

ROMANIA

Newsletter

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*National Agency for
Medicines
and
Medical Devices*

Medicinal product batches recalled during the 3rd quarter of 2017

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 2nd quarter of 2017

Medicinal products authorised for marketing during the 2nd quarter of 2017

Medicinal products authorised through centralised procedure by the EMA, notified for marketing in Romania during the 2nd quarter of 2017

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Medicinal product batches recalled during the 3rd quarter of 2017

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Proposed action	Date of recall
1	AUGMENTIN ES 600mg/42.9mg/5ml	powder for oral suspension	600mg/ 42.9mg/ 5ml	amoxicillin+ clavulanic acid	Smithkline Beecham Pharmaceuticals UK/ Smithkilne Beecham Ltd UK	1515, 1552	product whose 2-year shelf life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval of changes to the MA	Voluntary recall and destruction	14.07.2017
2	ATROPINE SULFATE TAKEDA 1 mg/ml	solution for injection	1mg/ml	atropine sulfate	Takeda GmbH Austria/ Takeda GmbH GERMANY	11159377	Product for which the ending of routine stability tests has shown one out-of-specifications result for parameter "tropic acid" for batch no. 11110600 (blocked for destruction within the company's own storehouse)	Voluntary recall (as a precaution for batch 11159377) and destruction	19.07.2017
3	LAMISIL cream 10 mg/g	cream	10 mg/g	terbinafine	Novartis Consumer Health GmbH GERMANY/ GSK Consumer Healthcare SRL Romania	R01610A, R02892A, R03501B	product whose 2-year shelf life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval of changes to the MA of 17.07.2015	Voluntary recall and destruction	10.08.2017

4	VENTOLIN 0.5 mg/ml	solution for injection	0.5 mg/ml	salbutamol	GSK Manufacturing SPA ITALY/ Glaxo Wellcome UK Ltd	5505, 5502, 4513AB, 4513A, 4513, 4510C, 4510B	product whose 2-year shelf life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval of changes to the MA	Voluntary recall and destruction	21.08.2017
5	PANADOL 500 mg	film-coated tablets	500 mg	paracetamol	GSK Dungarvan Ltd Ireland/ GSK Consumer Healthcare UK	025, 027, 028, 029, 030, 031, 032, 033, 034, 035, 036, 037, 038, 039, 040, 041, 042, 043, 044, 045, 046, 047, 048, 049, 050, 051, 052	product whose 2-year shelf life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval of changes to the MA of 07.08.2015	Voluntary recall and destruction	24.08.2017
6	TYVERB 250 mg	film-coated tablets	250 mg	lapatinib	Glaxo Operation UK Ltd/ Novartis Europharm Ltd UK	R94G	product whose CIM code validity (W533221006) has expired as of 01.07.2017	Voluntary recall and destruction	04.09.2017
7	FENISTIL gel 1 mg/g	gel	1 mg/g	dimetinden	Novartis Consumer Health GmbH GERMANY/ GSK Consumer Healthcare SRL Romania	R02394B, R02869A, T00538A, T00539A, T00540A, T00541A, T00734A, T01115A, T01116A, T01308B, T01309A, T01310A, T01311A, T01740A, T01741A, T01742A, T01743A,	product whose one-year shelf life has expired (as stipulated by Order of the Minister of Health no. 1810/2006) following NAMMD approval of changes to the MA of 08.09.2016	Voluntary recall and destruction	22.09.2017

						T02155A, T02156A, T04244B, T04246A, T04247A, T04248A, T04249A, T04250A, T04251A.			
8	VIBROCIL DUO 0.5 mg/ml+ 0.6 mg/ml	nasal spray, solution	0.5 mg/ml+ 0.6 mg/ml	xylometazoline + ipratropium	Novartis Consumer Health GmbH GERMANY/ GSK Consumer Healthcare SRL Romania	R02711E, R04347A, R04353B	product whose 2-year shelf life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval of changes to the MA of 04.09.2015	Voluntary recall and destruction	22.09.2017
9	DUOFILM	cutaneous solution	167 mg/g + 167 mg/g	combinations (salicylic acid + lactic acid)	Stiefel Laboratories Ireland LTD/GSK Consumer Healthcare SRL Romania	456T, 866T, 1111T	product whose 2-year shelf life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval of changes to the MA of 25.08.2015	Voluntary recall and destruction	22.09.2017
10	PARASINUS PENTA	tablets	500mg/25mg/ 5 mg/20mg/ 38 mg	combinations (paracetamol+ cofein+ phenylephrine + terpin hydrate+ ascorbic acid)	GSK Dungarvan Ltd Ireland/ GSK Consumer Healthcare UK	024, 025, 026, 027, 028, 029, 030, 031, 032, 033, 034, 035, 036, 037, 038, 039, 040, 041, 042, 043, 044, 045, 046, 047, 048, 049, 050, 051, 052, 5001, 5002, 6201, 6202, 6203	product whose 2-year shelf life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval of changes to the MA of 24.09.2015	Voluntary recall and destruction	29.09.2017

11	DRILL 3 mg+ 0.2 mg	lozenges	3 mg+ 0.2 mg	combinations	Pierre Fabre Medicament Production FRANCE/ Pierre Fabre Medicament FRANCE	A01333, A01338, A01343, A01344	product whose 2-year shelf life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval of changes to the MA of 28.08.2015	Voluntary recall and destruction	29.09.2017
12	DRILL FARA ZAHAR 3 mg+ 0.2 mg	lozenges	3 mg+ 0.2 mg	combinations	Pierre Fabre Medicament Production FRANCE/ Pierre Fabre Medicament FRANCE	A00455, A00455-A, A00456, A00457, A00459	product whose 2-year shelf life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval of changes to the MA of 28.08.2015	Voluntary recall and destruction	29.09.2017
13	DRILL MIERE CU AROMA DE TRANDAFIR 3 mg+ 0.2 mg	lozenges	3 mg+ 0.2 mg	combinations	Pierre Fabre Medicament Production FRANCE/ Pierre Fabre Medicament FRANCE	A00519, A00521, A00532, A00536	product whose 2-year shelf life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval of changes to the MA of 28.08.2015	Voluntary recall and destruction	29.09.2017

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 2nd quarter of 2017

During the 2nd quarter of 2017, **187** 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
A04 – ANTIEMETICS
A06 – DRUGS FOR CONSTIPATION
A07 - ANTIDIARRHEALS, INTESTINAL ANTI-INFLAMMATORY/ANTI-INFECTIVE AGENTS
A10 - DRUGS USED IN DIABETES
A12 - MINERAL SUPPLEMENTS
A16 – OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS
B01 - ANTITHROMBOTIC AGENTS
B02 – ANTIHEMORRHAGICS
B03 - ANTIANEMIC PREPARATIONS
C01 – CARDIAC THERAPY
C02.- ANTIHYPERTENSIVES
C08 – CALCIUM CHANNEL BLOCKERS
C09 – AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
D07 – CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS
D10 – ANTI-ACNE PREPARATIONS
G03 - SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM
G04 - UROLOGICALS
H01 - PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES
J01 - ANTIBACTERIALS FOR SYSTEMIC USE
J02 - ANTIMYCOTICS FOR SYSTEMIC USE
J05 - ANTIVIRALS FOR SYSTEMIC USE
L01 - ANTINEOPLASTIC AGENTS
L02 - ENDOCRINE THERAPY
L04- IMMUNOSUPPRESSANTS
M01 - ANTI-INFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
M04 – ANTIGOUT PREPARATIONS
M05 – DRUGS FOR TREATMENT OF BONE DISEASES
N01 - ANESTHETICS
N02 - ANALGESICS
N03 - ANTIEPILEPTICS
N04 - ANTI-PARKINSON DRUGS
N05 - PSYCHOLEPTICS
N06 - PSYCHOANALEPTICS
N07 – OTHER NERVOUS SYSTEM DRUG
R01 – NASAL PREPARATIONS

R03 - DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES
R06 – ANTIHISTAMINES FOR SYSTEMIC USE
S01 - OPHTHALMOLOGICALS
V03 - ALL OTHER THERAPEUTIC PRODUCTS
XRN – HOMEOPATHIC MEDICINAL PRODUCTS

Medicinal products authorised for marketing during the 2nd quarter of 2017

INN	Invented name	pharmaceut ical form	Strength	MAH	Country	MA number		
ACIDUM ACETYLSALICYLICUM+ ATORVASTATINUM+ RAMIPRILUM	TRINOMIA 100 mg/40 mg/2.5 mg	capsules	100mg/40mg/ 2.5mg	FERRER INTERNACIONAL, S.A.	SPAIN	9972	2017	01
ACIDUM ACETYLSALICYLICUM+ ATORVASTATINUM+ RAMIPRILUM	TRINOMIA 100 mg/40 mg/5 mg	capsules	100mg/40mg/ 5mg	FERRER INTERNACIONAL, S.A.	SPAIN	9973	2017	01
ACIDUM ACETYLSALICYLICUM+ ATORVASTATINUM+ RAMIPRILUM	TRINOMIA 100 mg/40 mg/10 mg	capsules	100mg/40mg/ 10mg	FERRER INTERNACIONAL, S.A.	SPAIN	9974	2017	01
ACIDUM ASCORBICUM	VITAMINA C SOPHARMA 100 mg/ml	solution for injection/inf usion	100mg/ml	SOPHARMA AD	BULGARIA	10054	2017	01
ACIDUM IBANDRONICUM	OSAGRAND 3 mg/3 ml	solution for injection	3mg/3ml	ZENTIVA K.S.	CZECH REPUBLIC	9963	2017	01
ACIDUM IBANDRONICUM	OSAGRAND 150 mg	film-coated tablets	150mg	ZENTIVA K.S.	CZECH REPUBLIC	9964	2017	01
ACIDUM ZOLEDRONICUM	ACID ZOLEDRONIC CIPLA 4 mg/100 ml	solution for infusion	4mg/100ml	CIPLA (EU) LIMITED	GREAT BRITAIN	9991	2017	01
ALBENDAZOLUM	ESKAZOLE 400 mg	tablets	400mg	GLAXOSMITHKLIN E EXPORT LIMITED	GREAT BRITAIN	9938	2017	01
AMIODARONUM	AMIODARONA ARENA 200 mg	tablets	200mg	ARENA GROUP S.A.	ROMANIA	9977	2017	01
ANASTROZOLUM	ANASTELB 1 mg	film-coated tablets	1mg	STADA ARZNEIMITTEL AG	GERMANY	10058	2017	01

AZATHIOPRINUM	IMURAN 50 mg	film-coated tablets	50mg	ASPEN PHARMA TRADING LIMITED	IRELAND	10042	2017	01
AZITHROMYCINUM	AZIBIOT 20 mg/ml	powder for solution for infusion	20mg/ml	KRKA, D.D., NOVO MESTO	SLOVENIA	9933	2017	01
AZITHROMYCINUM	AZIBIOT 40 mg/ml	powder for solution for infusion	40mg/ml	KRKA, D.D., NOVO MESTO	SLOVENIA	9934	2017	01
BECLOMETASONUM	CLENIL JET 250 mcg	pressurised solution for inhalation	250mcg	CHIESI FARMACEUTICI S.P.A.	ITALY	9978	2017	01
BENDAMUSTINUM	RIBOVACT 2.5 mg/ml	powder for concentrate for solution for infusion	2.5mg/ml	ASTELLAS PHARMA GMBH	GERMANY	10068	2017	01
BENZYDAMINUM	TANTUM ROSA 500 mg	granules for vaginal solution	500mg	ANGELINI PHARMA ÖSTERREICH GMBH	AUSTRIA	9982	2017	01
BETAHISTINUM	BETAHISTINA ATB 8 mg	tablets	8mg	ANTIBIOTICE S.A.	ROMANIA	9931	2017	01
BETAHISTINUM	BETAHISTINA ATB 24 mg	tablets	24mg	ANTIBIOTICE S.A.	ROMANIA	9932	2017	01
BICALUTAMIDUM	BICALUTAMIDA KABI 50 mg	film-coated tablets	50 mg	FRESENIUS KABI ONCOLOGY PLC	GREAT BRITAIN	10057	2017	01
BUTYLSCOPOLAMMONII BROMIDUM	BYSIMIN 20 mg/ml	solution for injection	20mg/ml	MEDOCHEMIE LTD.	CYPRUS	10063	2017	01
CANDESARTANUM CILEXETIL	CANZENO 8 mg	tablets	8mg	ZENTIVA, K.S.	CZECH REPUBLIC	10064	2017	01
CANDESARTANUM CILEXETIL	CANZENO 16 mg	tablets	16mg	ZENTIVA, K.S.	CZECH REPUBLIC	10065	2017	01
CANDESARTANUM CILEXETIL	CANZENO 32 mg	tablets	32mg	ZENTIVA, K.S.	CZECH REPUBLIC	10066	2017	01
CARBAMAZEPINUM	TEGRETOL 400 mg	tablets	400mg	NOVARTIS PHARMA GMBH	GERMANY	9998	2017	01

CARBAMAZEPINUM	TEGRETOL 200 mg	tablets	200mg	NOVARTIS PHARMA GMBH	GERMANY	9997	2017	01
CELECOXIBUM	CELEBREX 200 mg	capsules	200mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	10008	2017	01
CELECOXIBUM	CELEBREX 100 mg	capsules	100mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	10007	2017	01
CIPROFLOXACINUM	CIPROFLOXACINA ZENTIVA 10 mg/ml	concentrate for solution for infusion	100mg/10ml	ZENTIVA S.A.	ROMANIA	9864	2017	01
CLARITHROMYCINUM	KLERIMED 250	film-coated tablets	250mg	MEDOCHEMIE LTD.	CYPRUS	10031	2017	01
CLARITHROMYCINUM	KLERIMED 500	film-coated tablets	500mg	MEDOCHEMIE LTD.	CYPRUS	10032	2017	01
COMBINATIONS	ROCKLE'S	dental solution		SEPTODONT	FRANCE	9865	2017	01
COMBINATIONS	AMINOVEN 5%	solution for infusion	5%	FRESENIUS KABI AB	SUEDIA	9943	2017	01
COMBINATIONS	AMINOVEN 10%	solution for infusion	10%	FRESENIUS KABI AB	SUEDIA	9944	2017	01
COMBINATIONS	ROWATINEX	soft gastroresistant capsules		ROWA-WAGNER GMBH & CO. KG	GERMANY	10009	2017	01
COMBINATIONS	MACMIROR COMPLEX 100 mg+40000 IU/g	vaginal cream	10g/4000000 IU	POLICHEM SA	LUXEMBOURG	9980	2017	01
COMBINATIONS	ROWACHOL	capsules		ROWA-WAGNER GMBH & CO. KG	GERMANY	10033	2017	01
COMBINATIONS	ROWACHOL	oral drops, solution		ROWA-WAGNER GMBH & CO. KG	GERMANY	10050	2017	01
COMBINATIONS	NEPHROTECT	solution for infusion		FRESENIUS KABI DEUTSCHLAND GMBH	GERMANY	10051	2017	01
COMBINATIONS	FLUMETOL 2 mg/1 mg/ml	eye drops, solution	2mg/1mg/ml	THEA FARMA S.P.A.	ITALY	10046	2017	01

COMBINATIONS	MALTOFER FOL 100 mg/0.35 mg	chewable tablets	100mg/ 0.35mg	VIFOR FRANCE S.A.	FRANCE	9940	2017	01
COMBINATIONS	MULTILAC cu 2 mmol/l POTASIU	solution for hemodialysis /hemofiltrati on	2mmol/l	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	GERMANY	9924	2017	01
COMBINATIONS	MULTILAC FARA POTASIU	solution for hemodialysis /hemofiltrati on		FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	GERMANY	9923	2017	01
COMBINATIONS (ADAPALENUM+ BENZOYLIS PEROXIDUM)	EPIDUO 1 mg/25 mg/g	gel	1mg/25mg/g	GALDERMA INTERNATIONAL	FRANCE	9950	2017	01
COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	DILORYM 6.25 mg/5mg	film-coated tablets	6.25mg/5mg	EGIS PHARMACEUTICAL S PLC	HUNGARY	9854	2017	01
COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	DILORYM 6.25 mg/7.5mg	film-coated tablets	6.25mg/7.5mg	EGIS PHARMACEUTICAL S PLC	HUNGARY	9855	2017	01
COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	DILORYM 12.5 mg/5mg	film-coated tablets	12.5mg/5mg	EGIS PHARMACEUTICAL S PLC	HUNGARY	9856	2017	01
COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	DILORYM 12.5 mg/7.5mg	film-coated tablets	12.5mg/7.5mg	EGIS PHARMACEUTICAL S PLC	HUNGARY	9857	2017	01
COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	DILORYM 25 mg/5mg	film-coated tablets	25mg/5mg	EGIS PHARMACEUTICAL S PLC	HUNGARY	9858	2017	01
COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	DILORYM 25 mg/7.5mg	film-coated tablets	25mg/7.5mg	EGIS PHARMACEUTICAL S PLC	HUNGARY	9859	2017	01

COMBINATIONS (DESOGESTRELUM+ ETINILESTRADIOLUM)	NOVYNETTE CONTINUU 150 micrograms/ 20 micrograms	film-coated tablets	150micrograms/ 20micrograms	GEDEON RICHTER ROMANIA S.A.	ROMANIA	10087	2017	01
COMBINATIONS (DIENOGESTUM+ ETINILESTRADIOLUM)	SIBILLA 2 mg/0.03 mg	film-coated tablets	2mg/0.03mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	10067	2017	01
COMBINATIONS (DORZOLAMIDUM+ TIMOLOLUM)	DORZOLAMIDA/TIMOLO L DR. GERHARD MANN 20 mg/ml+5 mg/ml	eye drops, solution	20mg/ml+5mg/ ml	DR. GERHARD MANN CHEM.- PHARM.FABRIK GMBH	GERMANY	9929	2017	01
COMBINATIONS (GESTODENUM+ ETINILESTRADIOLUM)	VONILLE 60 micrograms/ 15 micrograms	film-coated tablets	60micrograms/ 15micrograms	EXELTIS MAGYARORSZÁG KFT	HUNGARY	9965	2017	01
COMBINATIONS (IBUPROFENUM+ PSEUDOEFEDRINUM)	IBUVALEN FLU 200 mg/30 mg	film-coated tablets	200mg/30mg	POLISANO PHARMACEUTICAL S S.R.L.	ROMANIA	9937	2017	01
COMBINATIONS (LATANOPROSTUM+ TIMOLOLUM)	ARUCOM 50 micrograms/ml + 5 mg/ml	eye drops, solution.	50micrograms/ ml+5mg/ml	DR. GERHARD MANN CHEM.- PHARM. FABRIK GMBH	GERMANY	9874	2017	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA /ENTACAPONA MYLAN 50 mg/12.5 mg/200 mg	film-coated tablets	50mg/12.5mg/ 200mg	GENERICS (UK) LTD	GREAT BRITAIN	9952	2017	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA /ENTACAPONA MYLAN 75 mg/18.75 mg/200 mg	film-coated tablets	75mg/18.75mg/ 200mg	GENERICS (UK) LTD	GREAT BRITAIN	9953	2017	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA /ENTACAPONA MYLAN 100 mg/25 mg/200 mg	film-coated tablets	100mg/25mg/ 200mg	GENERICS (UK) LTD	GREAT BRITAIN	9954	2017	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA /ENTACAPONA MYLAN 125 mg/31.25 mg/200 mg	film-coated tablets	125mg/31.25mg /200mg	GENERICS (UK) LTD	GREAT BRITAIN	9955	2017	01

COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA /ENTACAPONA MYLAN 150 mg/37.5 mg/200 mg	film-coated tablets	150mg/37.5mg/ 200mg	GENERICS (UK) LTD	GREAT BRITAIN	9956	2017	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA /ENTACAPONA MYLAN 200 mg/50 mg/200 mg	film-coated tablets	200mg/50mg/ 200mg	GENERICS (UK) LTD	GREAT BRITAIN	9957	2017	01
COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM)	BEATIL 4 mg/5 mg	tablets	4mg/5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9968	2017	01
COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM)	BEATIL 8 mg/5 mg	tablets	8mg/5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9969	2017	01
COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM)	BEATIL 4 mg/10 mg	tablets	4mg/10mg	GEDEON RICHTER ROMÂNIA S.A.	ROMANIA	9970	2017	01
COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM)	BEATIL 8 mg/10 mg	tablets	8mg/10mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9971	2017	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	RAMIPRIL/AMLODIPINA KRKA 5 mg/5 mg	capsules	5mg/5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10071	2017	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	RAMIPRIL/AMLODIPINA KRKA 5 mg/10 mg	capsules	5mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10072	2017	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	RAMIPRIL/AMLODIPINA KRKA 10 mg/5 mg	capsules	10mg/5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10073	2017	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	RAMIPRIL/AMLODIPINA KRKA 10 mg/10 mg	capsules	10mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10074	2017	01
COMPLEX DE HIDROXID DE FER (III) POLIMALTOZAT	FERRUM HAUSMANN 10 mg/ml	sirop	10mg/ml	VIFOR FRANCE	FRANCE	10043	2017	01
COMPLEX DE HIDROXID DE FER (III) POLIMALTOZAT	FERRUM HAUSMANN 50 mg/ml	oral drops, solution	50mg/ml	VIFOR FRANCE	FRANCE	10044	2017	01

COMPLEX DE HIDROXID DE FER (III) POLIMALTOZAT	MALTOFER 100 mg	chewable tablets	100mg	VIFOR FRANCE S.A.	FRANCE	9939	2017	01
CYTARABINUM	CITARABINA TEVA 100 mg/ml	solution for injection/infusion	100mg/ml	TEVA PHARMACEUTICAL S S.R.L.	ROMANIA	9888	2017	01
DARUNAVIRUM	DARUNAVIR ALVOGEN 400 mg	film-coated tablets	400mg	ALVOGEN MALTA OPERATIONS (ROW) LIMITED	MALTA	9879	2017	01
DARUNAVIRUM	DARUNAVIR ALVOGEN 600 mg	film-coated tablets	600mg	ALVOGEN MALTA OPERATIONS (ROW) LIMITED	MALTA	9880	2017	01
DARUNAVIRUM	DARUNAVIR ALVOGEN 800 mg	film-coated tablets	800mg	ALVOGEN MALTA OPERATIONS (ROW) LIMITED	MALTA	9881	2017	01
DEXTRANUM	DEXTRAN 40 INFOMED 100 g/l in solutie de GLUCOZA 50 g/l	solution for infusion		INFOMED FLUIDS S.R.L.	ROMANIA	10052	2017	01
DEXTRANUM	DEXTRAN 70 INFOMED 60 g/l in solutie de GLUCOZA 50 g/l	solution for infusion		INFOMED FLUIDS S.R.L.	ROMANIA	10053	2017	01
DIAZEPAMUM	DIAZEPAM DESITIN 5 mg/2.5 ml	rectal solution	5mg/2.5ml	DESITIN ARZNEIMITTEL GMBH	GERMANY	10040	2017	01
DIAZEPAMUM	DIAZEPAM DESITIN 10 mg/2.5 ml	rectal solution	10mg/2.5ml	DESITIN ARZNEIMITTEL GMBH	GERMANY	10041	2017	01
DIOSMINUM	DIOSMINA HASCO-LEK 1000 mg	film-coated tablets	1000mg	PRZEDSIEBIORSTWO PRODUKCJI FARMAC. HASCO-LEK S.A.	POLONIA	10075	2017	01
DIVERSE	OSTEOGENON 830 mg	film-coated tablets	830mg	PIERRE FABRE MEDICAMENT	FRANCE	10045	2017	01
DONEPEZILUM	ZILDON 5 mg	film-coated tablets	5mg	SANDOZ S.R.L.	ROMANIA	9907	2017	01

DONEPEZILUM	ZILDON 10 mg	film-coated tablets	10mg	SANDOZ S.R.L.	ROMANIA	9908	2017	01
ENALAPRILUM	ENALAPRIL LPH 5 mg	tablets	5mg	LABORMED PHARMA S.A.	ROMANIA	9984	2017	01
ENALAPRILUM	ENALAPRIL LPH 10 mg	tablets	10mg	LABORMED PHARMA S.A.	ROMANIA	9985	2017	01
ENALAPRILUM	ENALAPRIL LPH 20 mg	tablets	20mg	LABORMED PHARMA S.A.	ROMANIA	9986	2017	01
ENTECAVIRUM	ENTECAVIR TEVA 0.5 mg	film-coated tablets	0.5mg	TEVA PHARMACEUTICAL S S.R.L.	ROMANIA	10021	2017	01
ENTECAVIRUM	ENTECAVIR TEVA 1 mg	film-coated tablets	1mg	TEVA PHARMACEUTICAL S S.R.L.	ROMANIA	10022	2017	01
ENTECAVIRUM	ENTECAVIR GLENMARK 0.5 mg	film-coated tablets	0.5mg	GLENMARK PHARMACEUTICAL S S.R.O.	CZECH REPUBLIC	10024	2017	01
ENTECAVIRUM	ENTECAVIR GLENMARK 1 mg	film-coated tablets	1mg	GLENMARK PHARMACEUTICAL S S.R.O.	CZECH REPUBLIC	10025	2017	01
EPIRUBICINUM	EPISINDAN 10 mg	powder for solution for injection	10mg	ACTAVIS S.R.L.	ROMANIA	10048	2017	01
EPIRUBICINUM	EPISINDAN 50 mg	powder for solution for injection	50mg	ACTAVIS S.R.L.	ROMANIA	10049	2017	01
ERLOTINIBUM	ERLOTINIB GLENMARK 100 mg	film-coated tablets	100mg	GLENMARK PHARMACEUTICAL S S.R.O.	CZECH REPUBLIC	10083	2017	01
ERLOTINIBUM	ERLOTINIB GLENMARK 150 mg	film-coated tablets	150mg	GLENMARK PHARMACEUTICAL S S.R.O.	CZECH REPUBLIC	10084	2017	01
ETOFENAMATUM	RHEUMON 1 g/2 ml	solution for injection	1g/2ml	MEDA MANUFACTURING GMBH	GERMANY	10017	2017	01

ETOFENAMATUM	RHEUMON 100 mg/g	cream	100mg/g	MEDA MANUFACTURING GMBH	GERMANY	10016	2017	01
ETORICOXIBUM	ETORICOXIB AUROBINDO 30 mg	film-coated tablets	30mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	9895	2017	01
ETORICOXIBUM	ETORICOXIB AUROBINDO 60 mg	film-coated tablets	60mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	9896	2017	01
ETORICOXIBUM	ETORICOXIB AUROBINDO 90 mg	film-coated tablets	90mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	9897	2017	01
ETORICOXIBUM	ETORICOXIB AUROBINDO 120 mg	film-coated tablets	120mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	9898	2017	01
ETORICOXIBUM	ETORICOXIB TERAPIA 30 mg	film-coated tablets	30mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HOLLAND	9916	2017	01
ETORICOXIBUM	ETORICOXIB TERAPIA 60 mg	film-coated tablets	60mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HOLLAND	9917	2017	01
ETORICOXIBUM	ETORICOXIB TERAPIA 90 mg	film-coated tablets	90mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HOLLAND	9918	2017	01
ETORICOXIBUM	ETORICOXIB TERAPIA 120 mg	film-coated tablets	120mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HOLLAND	9919	2017	01
FENOFIBRATUM	FENOFIBRAT TORRENT 160 mg	film-coated tablets	160mg	TORRENT PHARMA S.R.L.	ROMANIA	10056	2017	01
FENTANYLUM	FENTANYL TORREX 0.05 mg/ml	solution for injection	0.05mg/ml	CHIESI PHARMACEUTICAL S GMBH	AUSTRIA	10001	2017	01
FLUOCINOLONI ACETONIDUM	FLUOCINOLON ACETONID LAROPHARM 0.25 mg/g	ointment	0.25mg/g	LAROPHARM S.R.L.	ROMANIA	10010	2017	01

FLUOROMETHOLONUM	FLUMETOL S 2 mg/ml	eye drops, suspension	2mg/ml	THEA FARMA S.P.A.	ITALY	10047	2017	01
FLURBIPROFEN	FARINGO INTENSIV 8.75 mg	lozenges	8.75mg	TERAPIA S.A.	ROMANIA	9891	2017	01
GINKGO BILOBA	GINKGO BILOBA BIOFARM 40 mg (see N06DX02)	film-coated tablets	40mg	BIOFARM S.A.	ROMANIA	10039	2017	01
GINKGO BILOBA	GINKGO BILOBA BIOFARM 40 mg (see C04AXN1)	film-coated tablets	40mg	BIOFARM S.A.	ROMANIA	10039	2017	01
GLIBENCLAMIDUM	MANINIL 1.75 mg	tablets	1.75mg	BERLIN-CHEMIE AG (MENARINI GROUP)	GERMANY	10005	2017	01
GLIBENCLAMIDUM	MANINIL 3.5 mg	tablets	3.5mg	BERLIN-CHEMIE AG (MENARINI GROUP)	GERMANY	10006	2017	01
HYDROCORTISONUM	SOFTACORT 3.35 mg/ml	eye drops, solution in single dose recipient	3.35mg/ml	LABORATOIRES THEA	FRANCE	10015	2017	01
IBUPROFENUM	MASIPREN 20 mg/ml	oral suspension	20mg/ml	PHARMASWISS CESKÁ REPUBLIKA S.R.O	CZECH REPUBLIC	9928	2017	01
IBUPROFENUM	IBUPROFEN B. BRAUN 400 mg	solution for infusion	400mg	B. BRAUN MELSUNGEN AG	GERMANY	10023	2017	01
IBUPROFENUM	IBUPROFEN B. BRAUN 600 mg	solution for infusion	600mg	B. BRAUN MELSUNGEN A.G.	GERMANY	10070	2017	01
IMATINIBUM	IMATINIB AUROBINDO 100 mg	film-coated tablets	100mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	9975	2017	01
IMATINIBUM	IMATINIB AUROBINDO 400 mg	film-coated tablets	400mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	9976	2017	01
IMIPENEMUM + CILASTATINUM	IMIPENEM/CILASTATIN AUROBINDO 500 mg/500 mg	powder for solution for infusion	500mg/500mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	9911	2017	01

IMUNOGLOBULINA ANTI-D	RHOPHYLAC 300 micrograms/2 ml	solution for injection in pre-filled syringe	300micrograms/ 2ml	CSL BEHRING GMBH	GERMANY	9966	2017	01
INSULINE UMANE	HUMULIN R 100 IU/ml	solution for injection	100 IU/ml	LILLY FRANCE S.A.S.	FRANCE	10080	2017	01
INSULINE UMANE	HUMULIN N 100 IU/ml	suspension for injection	100 IU/ml	LILLY FRANCE S.A.S.	FRANCE	10081	2017	01
INSULINE UMANE	HUMULIN M3 100 IU/ml	suspension for injection	100 IU/ml	LILLY FRANCE S.A.S.	FRANCE	10082	2017	01
IOMEPROLUM	IOMERON 300 mg/ml	solution for injection	612.4mg/ml	BRACCO IMAGING SpA	ITALY	10035	2017	01
IOMEPROLUM	IOMERON 350 mg/ml	solution for injection	714.4mg/ml	BRACCO IMAGING SpA	ITALY	10036	2017	01
IOMEPROLUM	IOMERON 400 mg/ml	solution for injection	816.5mg/ml	BRACCO IMAGING SpA	ITALY	10037	2017	01
IRINOTECANUM	IRINOTECAN HAMELN 20 mg/ml	concentrate for solution for infusion	20mg/ml	HAMELN RDS GMBH	GERMANY	9893	2017	01
IVABRADINUM	IVABRADINA TEVA 5 mg	film-coated tablets	5mg	TEVA PHARMACEUTICAL S S.R.L.	ROMANIA	9889	2017	01
IVABRADINUM	IVABRADINA TEVA 7.5 mg	film-coated tablets	7.5mg	TEVA PHARMACEUTICAL S S.R.L.	ROMANIA	9890	2017	01
IVABRADINUM	IVABRADINA MYLAN 5 mg	film-coated tablets	5mg	MYLAN S.A.S.	FRANCE	10085	2017	01
IVABRADINUM	IVABRADINA MYLAN 7.5 mg	film-coated tablets	7.5mg	MYLAN S.A.S.	FRANCE	10086	2017	01
KALII CHLORIDUM	CLORURA DE POTASIU INFOMED 149 mg/ml	concentrate for solution for infusion	149mg/ml	INFOMED FLUIDS S.R.L.	ROMANIA	10004	2017	01
KETOTIFENUM	ZABAK 0.25 mg/ml	eye drops, solution.	0.25mg/ml	LABORATOIRES THEA	FRANCE	9909	2017	01
LATANOPROSTUM	SIFITAN 50 micrograms/ml	eye drops, solution	50micrograms/ ml	NTC S.R.L.	ITALY	9882	2017	01

LEVOFLOXACINUM	LEVOFLOXACINA AUROBINDO 5 mg/ml	solution for infusion	5mg/ml	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	10014	2017	01
LORATADINUM	FLONIDAN 10 mg	tablets	10mg	LEK PHARMACEUTICAL S D.D.	SLOVENIA	10165	2017	01
MELOXICAMUM	MELOX 7.5 mg	tablets	7.5 mg	MEDOCHEMIE LTD.	CYPRUS	10019	2017	01
MELOXICAMUM	MELOX 15 mg	tablets	15mg	MEDOCHEMIE LTD.	CYPRUS	10020	2017	01
MEPIVACAINUM	SCANDONEST 3% PLAIN	solution for injection	3%	LABORATOIRES SEPTODONT	FRANCE	9866	2017	01
MESALAZINUM	PENTASA 500 mg	prolonged- release tablets	500mg	FERRING GMBH	GERMANY	9996	2017	01
METFORMINUM	METFORMIN ACCORD 500 mg	prolonged- release tablets	500mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	10069	2017	01
METOPROLOLUM	METOPROLOL SUCCINAT TEVA 23.75 mg	prolonged- release tablets	23.75mg	TEVA PHARMACEUTICAL S S.R.L.	ROMANIA	9870	2017	01
METOPROLOLUM	METOPROLOL SUCCINAT TEVA 47.5 mg	prolonged- release tablets	47.5mg	TEVA PHARMACEUTICAL S S.R.L.	ROMANIA	9871	2017	01
METOPROLOLUM	METOPROLOL SUCCINAT TEVA 95 mg	prolonged- release tablets	95mg	TEVA PHARMACEUTICAL S S.R.L.	ROMANIA	9872	2017	01
METOPROLOLUM	METOPROLOL SUCCINAT TEVA 190 mg	prolonged- release tablets	190mg	TEVA PHARMACEUTICAL S S.R.L.	ROMANIA	9873	2017	01
METRONIDAZOLUM	METRONIDAZOL A 5 g/l	solution for infusion	5g/l	INFOMED FLUIDS S.R.L.	ROMANIA	10038	2017	01
METRONIDAZOLUM	METRONIDAZOL VVB 500 mg/100 ml	solution for infusion	500mg/100ml	UAB "VVB"	LITHUANIA	9892	2017	01
MINOXIDILUM	HAIRGROW 20 mg/ml	cutaneous spray, solution	20mg/ml	DAR AL DAWA PHARMA S.R.L.	ROMANIA	10002	2017	01

MINOXIDILUM	HAIRGROW 50 mg/ml	cutaneous spray, solution	50 mg/ml	DAR AL DAWA PHARMA S.R.L.	ROMANIA	10003	2017	01
MINOXIDILUM	ALOPEXY 50 mg/ml	cutaneous solution	50mg/ml	PIERRE FABRE DERMATOLOGIE	FRANCE	9951	2017	01
MORPHYNUM	MORFINA ZENTIVA 20 mg/ml	solution for injection	20mg/ml	ZENTIVA S.A.	ROMANIA	9983	2017	01
NAFTIDROFURYLUM	DUSODRIL 200 mg	prolonged-release tablets	200 mg	MERCK SANTE S.A.S.	FRANCE	10000	2017	01
NAFTIDROFURYLUM	DUSODRIL 100 mg	capsules	100 mg	MERCK SANTE S.A.S.	FRANCE	9999	2017	01
NATRII TETRADECYL SULPHAT	FIBROVEIN 0.2%	solution for injection	0.2%	STD PHARMACEUTICAL PRODUCTS LIMITED	GREAT BRITAIN	9903	2017	01
NATRII TETRADECYL SULPHAT	FIBROVEIN 0.5%	solution for injection	0.5%	STD PHARMACEUTICAL PRODUCTS LIMITED	GREAT BRITAIN	9904	2017	01
NATRII TETRADECYL SULPHAT	FIBROVEIN 1%	solution for injection	1%	STD PHARMACEUTICAL PRODUCTS LIMITED	GREAT BRITAIN	9905	2017	01
NATRII TETRADECYL SULPHAT	FIBROVEIN 3%	solution for injection	3%	STD PHARMACEUTICAL PRODUCTS LIMITED	GREAT BRITAIN	9906	2017	01
NEVIRAPINUM	NEVIRAPINA ACCORD 400 mg	prolonged-release tablets	400mg	ACCORD HEALTHCARE LIMITED, UK	GREAT BRITAIN	9992	2017	01
NICERGOLINUM	SINERGOLIN 30	drops	30mg	SINTOFARM S.A.	ROMANIA	10018	2017	01
NIFURATELUM	MACMIROR 200 mg	drops	200mg	POLICHEM SA	LUXEMBOURG	9979	2017	01
ONDANSETRONUM	ZONDARON 2 mg/ml	solution for injection/infusion	2mg/ml	SOPHARMA AD	BULGARIA	9994	2017	01

OXIGENUM	OXIGEN LINDE 100% (v/v)	compressed medicinal gas	100%(v/v)	LINDE GAZ A.S.	ROMANIA	9910	2017	01
OXYBUTYNINUM	DRIPTANE 5 mg	tablets	5mg	MYLAN MEDICAL S.A.S.	FRANCE	9945	2017	01
PALONOSETRONUM	PALONOSETRON SANDOZ 250 micrograms	solution for injection	250micrograms	SANDOZ S.R.L.	ROMANIA	10028	2017	01
PARACETAMOLUM	GRIPPOSTAD HOT 600 mg/sachet	powder for oral solution	600mg/sachet	STADA ARZNEIMITTEL AG	GERMANY	9941	2017	01
PEFLOXACINUM	PEFLOXACIN LAROPHARM 400 mg	film-coated tablets	400mg	LAROPHARM S.R.L.	ROMANIA	9995	2017	01
PHYTOMENADIONUM	FITOMENADION TERAPIA 10 mg/ml	solution for injection	10mg/ml	TERAPIA S.A.	ROMANIA	9981	2017	01
PLANTE	SINUPRET	oral drops, solution		BIONORICA SE	GERMANY	9942	2017	01
PLANTE (CIMBRU)	BRONCHOSTOP	oral gum		KWIZDA PHARMA GMBH	AUSTRIA	9899	2017	01
PROGESTERONUM	PROGESTERON ACTAVIS 400 mg	ovules	400mg	ACTAVIS GROUP PTC EHF.	ICELAND	10055	2017	01
QUETIAPINUM	QUETIAPINA ACCORD 200 mg	prolonged- release tablets	200mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9925	2017	01
QUETIAPINUM	QUETIAPINA ACCORD 300 mg	prolonged- release tablets	300mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9926	2017	01
QUETIAPINUM	QUETIAPINA ACCORD 400 mg	prolonged- release tablets	400mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9927	2017	01
RAMIPRILUM	RAMIPRIL-AC 2.5 mg	tablets	2.5mg	AC HELCOR PHARMA S.R.L.	ROMANIA	9867	2017	01
RAMIPRILUM	RAMIPRIL-AC 5 mg	tablets	5mg	AC HELCOR PHARMA S.R.L.	ROMANIA	9868	2017	01

RAMIPRILUM	RAMIPRIL-AC 10 mg	tablets	10mg	AC HELCOR PHARMA S.R.L.	ROMANIA	9869	2017	01
RANITIDINUM	RANITIDINA ARENA 75 mg	capsules	75mg	ARENA GROUP S.A.	ROMANIA	10029	2017	01
RANITIDINUM	RANITIDINA ARENA 300 mg	capsules	300mg	ARENA GROUP S.A.	ROMANIA	10030	2017	01
RILUZOLUM	RILUZOL PMCS 50 mg	film-coated tablets	50 mg	PRO. MED. CS PRAHA A.S.	CZECH REPUBLIC	9930	2017	01
ROSUVASTATINUM	ASTRIUM 5 mg	film-coated tablets	5mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9875	2017	01
ROSUVASTATINUM	ASTRIUM 10 mg	film-coated tablets	10mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9876	2017	01
ROSUVASTATINUM	ASTRIUM 20 mg	film-coated tablets	20mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9877	2017	01
ROSUVASTATINUM	ASTRIUM 40 mg	film-coated tablets	40mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9878	2017	01
SALMETEROLUM+ FLUTICASONUM	AIRFLUSAL 25 micrograms/ 125 micrograms	pressurised suspension for inhalation	25micrograms/ 125micrograms	SANDOZ S.R.L.	ROMANIA	10026	2017	01
SALMETEROLUM+ FLUTICASONUM	AIRFLUSAL 25 micrograms/ 250micrograms	pressurised suspension for inhalation	25micrograms/ 250micrograms	SANDOZ S.R.L.	ROMANIA	10027	2017	01
SILDENAFILUM	SILDENAFIL TEVA 20 mg	film-coated tablets	20mg	TEVA PHARMACEUTICAL S S.R.L.	ROMANIA	9894	2017	01
SOLIFENACINUM SUCCINATE	VEZIMED 5 mg	film-coated tablets	5mg	MEDOCHEMIE LTD.	CYPRUS	9935	2017	01
SOLIFENACINUM SUCCINATE	VEZIMED 10 mg	film-coated tablets	10mg	MEDOCHEMIE LTD.	CYPRUS	9936	2017	01
SPIRAMYCINUM	ROVAMYCINE 1.5 Mil. UI	film-coated tablets	1.5 Mil. IU	SANOFI ROMANIA S.R.L.	ROMANIA	10034	2017	01

TADALAFILUM	TADALAFIL ACCORD 2.5 mg	film-coated tablets	2.5mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9987	2017	01
TADALAFILUM	TADALAFIL ACCORD 5 mg	film-coated tablets	5mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9988	2017	01
TADALAFILUM	TADALAFIL ACCORD 10 mg	film-coated tablets	10mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9989	2017	01
TADALAFILUM	TADALAFIL ACCORD 20 mg	film-coated tablets	20mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9990	2017	01
TADALAFILUM	TADALAFIL SANDOZ 2.5 mg	film-coated tablets	2.5mg	SANDOZ S.R.L.	ROMANIA	9860	2017	01
TADALAFILUM	TADALAFIL SANDOZ 5 mg	film-coated tablets	5mg	SANDOZ S.R.L.	ROMANIA	9861	2017	01
TADALAFILUM	TADALAFIL SANDOZ 10 mg	film-coated tablets	10mg	SANDOZ S.R.L.	ROMANIA	9862	2017	01
TADALAFILUM	TADALAFIL SANDOZ 20 mg	film-coated tablets	20mg	SANDOZ S.R.L.	ROMANIA	9863	2017	01
TADALAFILUM	TADILECTO 2.5 mg	film-coated tablets	2.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10076	2017	01
TADALAFILUM	TADILECTO 5 mg	film-coated tablets	5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10077	2017	01
TADALAFILUM	TADILECTO 10 mg	film-coated tablets	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10078	2017	01
TADALAFILUM	TADILECTO 20 mg	film-coated tablets	20mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10079	2017	01
TENOFOVIRUM DISOPROXIL	TENOFOVIR DISOPROXIL ACCORD 245 mg	film-coated tablets	245mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9967	2017	01
TIMOLOLUM	TIMOLOL EIPICO 5 mg/ml	eye drops, solution	5mg/ml	E.I.P.I.CO. MED S.R.L.	ROMANIA	9947	2017	01
TIMOLOLUM	TIMOLOL EIPICO 2.5 mg/ml	eye drops, solution	2.5mg/ml	E.I.P.I.CO. MED S.R.L.	ROMANIA	9946	2017	01

TOBRAMYCINUM	TOBRAMICINA SUN 300 mg	solution for nebuliser	300mg			9993	2017	01
VALSARTANUM	VAPRESS 40 mg	film-coated tablets	40mg	MEDOCHEMIE LTD.	CYPRUS	9900	2017	01
VALSARTANUM	VAPRESS 80 mg	film-coated tablets	80mg	MEDOCHEMIE LTD.	CYPRUS	9901	2017	01
VALSARTANUM	VAPRESS 160 mg	film-coated tablets	160mg	MEDOCHEMIE LTD.	CYPRUS	9902	2017	01
VANCOMYCINUM	VANCOMICINA MYLAN 500mg	powder for concentrate for solution for infusion	500mg	MYLAN S.A.S.	NORWAY	9920	2017	01
VANCOMYCINUM	VANCOMICINA MYLAN 1000 mg	powder for concentrate for solution for infusion	1000mg	MYLAN S.A.S.	NORWAY	9921	2017	01
VARDENAFILUM	VIAVARDIS 5 mg	film-coated tablets	5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10011	2017	01
VARDENAFILUM	VIAVARDIS 10 mg	film-coated tablets	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10012	2017	01
VARDENAFILUM	VIAVARDIS 20 mg	film-coated tablets	20mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10013	2017	01
VORICONAZOLUM	VORICONAZOL MEDOCHEMIE 50 mg	film-coated tablets	50mg	MEDOCHEMIE LTD.	CYPRUS	9948	2017	01
VORICONAZOLUM	VORICONAZOL MEDOCHEMIE 200 mg	film-coated tablets	200mg	MEDOCHEMIE LTD.	CYPRUS	9949	2017	01
XYLOMETAZOLINUM	SNUP 0.5 mg/ml	nasal spray, solution	0.5mg/ml	STADA M&D SRL	ROMANIA	9883	2017	01
XYLOMETAZOLINUM	SNUP 1mg/ml	nasal spray, solution	1mg/ml	STADA M&D SRL	ROMANIA	9884	2017	01

Medicinal products authorised through centralised procedure by the EMA, notified for marketing in Romania during the 2nd quarter of 2017

INN	Invented name	pharmaceutical form	Strength	MAH	Country	MA number		
COMBINATIONS (TRIFLURIDINUM+ TIPIRACILUM)	LONSURF 20 mg/8.19 mg	film-coated tablets	20 mg/8.19 mg	LES LABORATOIRES SERVIER	FRANCE	1096	2017	06
COMBINATIONS (TRIFLURIDINUM+ TIPIRACILUM)	LONSURF 15 mg/6.14 mg	film-coated tablets	15 mg/6.14 mg	LES LABORATOIRES SERVIER	FRANCE	1096	2017	03
ETANERCEPTUM	ERELZI 50 mg	solution for injection	50mg	SANDOZ GMBH	AUSTRIA	1195	2017	011
ETANERCEPTUM	ERELZI 50 mg	solution for injection	50mg	SANDOZ GMBH	AUSTRIA	1195	2017	007
INOTUZUMAB OZOGAMICIN	BESPONSA 1 mg	powder and concentrate for solution for infusion	1mg	PFIZER LIMITED	GREAT BRITAIN	1200	2017	01

IVABRADINUM	IVABRADINA ACCORD 5 mg	film-coated tablets	5mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	1190	2017	03
IVABRADINUM	IVABRADINA ACCORD 7.5 mg	film-coated tablets	7.5mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	1190	2017	10