	2012	04
SILDENAFILUM	SILDENAFIL TEVA 50 mg	chewable tablets	50 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	5066	2012	04
SULFASALAZINUM	SALAZIDIN GR 500 mg	gastroresistant tablets	500 mg	AC HELCOR PHARMA S.R.L.	ROMANIA	5042	2012	02
TACROLIMUSUM	TACROLIMUSUM ACCORD 5 mg	capsules	5 mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	5075	2012	04
TAMSULOSINUM	TAMSULOSIN AUROBINDO 400 micrograms	prolonged-release capsules	400 micrograms	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	5191	2012	17
TELMISARTANUM	TELMA 40 mg	tablets	40 mg	SANDOZ S.R.L.	ROMANIA	5103	2012	01
TELMISARTANUM	TELMA 80 mg	tablets	80 mg	SANDOZ S.R.L.	ROMANIA	5104	2012	01
TELMISARTANUM	TELMISARTAN RANBAXY 20 mg	tablets	20 mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	5094	2012	07
TELMISARTANUM	TELMISARTAN RANBAXY 40 mg	tablets	40 mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	5095	2012	07
TELMISARTANUM	TELMISARTAN RANBAXY 80 mg	tablets	80mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	5096	2012	07
TELMISARTANUM	TELMOTENS 40mg	film-coated tablets	40 mg	ALVOGEN IPCO S.AR.L.	LUXEMBURG	5209	2012	07
TELMISARTANUM	TELMOTENS 80mg	film-coated tablets	80 mg	ALVOGEN IPCO S.AR.L.	LUXEMBURG	5210	2012	07
TEMOZOLOMIDUM	BLASTOMAT 100 mg	capsules	100 mg	ALVOGEN IPCO S.AR.L.	LUXEMBURG	5274	2012	03
TEMOZOLOMIDUM	BLASTOMAT 140 mg	capsules	140 mg	ALVOGEN IPCO S.AR.L.	LUXEMBURG	5275	2012	03
TEMOZOLOMIDUM	BLASTOMAT 180 mg	capsules	180 mg	ALVOGEN IPCO S.AR.L.	LUXEMBURG	5276	2012	03
TEMOZOLOMIDUM	BLASTOMAT 20 mg	capsules	20 mg	ALVOGEN IPCO S.AR.L.	LUXEMBURG	5273	2012	03
TEMOZOLOMIDUM	BLASTOMAT 250 mg	capsules	250 mg	ALVOGEN IPCO S.AR.L.	LUXEMBURG	5277	2012	03
TEMOZOLOMIDUM	BLASTOMAT 5 mg	capsules	5 mg	ALVOGEN IPCO S.AR.L.	LUXEMBURG	5272	2012	03
TESTOSTERONUM	TESTIM 50 mg	transdermal gel	50 mg	FERRING GMBH	GERMANY	5149	2012	04
TINZAPARINUM	INNOHEP 10000 IU ANTI-XA/ml	solution for injection vials	10000 IU anti-XA/ml	LEO PHARMA A/S	DENMARK	5234	2012	01
TINZAPARINUM	INNOHEP 10000 IU ANTI-XA/ml	solution for injection in pre-filled syringes	10000 IU anti-XA/ml	LEO PHARMA A/S	DENMARK	5233	2012	04
TINZAPARINUM	INNOHEP 20000 IU ANTI-Xa/ml	solution for injection vials	20000 IU anti-Xa/ml	LEO PHARMA A/S	DENMARK	5236	2012	02

TINZAPARINUM	INNOHEP 20000 IU ANTI-Xa/ml	solution for injection in pre-filled syringes	20000 IU anti-Xa/ml	LEO PHARMA A/S	DENMARK	5235	2012	03
TRAMADOLUM	TRALGIT 50 mg	orodispersible tablets	50 mg	ZENTIVA, A.S.	SLOVAKIA	5043	2012	04
TRIHEXYPHENIDYLUM	ROMPARKIN 2 mg	tablets	2 mg	TERAPIA S.A.	ROMANIA	5186	2012	01
TRIMEBUTINUM	DEBRIDAT 200 mg	film-coated tablets	200 mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	5259	2012	01
INACTIVATED DIPHTHERIA, PERTUSSIS, TETANUS, POLIO VACCINE	BOOSTRIX-IPV	suspension for injection		GLAXOSMITHKLINE (GSK) S.R.L.	ROMANIA	5073	2012	2
INACTIVATED DIPHTHERIA, PERTUSSIS, TETANUS, POLIO VACCINE	BOOSTRIX-IPV	suspension for injection in pre-filled syringe		GLAXOSMITHKLINE (GSK) S.R.L.	ROMANIA	5074	2012	06
PURIFIED TYPHUS, POLYSACCHARIDE VACCINE	TYPHERIX	suspension for injection in pre-filled syringe		GLAXOSMITHKLINE BIOLOGICALS SA	BELGIUM	5126	2012	08
LIVE ATTENUATED VARICELLA VACCINE	VARILRIX, live attenuated varicella vaccine	powder and solvent for solution for injection	$10^{3,3}$ PFU / 0.5 ml	GLAXOSMITHKLINE BIOLOGICALS S.A.	BELGIUM	5064	2012	18
VENLAFAXINUM	VENLAFAXINA TERAPIA 150 mg	prolonged-release capsules	150 mg	TERAPIA S.A.	ROMANIA	5058	2012	14
VENLAFAXINUM	VENLAFAXINA TERAPIA 37.5 mg	prolonged-release capsules	37.5 mg	TERAPIA S.A.	ROMANIA	5056	2012	20
VENLAFAXINUM	VENLAFAXINA TERAPIA 75 mg	prolonged-release capsules	75 mg	TERAPIA S.A.	ROMANIA	5057	2012	16
XYLOMETAZOLINUM	OLYNTH HA 1 mg/ml	nasal spray, solution	1 mg/ml	MCNEIL PRODUCTS LIMITED C/O JOHNSON&JOHNSON	GREAT BRITAIN	5203	2012	01
ZOLPIDEMUM	EDLUAR 10 mg	sublingual tablets	10 mg	MEDA PHARMA GMBH & CO. KG	GERMANY	5247	2012	07
ZOLPIDEMUM	EDLUAR 5 mg	sublingual tablets	5 mg	MEDA PHARMA GMBH & CO. KG	GERMANY	5246	2012	07

Medicinal products authorised through centralised procedure by the EMA for which a marketing price was established in Romania during the 4th quarter of 2012

INN	Invented name	Pharmaceutical form	Strength	Manufacturer	Country	MA Number		
ABATACEPTUM	ORENCIA	solution for injection in pre-filled syringe	125 mg/ml	BRISTOL-MYERS SQUIBB PHARMA EEIG	GREAT BRITAIN	389	2012	06
APIXABANUM	ELIQUIS	film-coated tablets	5 mg	BRISTOL-MYERS SQUIBB/ PFIZER EEIG	GREAT BRITAIN	691	2012	07
CRIZOTINIBUM	XALKORI	capsules	200 mg	PFIZER LIMITED	GREAT BRITAIN	793	2012	02
CRIZOTINIBUM	XALKORI	capsules	250 mg	PFIZER LIMITED	GREAT BRITAIN	793	2012	02
DAPAGLIFOZINUM	FORXIGA 5 mg	film-coated tablets	5 mg	BRISTOL-MYERS SQUIBB/ ASTRA ZENECA EEIG	GREAT BRITAIN	795	2012	05
DAPAGLIFOZINUM	FORXIGA 10 mg	film-coated tablets	10 mg	BRISTOL-MYERS SQUIBB/ ASTRA ZENECA EEIG	GREAT BRITAIN	795	2012	05