ROMANIA

Newsletter

Year 19, No. 1 (73), 1st quarter of 2017

National Agency for Medicines and Medical Devices

ISSN 1583-347X

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ORDER
of the Minister of Health No. 269/2017 of 14 March 2017
on mandatory provision of medicinal product adequate and undisrupted stocks

ISSUING BODY: The Ministry of Health
published in: the Official Gazette No. 183 of 15 March 2017

On seeing the Approval Report No. FB 2.193/2017 of the Directorate for Policies on Medicinal Products and Medical Devices,

Taking into account provisions of Article no. 699 (19) and of Article no. 804 (2) of Law no. 95/2006 on healthcare reform republished as amended,

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

the Minister of Health hereby issues the following order:

Article 1

For the purposes of this order, terms and concepts used herein shall have the following meaning:

a) Beneficiaries - healthcare units under contract with health insurance houses, conducting national healthcare programs and pharmacies;

b) Legitimate request - order by fax or email for medicinal product delivery, containing information on the name and the quantity thereof, as well as batch, number and date relating to a medical prescription, placed by a pharmacy with contracted wholesalers, or, as the case may be, request by e-mail or fax for delivery of medicines, placed based on the contract between healthcare facilities under contract with health insurance houses or facilities conducting national healthcare programmes and a Marketing Authorisation Holder or their legal representative in Romania, hereinafter referred to as MAH, or wholesale distributor, providing for contract obligations clearly specifying medicinal product names, quantities and delivery deadlines under the contract;

c) Temporary list of medicinal products under surveillance - list of all trade names of a medicinal product, as defined by International Non-Proprietary Name, hereinafter referred to as INN, pharmaceutical form and strength, under temporary ban of intra-Community supply and export;

d) Intra-Community delivery - supply of medicinal products included in the Temporary list within the meaning of subparagraph e), delivered or transported from Romania to a Contracting State in the European Economic Area by the supplier or by the delivery recipient or a different body on the latter's behalf;

e) Enlisted medicinal products - trade names of medicinal products whose respective INNs are included in the List of International Non-Proprietary Names of

on-prescription medicinal products provided to insurants, irrespective of personal contribution within the healthcare insurance system, as well as International Non-Proprietary Names (INNs) of medicinal products provided in the frame of national healthcare programmes, approved by Government Decision No. 720/2008, as amended;

f) National alert - decrease under the average monthly turnover for 7 consecutive days of nationwide stocks for the medicinal product category with the same INN, pharmaceutical form and strength;

g) Average monthly turnover - monthly average turnover of the respective medicinal product for the past three months, representing the minimum necessary to meet public healthcare needs;

h) Exceptional circumstances - situations notified by the MAH to the National Agency for Medicines and Medical Devices, hereinafter the NAMMD, in accordance with the law, on matters of quality/safety, failure to supply active substances, withdrawal of the Certificate of compliance with the European Pharmacopoeia or of the Good Manufacturing Practice Certificate, temporary discontinuation of production;

I) Buffer stock - quantity of medicinal products included into the Temporary list available in the wholesale distributor's stock between two successive stocks, representing minimum adequate and undisrupted stocks able to meet any legitimate request order placed with the respective wholesaler;

j) Delivery times - maximum 24 hours for legitimate request orders related to a medical prescription for acute and subacute conditions or 48 hours, respectively, or legitimate request orders related to a medical prescription for chronic conditions.

Article 2

(1) Average monthly turnover is calculated based on information submitted to the Ministry of Health via the Electronic System for Inventory Reporting, hereinafter ESIR, as regulated by order of the Minister of Health no. 1345/2016 on daily reporting of stocks and trade operations carried out with medicinal products for human use included in the National catalogue of prices for medicinal products authorised for marketing in Romania by medicinal product distributors, importers, authorised manufacturers and closed- and open-circuit pharmacies.

(2) MAHs shall permanently warrant compliance with the public service obligation by providing a monthly minimum level equal to the average monthly turnover as defined under Article 10 g) for each listed medicinal product they hold an authorisation for in Romania.

(3) Wholesalers shall permanently warrant compliance with the public service obligation by setting up buffer equalling the average monthly turnover for each listed product they distribute.

(4) Wholesalers shall be required to meet any legitimate request orders submitted by contract beneficiaries, within terms of delivery pursuant to Article 1 j).

(5) Beneficiaries shall submit legitimate request orders to contracted wholesalers at least once for each wholesaler until the order is met.

(6) Beneficiaries shall ensure meeting of legitimate request orders within the terms of delivery pursuant to Article 1 j). As proof of legitimate request order, units dispensing medicinal products to the public may retain the medical prescription for not longer than 48 hours, on written consent by the patient.

(7) Wholesalers shall notify the submitted legitimate request order received to the MAH or other wholesalers under contract from whom they had purchased the medicinal product subject to the legitimate request order.

(8) When unable to meet a legitimate request order, wholesalers shall communicate the legitimate request order to the MAH or other wholesalers under contract. MAH or, where appropriate, wholesalers under contract are required to meet the legitimate request order submitted or notify the requesting party that they fall under the scope of one of the situations referred to in Article 1 (h), notified to the NAMMD.

(9) Where wholesalers are unable to meet the legitimate request order, beneficiaries shall notify the NAMMD, in electronic format, to lipsamedicament@anm.ro as well as, for electronic medical prescriptions, respective healthcare insurance houses to which they are allocated.

(10) MAHs, wholesalers and beneficiaries are exempt from compliance with the public service obligation in exceptional circumstances defined under Article 1 h).

Article 3

(1) Emergence of a nation-wide alert under Article 1 f) is publicly reported and communicated to the Ministry of Health through the ESIR.

(2) Within 3 days following emergence of the national alert, the Ministry of Health includes the category of medicinal products with the same INN, pharmaceutical form and strength into the Temporary list of medicinal products under surveillance.

(3) The Temporary list of medicinal products under surveillance is approved and updated as necessary by order of the Minister of Health and posted on the website of the Ministry of Health and the NAMMD.

(4) Immediately following the national alert reporting, the Ministry of Health requests the NAMMD to confirm whether the cause of the alert falls within one of the exceptional situations provided for in Article 1 h).

(5) In case of NAMMD confirmation that the cause of the national alert level falls within the exceptional situations provided for in Article 1 h), the Ministry of Health eliminates the medicinal product category of with the same INN, pharmaceutical form and strength from the Temporary list of medicinal products under surveillance.

(6) On depletion of stocks of medicinal products covered by an exceptional circumstance pursuant to Article 1 h), the MAH shall notify the National Health Insurance House thereof.

(7) Where the NAMMD does not confirm that the cause of the national alert falls within the exceptional circumstances pursuant to Article 1 h), the category of medicinal products with the same INN, pharmaceutical form and strength is preserved in the Temporary list of medicinal products under surveillance until recovery and retention for 14 consecutive days of national stocks in excess of the average monthly turnover from the moment the respective category's inclusion into the list.

(8) For medicines included in the Temporary list of medicinal products under surveillance, MAHs are required to notify the NAMMD and the Ministry of Health no later than 3 days after the date of Temporary list publication on the Ministry of Health web page under the "Decision-making transparency" section related to wholesalers contracted to ensure distribution of respective medicinal products; the same information is posted by the NAMMD and the Ministry of Health on their own web sites.

Article 4

In case of Ministry of Health reporting by means of the ESIR of decrease for 7 consecutive days of wholesaler stocks of products in the list below the average monthly turnover of the respective wholesaler, the Ministry of Health shall notify the NAMMD, who immediately initiates an inspection procedure according to the law.

Article 5

(1) 10 days before conduct of an intra-Community delivery, transactions between two or more representative offices of the same company in different countries included, the MAH, the wholesaler or pharmacies shall notify the NAMMD by submission of the filled in the statutory declaration in respect of compliance with the public service obligation, in accordance with the annex integral to this order.

(2) Data identifying the respective medicinal product (i.e. trade name, pharmaceutical form, INN, pack size, quantity, batch) covered by the notification referred to in (1) shall be posted on the NAMMD website within 5 days from notice submission.

(3) For legal entities authorised for concomitant conduct of medicinal product dispensing to the public and wholesale, records shall be specific whether the medicinal products are received or held in stock in the capacity of retail dealer or as a wholesaler. Where medicinal products are received or held in stock in the capacity of retail distributor, they may not be subject to wholesale distribution.

Article 6

This Order shall be published in the Official Gazette of Romania, Part I.

Minister of Health,
Florian-Dorel Bodog

Bucharest, 14 March 2017
No. 269.

ANNEX

NOTIFICATION OF INTRA-COMMUNITY DELIVERY
Medicinal products for human use

Name of the wholesaler .....
Address .....
Unique registration code (CUI) .....
Wholesale distribution authorisation no. .....
Retail distribution authorisation for the same CUI YES NO
Trade name of the medicinal product (pursuant to MA) .....
INN .....
Pharmaceutical form.....
Strength .....
Package size .....
CIM Code: .....
ATC Code .....
MAH .....
Quantity .....
Purchased from .....
Country intended for distribution .....
Stocks on notification (excluding the quantity notified above.....

I, the undersigned ... ... in my capacity as ... ... of the wholesaler ... ..., holder of Wholesale Distribution Authorisation no. ... ..., fully aware of legal provisions relating to false statements, hereby declare under my own responsibility that all orders received for the medicinal product covered by this notification have been met, and that the notified intra-Community delivery does not affect my public service obligation.

Legal representative,

Ministry of Health - MH – Order no. 272/2017 of 14 March 2017

Order of the Minister of Health no. 272/2017 of 14 March 2017 on amendment and supplementation of Rules for implementation of provisions of articles 703 (1) and (2) of Law 95/2006 on healthcare reform on medicinal products for special needs, approved through Order of the Minister of Health no. 85/2013

In force since 15 March 2017
Published in the Official Gazette of Romania, Part I, no. 183 of 15 March 2017. There are no amendments until 17 March 2017.

On seeing the Approval report of the Medicinal Product Policy and Medical Devices Directorate No. 2.195/2017 and NAMMD notification no. 57.679E/2014, registered at the Ministry of Health with no. 69.569/2014,

taking into account provisions of Article 703 of Law 95/2006 on healthcare reform, republished, as amended,

provisions of Article 4 (2) a) 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 Article 7 (4) of Government Decision No. 144/2010 on the organisation and operation of the Ministry of Health, as amended,

the minister of health hereby issues the following order:

Article 1. – The Rules for implementation of provisions of articles 703 (1) and (2) of Law No. 95/2006 on healthcare reform on medicinal products for special needs, approved through Order of the Minister of Health no. 85/2013, published in the Official Gazette of Romania, Part I, no. 93 of 14 February 2013, as amended, are amended as follows:

1. Article 5 is amended and will read as follows:

“Art. 5. - (1) 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.

(2) For issuance and inclusion of the authorisation for supply of medicinal products for special needs in the Index of medicinal products for human use, no fees are required, in line with Article 896 of Law 95/2006, republished, as amended."

2. Under Article 11, three new paragraphs are introduced after (2), namely (2^1) - (2^3), reading as follows:

“(2^1) In cases under (2), the National Agency for Medicines and Medical Devices shall notify the specialised directorate of the Ministry of Health on termination of marketing of the respective product, 60 days before expiry of the MAH’s duty to ensure adequate and undisrupted supply.

(2^2) Within 3 working days after receipt of the notification mentioned in Article (2^1), the Ministry of Health, via its specialised directorate, shall require the specialist commission/the National Health Insurance House, as necessary, for transmission of stocks for 12-months use.

(2^3) The specialist commission/the National Health Insurance House shall notify the Ministry of Health about the stocks for 12-months use within 5 days from receipt of the request. The Ministry of Health, via its specialised directorate, shall notify the applicant about the stocks for 12-months use received from the specialist commission/the National Health Insurance House within 3 days after receipt."

3. Under Article 14, a new paragraph is introduced after (2), namely (2^1), reading as follows:

"(2^1) Should a medicinal product not require grant of a new authorisation for supply of medicinal products for special needs, in case the amount specified in (2) is not used up until expiry of authorisation validity, the holder may require the NAMMD to extend the authorisation validity until depletion of the respective amount, but no longer than 6 months after expiry of its validity."

4. Article 21 (2) is amended and will read as follows:

"(2) Documentation mentioned in (1) shall be submitted in writing."

5. Under Article 22, two new paragraphs are introduced after (4), namely (5) and (6), reading as follows:

"(5) In the case mentioned in Article 2 (2) of these Rules, the price of the medicinal product for special needs shall be less than or equal to the price approved in the National Index of Prices for On-Prescription Medicinal Products for Human Use (CaNaMed) for the medicinal product authorised for marketing but temporarily unavailable by the regular distribution channels.

(6) In case of special needs medicinal product price not compliant with these Rules, the Ministry of Health can temporarily approve the price proposed for the period of validity of the special needs authorisation."

6. Article 26 is hereby repealed.

7. Article 31 is hereby repealed.

8. Article 32 is hereby repealed.

Art. II. - This Order shall be published in the Official Gazette of Romania, Part I

Minister of Health,
Florian-Dorel Bodog

Bucharest, 14 March 2017.
No. 272.

Medicinal product batches recalled during the 1st quarter of 2017

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Proposed action	Date of recall
1	ALINDOR	tablets	500 mg	metamizole sodium	Laropharm SRL Romania	16.07.244 (exp. 06.2018)	voluntary recall initiated by the manufacturer following the finding of blisters missing tablets	Voluntary recall and destruction	10.01.2017
2	FLUMETOL	eye drops, suspension	2 mg/1 mg/ ml	combinations	Farmila-Thea Farmaceutici SPA ITALY/Thea Farma SPA ITALY	007017 (exp. 09.2017)	Batch with out-of-specification result for tests performed during long-term stability studies (impurities)	Voluntary recall and destruction	10.01.2017
3	TAVEGYL	tablets	1 mg	clemastine	Famar ITALY SPA Elvetia/ Novartis Consumer Health GmbH GERMANY	W0064 (exp. 05.2019)	Product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) as of reauthorisation of 22.12.2014	Voluntary recall and destruction	10.01.2017
4	NUROFEN EXPRESS	soft capsules	200 mg, box x 10 soft capsules	ibuprofen	Reckitt Benckiser Healthcare International Ltd GREAT BRITAIN	BL937(exp.03.2017), BL953(exp.03.2017), BM599(exp.04.2017)	Product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) as of reauthorisation	Voluntary recall and destruction	13.01.2017
5	NUROFEN EXPRESS	soft capsules	200 mg, box x 20 soft capsules	ibuprofen	Reckitt Benckiser Healthcare International Ltd GREAT BRITAIN	BL442(exp.02.2017), BL443(exp.02.2017), BM383(exp.04.2017)	Product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) as of	Voluntary recall and destruction	13.01.2017

						BM384(exp.03.2018)	reauthorisation		
6	COSOPT	eye drops, solution	20mg/ml+ 5mg/ml	combinations (dorzolamide+ timolol)	Lab. Merck Sharp& Dohme- Chibret-FRANCE/ Santen Oy FINLAND	2170410, 2171630, 2173790, 2176070, 2179070, 2181870, 2185870, 2189890, 2194370, 2196530, 2200930, 2200840	Product whose 1-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 1810/2006) following NAMMD approval of MA transfer from the MSD to Santen Oy	Voluntary recall and destruction	13.01.2017
7	PARACETAMOL	tablets	500 mg	paracetamol	BIOFARM SA	116 (exp. 09.2018)	Batch containing the leaflet of Acetylsalicylic Acid T Biofarm 500 mg, tablets	Recall and destruction	27.01.2017
8	ALKA SELTZER	effervescent tablets	324 mg	acetylsalicylic acid	Bayer Bitterfeld GmbH GERMANY/ Bayer SRL Romania	BTAH1L0 (exp. 01.2019)	Batch with noncompliant primary packaging (cracks in the aluminium layer of the blister foil)	Voluntary recall and destruction	08.02.2017
9	APIRIN PLUS C	effervescent tablets	400 mg/ 240 mg	combinations (acetylsalicylic acid + ascorbic acid)	Bayer Bitterfeld GmbH GERMANY/ Bayer SRL Romania	BTAH7P1 (exp. 03.2019)	batch with a noncompliant primary packaging (cracks in the aluminium layer of the blister foil)	Voluntary recall and destruction	08.02.2017
10	STANGEN	chewable tablets	4 mg	montelukast	Dr. Reddy's Lab. UK/ Dr. Reddy's Lab. Romania SRL	all batches	Product recalled from supplier level following a legal dispute	Voluntary recall and destruction	08.02.2017

11	STANGEN	chewable tablets	5 mg	montelukast	Dr. Reddy's Lab. UK/ Dr. Reddy's Lab. Romania SRL	all batches	Product recalled from supplier level following a legal dispute	Voluntary recall and destruction	08.02.2017
12	STANGEN	tablets filmate	10 mg	montelukast	Dr. Reddy's Lab. UK/ Dr. Reddy's Lab. Romania SRL	all batches	Product recalled from supplier level following a legal dispute	Voluntary recall and destruction	08.02.2017
13	ASPIMAX T	tablets	500 mg/250 mg	acetylsalicylic acid	Laropharm SRL Romania	16 03 102 (exp. 02.2017)	out-of-specification results for parameters: "Aspect", "Mass uniformity", "Acetylsalicylic acid g%", "Dosage, mg/tablet", "Friability".	Recall and destruction	16.02.2017
14	ALGOCALMIN	vials	1g/2ml	solution for injection	Zentiva SA Romania	6ZR1503A, 6ZR2082A	Identification of black particles in the solution	Recall and destruction	16.02.2017
15	FENISTIL	gel	1mg/g	dimetinden	Novartis Consumer Health GmbH GERMANY	P02940A, R00742A, R00743A, R00902A, R01227B, R01229A, R01230A, R01228A, R01972A, R01977A.	Product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) as of reauthorisation,	Voluntary recall and destruction	20.03.2017
16	EPIPEN 300 µgr	solution for injection in pre-filled pen	300microgame %	epinephrine	Meda Pharma GmbH & CO.KG - GERMANY	5FA665M	Difficult activation of administration mechanism	Recall and destruction	24.03.2017
17	RECOTENS	tablets	5 mg	amlodipine	Valeant Pharma SRL	all batches	product whose MA no. 3930/2011/01-11 had expired as of 04.08.2016	Voluntary recall and destruction	28.03.2017

18	RECOTENS	tablets	10 mg	amlodipine	Valeant Pharma SRL	all batches	product whose MA no. 3931/2011/01-11 had expired as of 04.08.2016	Voluntary recall and destruction	28.03.2017

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 4th quarter of 2016

During the 4th quarter of 2016, **43** marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

A02 - DRUGS FOR ACID RELATED DISORDERS
A04 - ANTIEMETICS AND ANTINAUSEANTS
A06 – DRUGS FOR CONSTIPATION
A07 - ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS
A10 - DRUGS USED IN DIABETES
A11 - VITAMINS
A16 - OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS
B01 - ANTITHROMBOTIC AGENTS
B02 - ANTIHEMORRHAGICS
C03 - DIURETICS
C08 – CALCIUM CHANNEL BLOCKERS
C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
C10 - LIPID MODIFYING AGENTS
D01 – ANTIFUNGALS FOR DERMATOLOGICAL USE
D06 – ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE
D10 – ANTI-ACNE PREPARATIONS
D11 – OTHER DERMATOLOGICAL PREPARATIONS
G03 - SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM
G04 - UROLOGICALS
H01 – PITUITARY AND HIPOTHALAMIC HORMONES AND ANALOGUES
J01 - ANTIBACTERIALS FOR SYSTEMIC USE
J02 - ANTIMYCOTICS FOR SYSTEMIC USE
J05 - ANTIVIRALS FOR SYSTEMIC USE
L01 – ANTINEOPLASTIC AGENTS L04- IMMUNOSUPPRESSANTS
M01 - ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
M02 – TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAINS
M03 – MUSCLE RELAXANTS
M04 - ANTIGOUT PREPARATIONS
M05 - DRUGS FOR TREATMENT OF BONE DISEASES
N01 - ANESTHETICS
N02 - ANALGESICS
N03 - ANTIEPILEPTICS
N04 - ANTI-PARKINSON DRUGS
N05 - PSYCHOLEPTICS
N06 - PSYCHOANALEPTICS
R01 - NASAL PREPARATIONS

R02 - THROAT PREPARATIONS
R03 - DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES
R05 - COUGH AND COLD PREPARATIONS
S01 - OPHTHALMOLOGICALS
V03 – ALL OTHER THERAPEUTIC PRODUCTS
XRN – HOMEOPATHIC MEDICINAL PRODUCTS

Medicinal products authorised for marketing during the 4th quarter of 2016

INN	Invented name	pharmaceutical form	Strength	MAH	Country	MA number		
ABACAVIRUM+LAMIVUDINUM	ABACAVIR/LAMIVUDINA AUROBINDO 600 mg/300mg	film-coated tablets	600mg/ 300mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	9491	2016	01
ACETYLCYSTEINUM	ACC 200 mg	capsules	200mg	HEXAL AG	GERMANY	9363	2016	01
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC - RICHTER 100 mg	tablets	100mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9507	2016	01
ACIDUM ALENDRONICUM+ COLECALCIFEROLUM	DA-BONE 70 mg/5600 UI	tablets	70mg/ 5600 IU	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9543	2016	01
ACIDUM GADOXETICUM	PRIMOVIST 0.25 mmole/ml	solution for injection in PRE-FILLED SYRINGE	181.430mg	BAYER PHARMA AG	GERMANY	9524	2016	01
ACIDUM ZOLEDRONICUM	DESINOBON 4 mg/5 ml	concentrate for solution for infusion	4mg/5ml	ALVOGEN IPCO S.AR.L.	LUXEMBOURG	9368	2016	01
ALBUMINA UMANA NANOCOLOIDALA	NANOSCAN 500 µgr	kit for radiopharmaceutical preparation	500 µgr	RADIOPHARMACY LABORATORY LTD.	HUNGARY	9353	2016	01
ALFUZOSINUM	ALFUZOSINA AUROBINDO 10 mg	prolonged-release tablets	10mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	9539	2016	01
ALPRAZOLAMUM	PRAZOLEX 0.25 mg	tablets	0.25mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9551	2016	01
ALPRAZOLAMUM	PRAZOLEX 1 mg	tablets	1mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9553	2016	01
ALPRAZOLAMUM	PRAZOLEX 0.5 mg	tablets	0.5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9552	2016	01
AMBROXOLUM	AMBROXOL LAROPHARM 30 mg	tablets	30mg	LAROPHARM S.R.L.	ROMANIA	9523	2016	01

AMISULPRIDUM	AMISULPRIDA AUROBINDO 200 mg	tablets	200mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	9489	2016	01
AMISULPRIDUM	AMISULPRIDA AUROBINDO 400 mg	film-coated tablets	400mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	9490	2016	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOXIPLUS 500 mg/125 mg	film-coated tablets	500mg/125 mg	ANTIBIOTICE S.A.	ROMANIA	9459	2016	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOXIPLUS 875 mg/125 mg	film-coated tablets	875mg/125 mg	ANTIBIOTICE S.A.	ROMANIA	9460	2016	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AUGMENTIN BIS 400 mg/57 mg/5 ml	powder for oral suspension	400mg/ 57mg/ 5ml	SMITHKLINE BEECHAM LIMITED	GREAT BRITAIN	9385	2016	01
AMPICILLINUM	AMPICILINA SANDOZ 250 mg/5 ml	powder for oral suspension	250mg/ 5ml	SANDOZ SRL	ROMANIA	9415	2016	02
AMPICILLINUM	AMPICILINA SANDOZ 250 mg	capsules	250mg	SANDOZ S.R.L.	ROMANIA	9388	2016	01
AMPICILLINUM	AMPICILINA SANDOZ 500 mg	capsules	500mg	SANDOZ S.R.L.	ROMANIA	9389	2016	01
AMPICILLINUM	AMPICILINA SANDOZ 125 mg/5 ml	powder for oral suspension	125mg/ 5ml	SANDOZ SRL	ROMANIA	9414	2016	01
ASPARAGINAZUM	ASPARAGINASE 5000 MEDAC	powder for solution for injection/infusion	5000 IU	MEDAC GESELLSCHAFT FÜR KLINISCHE SPEZIALPRÄPARATE	GERMANY	9412	2016	01
ASPARAGINAZUM	ASPARAGINASE 10000 MEDAC	powder for solution for injection/infusion	10000 IU	MEDAC GESELLSCHAFT FÜR KLINISCHE SPEZIALPRÄPARATE	GERMANY	9413	2016	01
AZITHROMYCINUM	AZITROMICINA AUROBINDO 250 mg	film-coated tablets	250mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	9358	2016	01
AZITHROMYCINUM	AZITROMICINA AUROBINDO 500 mg	film-coated tablets	500mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	9359	2016	01
AZOTUM OXIDUM	MONOXID DE AZOT MESSER 800 PPM (V/V)	medicinal gas, compressed		MESSER ROMANIA GAZ SRL	ROMANIA	9517	2016	01
BENZYDAMINUM	BENZIDAMINA TEVA 3 mg	lozenges	3mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9485	2016	01

BIMATOPROSTUM	BIMATOPROST SANDOZ 0.1 mg/ml	eye drops, solution.	0.1mg/ml	SANDOZ S.R.L.	ROMANIA	9350	2016	01
BIMATOPROSTUM	BIMATOPROST PHARMATHEN 0.1 mg/ml	eye drops, solution.	0.1mg/ml	PHARMATHEN S.A.	GREECE	9454	2016	01
BIMATOPROSTUM	BIMATOPROST PHARMATHEN 0.3 mg/ml	eye drops, solution.	0.3mg/ml	PHARMATHEN S.A.	GREECE	9455	2016	01
BROMHEXINUM	BROMHEXIN ATB 8 mg	tablets	8mg	ANTIBIOTICE SA	ROMANIA	9545	2016	01
BUPIVACAINUM	BUPIVACAINA INFOMED 5 mg/ml	solution for injection	5 mg/ml	INFOMED FLUIDS S.R.L.	ROMANIA	9418	2016	01
BUPIVACAINUM	BUPIVACAINA INFOMED 2.5 mg/ml	solution for injection	2.5mg/ml	INFOMED FLUIDS S.R.L.	ROMANIA	9417	2016	01
CALCII DOBESILAS	DOXIUM 500	capsules	500mg	OM PHARMA S.A.	PORTUGAL	9361	2016	01
CARBOPLATINUM	CARBOPLATIN ACTAVIS 10mg/ml	concentrate for solution for infusion	10mg/ml	ACTAVIS S.R.L.	ROMANIA	9544	2016	01
CETILPIRIDINIUM	SEPTOLETE APPLE 1.2 mg	lozenges	1.2mg	KRKA D.D. NOVO MESTO	SLOVENIA	9534	2016	01
CETILPIRIDINIUM	SEPTOLETE LEMON 1.2 mg	lozenges	1.2mg	KRKA D.D. NOVO MESTO	SLOVENIA	9533	2016	01
CETILPIRIDINIUM	SEPTOLETE CHERRY 1.2 mg	lozenges	1.2mg	KRKA D.D. NOVO MESTO	SLOVENIA	9535	2016	01
COMBINATIONS	GRIPPOSTAD C	capsules		STADA ARZNEIMITTEL AG	GERMANY	9421	2016	01
COMBINATIONS	MILGAMMA N	soft capsules		WORWAG PHARMA GMBH & CO. KG	GERMANY	9457	2016	01
COMBINATIONS	NEUROSSEN INJEKT	solution for injection		AAA-PHARMA GMBH	GERMANY	9499	2016	01
COMBINATIONS	SEPTOLETE PLUS 1 mg+5 mg	orodispersible tablets	1mg+ 5mg	KRKA D.D. NOVO MESTO	SLOVENIA	9536	2016	01
COMBINATIONS	MILGAMMA NA	solution for injection		WORWAG PHARMA GMBH & CO. KG	GERMANY	9498	2016	01
COMBINATIONS	XYLONOR 137 mg/1.37 mg/ml	oromucosal spray, solution	137mg/ 1.37mg/ml	LABORATOIRES SEPTODONT	FRANCE	9456	2016	01
COMBINATIONS	TONOTIL N	powder and solution for oral solution		VIANEX S.A.	GREECE	9360	2016	01
COMBINATIONS	CODAMIN P	tablets		TERAPIA S.A.	ROMANIA	9561	2016	01

COMBINATIONS	DOXIPROCT 40 mg+20 mg/g	rectal ointment	40mg+ 20mg/g	OM PHARMA S.A.	PORTUGAL	9505	2016	01
COMBINATIONS	DOXIPROCT PLUS 40 mg+20 mg+0.25 mg/g	rectal ointment	40mg+ 20mg+ 0.25mg/g	OM PHARMA S.A.	PORTUGAL	9506	2016	01
COMBINATIONS	GAVISCON MENTOL	oral suspension		RECKITT BENCKISER HEALTHCARE LTD.	GREAT BRITAIN	9538	2016	01
COMBINATIONS	BIOFLU EXPECTORANT 100 mg+30 mg/5 ml	syrup	100mg+ 30mg/5ml	BIOFARM S.A.	ROMANIA	9458	2016	01
COMBINATIONS	CITRAFLEET	powder for oral solution		CASEN RECORDATI, S.L.	SPAIN	9349	2016	01
COMBINATIONS	CEMOLPLUS 500 mg/3 mg	tablets	500mg/ 3mg	SANOSAN S.R.L.	ROMANIA	9563	2016	01
COMBINATIONS	CLENSIA	powder for oral suspension		ALFA WASSERMANN S.P.A.	ROMANIA	9386	2016	01
COMBINATIONS (ACIDUM ACETYLSALICYLICUM+BISOPROLOLUM)	BETAPRES 5 mg/75 mg	capsules	5mg/75mg	PHARMACEUTICAL WORKS POLPHARMA SA	POLAND	9450	2016	01
COMBINATIONS (ACIDUM ACETYLSALICYLICUM+BISOPROLOLUM)	BETAPRES 10 mg/75 mg	capsules	10mg/ 75mg	PHARMACEUTICAL WORKS POLPHARMA SA	POLAND	9451	2016	01
COMBINATIONS (CIPROFLOXACINUM+FLUOCINOLONUM)	CEXIDAL 3 mg/ml+0.25 mg/ml	ear drops, solution	3mg/ml+ 0.25mg/ml	LABORATORIOS SALVAT, S.A.	SPAIN	9556	2016	01
COMBINATIONS (DEXPANTENOLUM + CLORHEXIDINUM)	BEPANSEPT 50mg/5mg/g	cream	50mg/ 5mg/g	BAYER S.R.L.	ROMANIA	9546	2016	01
COMBINATIONS (IBUPROFENUM+PSEUDOEFEDRINUM)	LAROFEN PLUS 200 mg/30 mg	film-coated tablets	200mg/ 30mg	LAROPHARM S.R.L.	ROMANIA	9424	2016	01

COMBINATIONS (LACTOBACILLUS ACIDOPHILUS+ESTRIOLUM)	VIVIFLOR	vaginal tablets		PHARMASWISS CESKÁ REPUBLIKA S.R.O.	THE CZECH REPUBLIC	9432	2016	01
COMBINATIONS (LEVODOPUM+CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TEVA 50 mg/12.5 mg/200 mg	film-coated tablets	50mg/ 12.5mg/ 200mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9474	2016	01
COMBINATIONS (LEVODOPUM+CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TEVA 75 mg/18.75 mg/200 mg	film-coated tablets	75mg/ 18.75mg/ 200mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9475	2016	01
COMBINATIONS (LEVODOPUM+CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TEVA 100 mg/25 mg/200 mg	film-coated tablets	100mg/ 25mg/ 200mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9476	2016	01
COMBINATIONS (LEVODOPUM+CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TEVA 125 mg/31.25 mg/200 mg	film-coated tablets	125mg/ 31.25mg/ 200mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9477	2016	01
COMBINATIONS (LEVODOPUM+CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TEVA 150 mg/37.5 mg/200 mg	film-coated tablets	150mg/ 37.5mg/ 200mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9478	2016	01
COMBINATIONS (LEVODOPUM+CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TEVA 175 mg/43.75 mg/200 mg	film-coated tablets	175mg/ 43.75mg /200mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9479	2016	01
COMBINATIONS (LEVODOPUM+CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TEVA 200 mg/50 mg/200 mg	film-coated tablets	200mg/ 50mg/ 200mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9480	2016	01
COMBINATIONS (LISINOPRILUM+HYDROCHLOROTHIAZIDUM)	SKOPRYL PLUS 20 mg/12.5 mg	tablets	20mg/ 12.5mg	ALKALOID-INT D.O.O.	SLOVENIA	9541	2016	01
COMBINATIONS (METRONIDAZOLUM+CLOTRIMAZOLUM)	MECLON	vaginal cream	40mg/g+ 200mg/g	ALFA WASSERMAN S.P.A.	ITALY	9426	2016	01

COMBINATIONS (METRONIDAZOLUM+CLOTRIMAZOLUM)	MECLON	cream	50mg/g+ 10mg/g	ALFA WASSERMANN S.P.A.	ITALY	9427	2016	01
COMBINATIONS (NAPROXEN + ESOMEPRAZOL)	VIMOVO 500 mg/20 mg	modified-release tablets	500mg/ 20mg	ASTRA ZENECA AB	SWEDEN	9516	2016	01
DEFEROXAMINUM	DESFERAL 500 mg	powder for solution for injection/infusion	500mg	NOVARTIS PHARMA GMBH	GERMANY	9446	2016	01
DESLORATADINUM	DESLORATADINA ALVOGEN 0.5 mg/ml	oral solution	0.5mg/ml	ALVOGEN IPCO S.AR.L.	LUXEMBOURG	9366	2016	01
DESLORATADINUM	DESLORATADINA ALVOGEN 5 mg	film-coated tablets	5mg	ALVOGEN IPCO S.AR.L.	LUXEMBOURG	9367	2016	01
DEXAMETHASONUM	DEXAMETAZONA KRKA 4 mg	tablets	4mg	KRKA D.D. NOVO MESTO	SLOVAKIA	9371	2016	01
DEXAMETHASONUM	DEXAMETAZONA KRKA 8 mg	tablets	8mg	KRKA D.D. NOVO MESTO	SLOVAKIA	9372	2016	01
DEXAMETHASONUM	DEXAMETAZONA KRKA 20 mg	tablets	20mg	KRKA D.D. NOVO MESTO	SLOVAKIA	9373	2016	01
DEXAMETHASONUM	DEXAMETAZONA KRKA 40 mg	tablets	40mg	KRKA D.D. NOVO MESTO	SLOVAKIA	9374	2016	01
DEXTRANUM	DEXTRAN 40, 100g/l in SODIUM CHLORIDE solution, 9 g/l	solution for infusion		INFOMED FLUIDS S.R.L.	ROMANIA	9559	2016	01
DEXTRANUM	DEXTRAN 70, 60 g/l in SODIUM CHLORIDE solution, 9 g/l	solution for infusion		INFOMED FLUIDS S.R.L.	ROMANIA	9560	2016	01
DIAZEPAMUM	DIAZEPAM TERAPIA 5 mg/ml	solution for injection	5mg/ml	TERAPIA S.A.	ROMANIA	9509	2016	01
DIAZEPAMUM	DIAZEPAM LAROPHARM 10 mg	tablets	10mg	LAROPHARM S.R.L.	ROMANIA	9392	2016	01
DICLOFENACUM	REFEN RETARD 100 mg	prolonged-release tablets	100mg	STADA HEMOFARM S.R.L.	ROMANIA	9431	2016	01
DICLOFENACUM	DICLOFENAC ROMPHARM 1 mg/ml	eye drops, solution	1mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	9433	2016	01
DILTIAZEMUM	DILTIAZEM BIOEEL 60 mg	tablets	60mg	BIO EEL S.R.L.	ROMANIA	9430	2016	01
DILTIAZEMUM	DILTIAZEM ARENA 60 mg	tablets	60mg	ARENA GROUP S.A.	ROMANIA	9501	2016	01
DULOXETINUM	DULOXETINA DR. REDDY'S 45 mg	gastroresistant capsules	45mg	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	9520	2016	01

DUTASTERIDUM	DUTALAN 0.5 mg	soft capsules	0.5mg	LANNACHER HEILMITTEL GES.M.B.H	AUSTRIA	9515	2016	01
ERLOTINIBUM	VARLOTA 100 mg	film-coated tablets	100mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	9518	2016	01
ERLOTINIBUM	VARLOTA 150 mg	film-coated tablets	150mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	9519	2016	01
ESCITALOPRAMUM	ESCITALOPRAM SANDOZ 5 mg	film-coated tablets	5mg	SANDOZ S.R.L.	ROMANIA	9467	2016	01
ESCITALOPRAMUM	ESCITALOPRAM SANDOZ 10 mg	film-coated tablets	10mg	SANDOZ S.R.L.	ROMANIA	9468	2016	01
ESCITALOPRAMUM	ESCITALOPRAM SANDOZ 15 mg	film-coated tablets	15mg	SANDOZ S.R.L.	ROMANIA	9469	2016	01
ESCITALOPRAMUM	ESCITALOPRAM SANDOZ 20 mg	film-coated tablets	20mg	SANDOZ S.R.L.	ROMANIA	9470	2016	01
ESOMEPRAZOLUM	ESOMEPRAZOL SANDOZ 40 mg	powder for solution for injection/infusion	40mg	SANDOZ S.R.L.	ROMANIA	9409	2016	01
ETORICOXIBUM	ETORICOXIB STADA 30 mg	film-coated tablets	30mg	STADA ARZNEIMITTEL AG	GERMANY	9354	2016	01
ETORICOXIBUM	ETORICOXIB STADA 60 mg	film-coated tablets	60mg	STADA ARZNEIMITTEL AG	GERMANY	9355	2016	01
ETORICOXIBUM	ETORICOXIB STADA 90 mg	film-coated tablets	90mg	STADA ARZNEIMITTEL AG	GERMANY	9356	2016	01
ETORICOXIBUM	ETORICOXIB STADA 120 mg	film-coated tablets	120mg	STADA ARZNEIMITTEL AG	GERMANY	9357	2016	01
ETORICOXIBUM	ROTICOX 30 mg	film-coated tablets	30mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9481	2016	01
ETORICOXIBUM	ROTICOX 60 mg	film-coated tablets	60mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9482	2016	01
ETORICOXIBUM	ROTICOX 90 mg	film-coated tablets	90mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9483	2016	01
ETORICOXIBUM	ROTICOX 120 mg	film-coated tablets	120mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9484	2016	01
FELODIPINUM	FELODIPIN SANDOZ 5 mg	prolonged-release tablets	5mg	HEXAL AG	GERMANY	9410	2016	01
FELODIPINUM	FELODIPIN SANDOZ 10 mg	prolonged-release tablets	10mg	HEXAL AG	GERMANY	9411	2016	01
FENSPIRIDUM	EPISTAT 80 mg	prolonged-release tablets	80mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9493	2016	01
FENTICONAZOLUM	LOMEXIN 20 mg/g	vaginal cream	20mg/g	RECORDATI S.P.A.	ITALY	9428	2016	01
FENTICONAZOLUM	LOMEXIN 20 mg/g	cream	20mg/g	RECORDATI S.P.A.	ITALY	9429	2016	01

FLUCONAZOLUM	FLUCONAZOL LAROPHARM 150 mg	capsules	150mg	LAROPHARM S.R.L.	ROMANIA	9445	2016	01
FLUTICASONUM PROPIONAT	CUTIVATE 0.05 mg/g	ointment	0.05mg/g	GLAXO WELLCOME UK LIMITED	GREAT BRITAIN	9564	2016	01
FLUTICASONUM PROPIONAT	CUTIVATE 0.5mg/g	cream	0.5mg/g	GLAXO WELLCOME UK LIMITED	GREAT BRITAIN	9565	2016	01
FLUVASTATINUM	FLUVASTATIN ARENA 80 mg	prolonged-release tablets	80mg	ARENA GROUP S.A.	ROMANIA	9437	2016	01
GABAPENTINUM	GABARAN 300 mg	capsules	300mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	9494	2016	01
GABAPENTINUM	GABARAN 400 mg	capsules	400mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	9495	2016	01
GABAPENTINUM	GABARAN 600 mg	film-coated tablets	600mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	9496	2016	01
GUAIFENESINUM	VICKS EXPECTORANT MIERE&GHIMBIR 200 mg/15 ml	syrup	200mg/ 15ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9441	2016	01
HYDROXYCHLOROQUINUM	PLAQUENIL 200 mg	film-coated tablets	200mg	SANOFI ROMANIA S.R.L.	ROMANIA	9504	2016	01
IMUNOGLOBULINA ANTI-D	RHOGAM Ultra-Filtered PLUS 300 µgr	solution for injection	300µgr	KEDRION S.P.A.	ITALY	9547	2016	01
ISOSORBIDI MONONITRAS	OLICARD RETARD 40 mg	prolonged-release capsules	40mg	MYLAN HEALTHCARE GMBH	GERMANY	9425	2016	01
ITRACONAZOLUM	ITRACONAZOL IENZIMED 100 mg	capsules	100mg	IENZIMED INTERNATIONAL GROUP LTD.	ROMANIA	9382	2016	01
KETOPROFENUM	KETONAL 25 mg/g	gel	25mg/g	LEK PHARMACEUTICALS D.D.	SLOVENIA	9562	2016	01
LANDIOLOLUM	RAPIBLOC 20 mg/2 ml	concentrate for solution for injection	20mg/2ml	AOP ORPHAN PHARMACEUTICALS AG	AUSTRIA	9440	2016	01
LANDIOLOLUM	RAPIBLOC 300 mg	powder for solution for infusion	300mg	AOP ORPHAN PHARMACEUTICALS AG	AUSTRIA	9438	2016	01

LANDIOLOLUM	RAPIBLOC 600 mg	powder for solution for infusion	600mg	AOP ORPHAN PHARMACEUTICALS AG	AUSTRIA	9439	2016	01
LANSOPRAZOLUM	LEVANT 15 mg	gastroresistant capsules	15mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	9554	2016	01
LANSOPRAZOLUM	LEVANT 30 mg	gastroresistant capsules	30mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	9555	2016	01
LISINOPRILUM	RANOLIP 5 mg	tablets	5mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	9548	2016	01
LISINOPRILUM	RANOLIP 10 mg	tablets	10mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	9549	2016	01
LISINOPRILUM	RANOLIP 20 mg	tablets	20mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	9550	2016	01
MAPROTILINUM	LUDIOMIL 25 mg	film-coated tablets	25mg	AMDIPHARM LIMITED	IRELAND	9423	2016	01
MAPROTILINUM	LUDIOMIL 10 mg	film-coated tablets	10mg	AMDIPHARM LIMITED	IRELAND	9422	2016	01
MEBENDAZOLUM	VERMOX 100 mg	tablets	100mg	JANSSEN PHARMACEUTICA NV	BELGIUM	9447	2016	01
METHADONUM	METHASAN 10 mg/ml	concentrate for oral solution	10mg/ml	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	9463	2016	01
METHYLPREDNISOLONUM	LEMOD SOLU 500 mg	powder and solvent for solution for injection/infusion	500mg	STADA HEMOFARM S.R.L.	ROMANIA	9503	2016	01
METHYLPREDNISOLONUM	LEMOD SOLU 125 mg	powder and solvent for solution for injection/infusion	125mg	STADA HEMOFARM S.R.L.	ROMANIA	9502	2016	01
MONTELUKASTUM	MONTELUKAST ARENA 4 mg	chewable tablets	4mg	ARENA GROUP S.A.	ROMANIA	9434	2016	01
MONTELUKASTUM	MONTELUKAST ARENA 5 mg	chewable tablets	5mg	ARENA GROUP S.A.	ROMANIA	9435	2016	01
MONTELUKASTUM	MONTELUKAST ARENA 10 mg	film-coated tablets	10mg	ARENA GROUP S.A.	ROMANIA	9436	2016	01
NEBIVOLOLUM	NEBIVOLOL TERAPIA 5mg	tablets	5mg	TERAPIA S.A.	ROMANIA	9448	2016	01
NICOTINUM	NICORETTE ICEMINT 2 mg	medicated chewing gum	2mg	MCNEIL AB	SWEDEN	9364	2016	01

NICOTINUM	NICORETTE ICEMINT 4 mg	medicated chewing gum	4mg	MCNEIL AB	SWEDEN	9365	2016	01
NIMODIPINUM	NIMOTOP 10 mg/50 ml	solution for infusion	10mg/50ml	BAYER PHARMA AG	GERMANY	9416	2016	01
NITRAZEPAMUM	NITRAZEPAM LPH 5 mg	tablets	5mg	LABORMED PHARMA S.A.	ROMANIA	9462	2016	01
NITRAZEPAMUM	NITRAZEPAM LPH 2.5 mg	tablets	2.5mg	LABORMED PHARMA S.A.	ROMANIA	9461	2016	01
NITROGLYCERINUM	NITROGLICERINA 0.5 mg	sublingual tablets	0.5mg	ZENTIVA S.A.	ROMANIA	9419	2016	01
OLOPATADINUM	OLOPATADINA ROMPHARM 1 mg/ml	eye drops, solution.	1mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	9375	2016	01
OMEPRAZOLUM	XANTRAZOL 20 mg	gastroresistant tablets	20 mg	BAYER S.R.L.	ROMANIA	9387	2016	01
OXALIPLATINUM	OXALIPLATINA MYLAN 5 mg/ml	concentrate for solution for infusion	5mg/ml	MYLAN S.A.S.	FRANCE	9540	2016	01
PACLITAXELUM	PACLITAXEL PHARMEXPRESS 6 mg/ml	concentrate for solution for infusion	6mg/ml	PHARMEXPRESS S.R.L.	ROMANIA	9390	2016	01
PALONOSETRONUM	PALONOSETRON TEVA 250 µgr	solution for injection	250µgr	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9465	2016	01
PALONOSETRONUM	PALONOSETRON DR. REDDY'S 250 µgr	solution for injection	250µgr	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	9521	2016	01
PANTOPRAZOLUM	PANTOPRAZOL MACLEODS 40 mg	gastroresistant tablets	40mg	MACLEODS PHARMA UK LIMITED	GREAT BRITAIN	9537	2016	01
PANTOPRAZOLUM	ZENCOPAN 40 mg	gastroresistant tablets	40 mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	9384	2016	01
PANTOPRAZOLUM	ZENCOPAN 20 mg	gastroresistant tablets	20 mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	9383	2016	01
PARACETAMOLUM	SANADOR 500 mg	tablets	500mg	LAROPHARM S.R.L.	ROMANIA	9391	2016	01
PARICALCITOLUM	ZEMPLAR 5 µgr/ml	solution for injection	5µgr/ml	ABBVIE SPAIN S.L.U.	SPAIN	9420	2016	01

PLANTE	ENDOTELON 150 mg	gastroresistant lozenges	150mg	CHEPLAPHARM ARZNEIMITTEL GMBH	GERMANY	9500	2016	01
PLANTE	ECHINACIN MADAUS 0.8 g/ml	oral solution	0.8g/ml	MADAUS GMBH	GERMANY	9362	2016	01
PLANTE (TINCTURA DIN FLORI DE ARNICA)	ARNIMED	gel		DR. THEISS NATURWAREN GMBH	GERMANY	9466	2016	01
PREGABALINUM	SIRANALEN 75 mg	capsules	75mg	MEDOCHEMIE LTD.	CYPRUS	9399	2016	01
PREGABALINUM	SIRANALEN 150 mg	capsules	150mg	MEDOCHEMIE LTD.	CYPRUS	9400	2016	01
PREGABALINUM	SIRANALEN 300 mg	capsules	300mg	MEDOCHEMIE LTD.	CYPRUS	9401	2016	01
QUETIAPINUM	QUETIAPINA TEVA 50 mg	prolonged-release tablets	50mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9510	2016	01
QUETIAPINUM	QUETIAPINA TEVA 200 mg	prolonged-release tablets	200mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9512	2016	01
QUETIAPINUM	QUETIAPINA TEVA 150 mg	prolonged-release tablets	150mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9511	2016	01
QUETIAPINUM	QUETIAPINA TEVA 300 mg	prolonged-release tablets	300mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9513	2016	01
QUETIAPINUM	QUETIAPINA TEVA 400 mg	prolonged-release tablets	400mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9514	2016	01
QUETIAPINUM	Q MIND 50 mg	prolonged-release tablets	50 mg	TORRENT PHARMA S.R.L.	ROMANIA	9393	2016	01
QUETIAPINUM	Q MIND 200 mg	prolonged-release tablets	200 mg	TORRENT PHARMA S.R.L.	ROMANIA	9394	2016	01
QUETIAPINUM	Q MIND 300 mg	prolonged-release tablets	300 mg	TORRENT PHARMA S.R.L.	ROMANIA	9395	2016	01
QUETIAPINUM	Q MIND 400 mg	prolonged-release tablets	400 mg	TORRENT PHARMA S.R.L.	ROMANIA	9396	2016	01

QUETIAPINUM	SEROQUEL XR 150 mg	prolonged-release tablets	150mg	ASTRAZENECA UK LIMITED	GREAT BRITAIN	9529	2016	01
QUETIAPINUM	SEROQUEL XR 200 mg	prolonged-release tablets	200mg	ASTRAZENECA UK LIMITED	GREAT BRITAIN	9530	2016	01
QUETIAPINUM	SEROQUEL XR 300 mg	prolonged-release tablets	300mg	ASTRAZENECA UK LIMITED	GREAT BRITAIN	9531	2016	01
QUETIAPINUM	SEROQUEL XR 400 mg	prolonged-release tablets	400mg	ASTRAZENECA UK LIMITED	GREAT BRITAIN	9532	2016	01
QUETIAPINUM	SEROQUEL XR 50 mg	prolonged-release tablets	50mg	ASTRAZENECA UK LIMITED	GREAT BRITAIN	9528	2016	01
QUINAPRILUM	ACCUPRO 20 mg	film-coated tablets	20mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	9378	2016	01
QUINAPRILUM	ACCUPRO 5 mg	film-coated tablets	5mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	9376	2016	01
QUINAPRILUM	ACCUPRO 10 mg	film-coated tablets	10mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	9377	2016	01
RAMIPRILUM	VIVACE 2.5 mg	tablets	2.5 mg	ACTAVIS GROUP HF.	ICELAND	9379	2016	01
RAMIPRILUM	VIVACE 5 mg	tablets	5 mg	ACTAVIS GROUP HF.	ICELAND	9380	2016	01
RAMIPRILUM	VIVACE 10 mg	tablets	10 mg	ACTAVIS GROUP HF.	ICELAND	9381	2016	01
RASAGILINUM	RASAGILINA EGIS 1 mg	tablets	1mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	8606	2016	01
ROSUVASTATINUM	ROSUVASTATINA MYLAN 5 mg	film-coated tablets	5mg	GENERICS (UK) LTD. T/A MYLAN	GREAT BRITAIN	9471	2016	01
ROSUVASTATINUM	ROSUVASTATINA MYLAN 10 mg	film-coated tablets	10mg	GENERICS (UK) LTD. T/A MYLAN	GREAT BRITAIN	9472	2016	01
ROSUVASTATINUM	ROSUVASTATINA MYLAN 20 mg	film-coated tablets	20mg	GENERICS (UK) LTD. T/A MYLAN	GREAT BRITAIN	9473	2016	01
SALBUTAMOLUM	SALBUTAMOL SANDOZ 100 µgr/dose	press. susp. for inhal.	100µgr/ dose	SANDOZ S.R.L.	ROMANIA	9542	2016	01

SILDENAFILUM	SILDENAFIL PFIZER 50 mg	film-coated tablets	50mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	9407	2016	01
SILDENAFILUM	SILDENAFIL PFIZER 100 mg	film-coated tablets	100mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	9408	2016	01
SILDENAFILUM	OLVION 50 mg	film-coated tablets	50mg	MEDOCHEMIE LTD.	CYPRUS	9397	2016	01
SILDENAFILUM	OLVION 100 mg	film-coated tablets	100mg	MEDOCHEMIE LTD.	CYPRUS	9398	2016	01
SILDENAFILUM	ENTRANIN 50mg	chewable tablets	50mg	LABORMED PHARMA S.A.	ROMANIA	9452	2016	01
SILDENAFILUM	ENTRANIN 100mg	chewable tablets	100mg	LABORMED PHARMA S.A.	ROMANIA	9453	2016	01
SILDENAFILUM	SILDENAFIL PFIZER 25 mg	film-coated tablets	25mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	9406	2016	01
SIMETHICONUM	ESPUMISAN 40 mg	soft capsules	40mg	BERLIN-CHEMIE AG (MENARINI GROUP)	GERMANY	9444	2016	01
SITAGLIPTINUM	SITAGLIPTINA TEVA 100 mg	film-coated tablets	100mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9492	2016	01
TADALAFILUM	TADALAFIL ACTAVIS 2.5 mg	film-coated tablets	2.5mg	ACTAVIS GROUP PTC EHF.	ICELAND	9402	2016	01
TADALAFILUM	TADALAFIL ACTAVIS 5 mg	film-coated tablets	5mg	ACTAVIS GROUP PTC EHF.	ICELAND	9403	2016	01
TADALAFILUM	TADALAFIL ACTAVIS 10 mg	film-coated tablets	10mg	ACTAVIS GROUP PTC EHF.	ICELAND	9404	2016	01
TADALAFILUM	TADALAFIL ACTAVIS 20 mg	film-coated tablets	20mg	ACTAVIS GROUP PTC EHF.	ICELAND	9405	2016	01
TAMSULOSINUM	CONTIFLO MR 0.4 mg	prolonged-release capsules	0.4mg	RANBAXY (U.K.) LIMITED	GREAT BRITAIN	9497	2016	01
TELMISARTANUM	TEZEO 40 mg	tablets	40mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	9442	2016	01
TELMISARTANUM	TEZEO 80 mg	tablets	80mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	9443	2016	01
TIOTROPIUM	GREGAL 10 µgr	inhalation powder (capsule)	10µgr	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9464	2016	01
TOBRAMYCINUM	TOBROM 3 mg/ml	eye drops, solution	3mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	9449	2016	01

TROXERUTINUM	VENORUTON 300 mg	capsules	300mg	GLAXOSMITHKLINE CONSUMER HEALTHCARE S.R.L.	ROMANIA	9525	2016	01
VERAPAMILUM	ISOPTIN RR 240 mg	prolonged-release tablets	240mg	MYLAN HEALTHCARE GMBH	GERMANY	9522	2016	01
XYLOMETAZOLINUM	MARESYL 0.5 mg/ml	nasal spray, solution	0.5mg/ml	JADRAN-GALENSKI LABORATORIJ D.D.	CROATIA	9369	2016	01
XYLOMETAZOLINUM	MARESYL 1 mg/ml	nasal spray, solution	1mg/ml	JADRAN-GALENSKI LABORATORIJ D.D.	CROATIA	9370	2016	01
XYLOMETAZOLINUM	PINEX NAZAL 0.5 mg/ml	nasal spray, solution	0.5mg/ml	ACTAVIS GROUP PTC EHF.	ICELAND	9352	2016	01
XYLOMETAZOLINUM	PINEX NAZAL 1 mg/ml	nasal spray, solution	1mg/ml	ACTAVIS GROUP PTC EHF.	ICELAND	9351	2016	01
ZOLMITRIPTANUM	ZOLMITRIPTAN MYLAN 5 mg	orodispersible tablets	5mg	GENERICS (UK) LTD	GREAT BRITAIN	9558	2016	01
ZOLMITRIPTANUM	ZOLMITRIPTAN MYLAN 2.5 mg	orodispersible tablets	2.5mg	GENERICS (UK) LTD	GREAT BRITAIN	9557	2016	01
ZOLPIDEMUM	SANVAL 10 mg	film-coated tablets	10mg	LEK PHARMACEUTICALS D.D.	SLOVENIA	9508	2016	01

Medicinal products authorised through centralised procedure by the EMA, notified for marketing in Romania during the 4th quarter of 2016

INN	Invented name	Pharmaceutical form	Strength	MAH	Country	MA number		
COMBINATIONS (EMTRICITABINUM+TENOFOVIRUM)	EMTRICITABINA/TENOFOVIR DISOPROXIL MYLAN 200 mg/245 mg	FILM-COATED TABLETS	200 mg/245 mg	MYLAN S.A.S	FRANCE	1133	2016	03
ETELCALCETIDUM	PARSABIV 2.5 mg	SOLUTION FOR INJECTION	2.5mg	AMGEN EUROPE B.V.	HOLLAND	1142	2016	01
ETELCALCETIDUM	PARSABIV 5 mg	SOLUTION FOR INJECTION	5mg	AMGEN EUROPE B.V.	HOLLAND	1142	2016	05
ETELCALCETIDUM	PARSABIV 10 mg	SOLUTION FOR INJECTION	10mg	AMGEN EUROPE B.V.	HOLLAND	1142	2016	09
FOLLITROPINUM DELTA	REKOVELLE 12 µgr/0.36 ml	SOLUTION FOR INJECTION	12µgr/0.36ml	FERRING PHARMACEUTICALS A/S	DENMARK	1150	2016	01
FOLLITROPINUM DELTA	REKOVELLE 36 µgr/1.08 ml	SOLUTION FOR INJECTION	36µgr/1.08ml	FERRING PHARMACEUTICALS A/S	DENMARK	1150	2016	02

FOLLITROPINUM DELTA	REKOVELLE 72 µgr/2.16 ml	SOLUTION FOR INJECTION	72microgram/ 2.16ml	FERRING PHARMACEUTICALS A/S	DENMARK	1150	2016	03
IVABRADINUM	IVABRADINE ZENTIVA 5 mg	FILM-COATED TABLETS	5 mg	ZENIVA K.S.	THE CZECH REPUBLIC	1144	2016	07
IVABRADINUM	IVABRADINE ZENTIVA 7.5 mg	FILM-COATED TABLETS	7.5mg	ZENIVA K.S.	THE CZECH REPUBLIC	1144	2016	14
IXAZOMIB	NINLARO 2.3 mg	CAPSULES	2.3mg	TAKEDA PHARMA A/S	DENMARK	1094	2016	01
IXAZOMIB	NINLARO 3 mg	CAPSULES	3mg	TAKEDA PHARMA A/S	DENMARK	1094	2016	01
IXAZOMIB	NINLARO 4 mg	CAPSULES	4mg	TAKEDA PHARMA A/S	DENMARK	1094	2016	01
PALBOCICLIBUM	IBRANCE 75 mg	CAPSULES	75mg	PFIZER LIMITED	GREAT BRITAIN	1147	2016	01
PALBOCICLIBUM	IBRANCE 100 mg	CAPSULES	100mg	PFIZER LIMITED	GREAT BRITAIN	1147	2016	03
PALBOCICLIBUM	IBRANCE 125 mg	CAPSULES	125mg	PFIZER LIMITED	GREAT BRITAIN	1147	2016	05
TENOFOVIRUM DISOPROXIL	TENOFOVIR DISOPROXIL MYLAN	FILM-COATED	245mg	MYLAN S.A.S	FRANCE	1129	2016	01

		TABLETS						
VENETOCLAX	VENCLYXTO 10 mg	FILM-COATED TABLETS	10mg	ABBVIE LTD.	GREAT BRITAIN	1138	2016	01
VENETOCLAX	VENCLYXTO 50 mg	FILM-COATED TABLETS	50mg	ABBVIE LTD.	GREAT BRITAIN	1138	2016	03
VENETOCLAX	VENCLYXTO 100 mg	FILM-COATED TABLETS	100mg	ABBVIE LTD.	GREAT BRITAIN	1138	2016	05