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Newsletter

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*National Agency for
Medicines
and
Medical Devices*

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Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 1st quarter of 2017

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DECISION

no. 1/26.06.2017

on approval of the Communication strategy of the National Agency for Medicines and Medical Devices (2017-2020)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, convened on summons by the NAMMD President in the ordinary session of 26.06.2017, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government no. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Single Article – The Communication strategy of the National Agency for Medicines and Medical Devices (2017 – 2020) is approved.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Prof. Dr. Anca-Dana Buzoianu

ANNEX to SCD no. 1/26.06.2017

Please go to:

https://www.anm.ro/en/_/STRATEGII/Communication%20strategy_2017.pdf

DECISION

no. 2/26.06.2017

on adoption of the Guideline on Good Manufacturing Practice for Medicinal Products for human use

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, convened on summons by the NAMMD President in the ordinary session of 26.06.2017, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government no. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

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

Article 2. – On this Decision coming into force, Scientific Council Decision no. 23/03.07.2015 on adoption of the Guideline on Good Manufacturing Practice for Medicinal Products for human use is repealed.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Prof. Dr. Anca-Dana Buzoianu

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the document "The rules governing medicinal products in the European Union", Volume 4, Good manufacturing practice (GMP) Guidelines, published by the European Commission.

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

Therefore, for the Annex to this Decision, please see the "The rules governing medicinal products in the European Union", Volume 4, Good manufacturing practice (GMP) Guidelines, available at

https://ec.europa.eu/health/documents/eudralex/vol-4_en

Decision no. 3/26.06.2017
on amendment of SCD no. 19/12.08.2013 on approval of the Guideline on details concerning the various categories of variations to the terms of marketing authorisations and on their examination by the National Agency for Medicines and Medical Devices by the purely national procedure for authorisation of medicinal products for human use, in accordance with Regulation (EC) no. 1234/2008 of the Commission, as amended through Regulation (EU) no. 712/2012

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, setup on summons of the NAMMD President in the ordinary meeting of 26.06.2017, in accordance with Article 12 (5) of Government Decision no. 734 / 21.07.2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Art. 1. - Annex 2 to NAMMD Scientific Council Decision (SCD) no. 19/12.08.2013 on approval of the Guideline on details concerning the various categories of variations to the terms of marketing authorisations and on their examination by the National Agency for Medicines and Medical Devices by the purely national procedure for authorisation of medicinal products for human use is repealed, in accordance with Regulation (EC) no. 1234/2008 of the Commission, as amended through Regulation (EU) no. 712/2012.

Art. 2. – Under Article 14 of Annex to NAMMD SCD no. 19/12.08.2013, paragraph:

The EU application form for variations to a marketing authorisation for medicinal products (human and veterinary) translated into Romanian (Annex 2) is available on the NAMMD website under heading "Forms and fees".

is replaced with

The EU application form for variations to a marketing authorisation for medicinal products (human and veterinary) is available in the EudraLex Volume 2 B – Presentation and content of the dossier eSubmission: EU Electronic Application Forms (Module 1.2 application, variation and renewal form: https://ec.europa.eu/health/documents/eudralex/vol-2_en ..,

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Prof. Dr. Anca-Dana Buzoianu

Medicinal product batches recalled during the 2nd quarter of 2017

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Proposed action	Date of recall
1	ALUPIRIN 75 mg	gastroresistant tablets	75 mg	acid acetilsalicilic	Labormed Pharma SA	5040080401, 5040090402, 5050110480, 6010010095, 6010020096, 6060050729, 6060060730, 6080080960, 6080100961, 6080110983, 6080120984, 5050100479, 6040030419, 6040040420, 6080070957	During long-term stability trials, the product obtained one out-of-specification result under parameter "dissolution"	Voluntary recall and destruction	05.04.2017
2	LEVALOX 250 mg	film-coated tablets	250 mg	levofloxacin	Pharmathen SA GREECE/ KRKA DD Novo Mesto Slovenia	J66469	During accelerated stability trials, the product obtained one out-of-specification result under parameter "dissolution"	Voluntary recall and destruction	13.04.2017
3	THERAFLU EXTRA RACEALA SI GRIPA	powder for oral solution	650 mg/ 20mg/ 10mg	combinations	Famar, FRANCE/GSK Consumer Healthcare SRL, Romania	H4706, H4775, H4776, H4777, H4778, H5435, H5821, H5927, H5928, H5929, H5930, H5996, H6444, H6446, H6447, J0088, J0141	product whose one-year shelf life following approval of MA transfer from Novartis Consumer Health GmbH to GSK Consumer Healthcare SRL in accordance with Order of the Minister of Health no 1810/2006	Voluntary recall and destruction	13.04.2017

4	THERAFLU SINUS RACEALA SI GRIPA	powder for oral solution	650 mg/ 10mg	combinations (paracetamol+ fenilefrina)	Famar, FRANCE/GSK Consumer Healthcare SRL, Romania	H4547, H4774, H5720, H5721, H6062, H6063, H6085, H6086, H6065, H6087, H6204, H6205, H6209, H6502, H6504, H3988	product whose one-year shelf life following approval of MA transfer from Novartis Consumer Health GmbH to GSK Consumer Healthcare SRL in accordance with Order of the Minister of Health no 1810/2006 has expired	Recall and destruction	13.04.201 7
5	VENORUTON 300 mg	capsules	300 mg	troxerutin	Kemwell AB Suedia/GSK Consumer Healthcare SRL, Romania	VCA14015A	Product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval of a modificarilor la APP din 21.01.2013 si 17.04.2014	Recall and destruction	13.04.201 7
6	VOLTAREN EMULGEL 11.6 mg/g	gel	11.6 mg/g	diclofenac	Novartis Consumer Health GmbH, GERMANY/GSK Consumer Healthcare SRL Romania	W7392, W7393, W7394, W7395, W7396, W7397, W7398, W7399, W7400, W7401, W7402, W7403, W7404, W7405, W7406, W7407, W7408, W7409, W7410, W7411, W7412, W7413, WC368, WC369, WC370, WC671, WC672, WC673, W0036, W0037, W0038, W0039, W0040, W0041, W0042, W0043, W0044, W0045, W0046, W0047, W0048, W0049, W0050, WC363, WC364, WC365, WC366,	product whose one-year shelf life following approval of MA transfer from Novartis Consumer Health GmbH to GSK Consumer Healthcare SRL in accordance with Order of the Minister of Health no 1810/2006 has expired	Voluntary recall and destruction	13.04.201 7
7	VOLTAREN FORTE 23.2 mg/g	gel	23.2 mg/g	diclofenac	Novartis Consumer Health GmbH, GERMANY/GSK Consumer Healthcare SRL Romania	R02294B, R02295A,, R03222A, R03223A, R03982A, R04295A, R04899B, R04911A, R05477B, T00001A, T00002A, T00003A, T00741A, T00742A,	product whose one-year shelf life following approval of MA transfer from Novartis Consumer Health GmbH to GSK Consumer Healthcare SRL in accordance with Order	Voluntary recall and destruction	13.04.201 7

						T00743A, T00744A, T01491A, T01492A, T01493A, T01494A, T01495A	of the Minister of Health no 1810/2006 has expired		
8	PANADOL EXTRA	film-coated tablets	500mg/65 mg	combinations	GSK Dunganvan Ltd. Ireland/GSK Consumer Healthcare Great Britain	KW9H	product whose 2-year shelf life (as specified in Order of the Minister of Health no. 279/2005) following NAMMD approval of (on 03.05.2015) of amendments to MA no. 5550/2005/01-08 has expired	Voluntary recall and destruction	18.04.201 7
9	COLDREX MAXGRIP LEMON	powder for oral suspension		combinations	Smithkline Beecham SA SPAIN/Hipocrate 2000 SRL Romania	4609, 4613, 4614, 4620, 4626, 4627, 4628, 4631, 4654, 4656, 4657, 4658, 4660, 4662, 4661, 4663, 4664, 4665, 4666, 4667, 4669, 4670, 4671, 4673, 4674, 4675, 4802, 4803, 4804, 4805, 4814, 4815, 4818, 4819, 5016, 5017, 5018, 5019, 5027, 5028, 5029, 5030, 5031, 5032, 5033, 5034, 5005, 5036, 5038,5039, 5006, 5047, 5001, 5002, 5048, 5301, 5302, 5049, 5051, 5050, 5318, 5319, 5320, 5327, 5328, 5329, 5335, 5337, 5058, 5338, 5059, 5336, 6203, 6204, 6208, 6209, 6211	product whose one-year shelf life following approval of MA transfer from GSK Consumer Healthcare - Great Britain la Hipocrate 2000 SRL in accordance with Order of the Minister of Health no 1810/2006 has expired	Voluntary recall and destruction	09.05.201 7

10	COLDREX LEMON	powder for oral suspension		combinations	Smithkline Beecham SA SPAIN/Hipocrate 2000 SRL Romania	4007, 4601, 4605, 4606, 4607, 4613, 4614, 4615, 4618, 4624, 4501, 4504, 4505, 4652, 4653, 4655, 4658, 4659, 4660, 4801, 4803, 4804, 5002, 5005, 5006, 5011, 5016, 5017, 5022, 5005, 5006, 5011, 5016, 5017, 5027, 5039, 5057, 6201, 6202	product whose one-year shelf life following approval of MA transfer from GSK Consumer Healthcare - Great Britain la Hipocrate 2000 SRL in accordance with Order of the Minister of Health no 1810/2006 has expired	Voluntary recall and destruction	09.05.2017
11	COLDREX HONEY & LEMON	powder for oral suspension	750mg/60mg/10mg	combinations	Smithkline Beecham SA SPAIN/Hipocrate 2000 SRL Romania	5002, 5006, 5009, 5024, 5025	product whose one-year shelf life following approval of MA transfer from GSK Consumer Healthcare - Great Britain la Hipocrate 2000 SRL in accordance with Order of the Minister of Health no 1810/2006 has expired	Voluntary recall and destruction	09.05.2017
12	COLDREX JUNIOR 250mg/100mg/5mg	film-coated tablets	250mg/100mg/5mg	combinations	Famar SA GREECE/Hipocrate 2000 SRL Romania	4004, 4613, 4635, 4657, 4683, 5820, 5827, 5830, 5901, 5914, 5921, 6212	product whose one-year shelf life following approval of MA transfer from GSK Consumer Healthcare - Great Britain la Hipocrate 2000 SRL in accordance with Order of the Minister of Health no 1810/2006 has expired	Voluntary recall and destruction	09,05,2017
13	COLDREX JUNIOR HOT REM 300mg/20mg/5mg	powder for oral suspension	300mg/20mg/5mg	combinations	Smithkline Beecham SA SPAIN/Hipocrate 2000 SRL Romania	4802, 4804, 4805, 4807, 4810, 4701, 5001, 5002, 5004, 5007, 5010, 5013, 6202, 6201	product whose one-year shelf life following approval of MA transfer from GSK Consumer Healthcare - Great Britain la Hipocrate 2000 SRL in accordance with Order of the Minister of Health no 1810/2006 has expired	Voluntary recall and destruction	09,05,2017

14	BLEOMYCIN MYLAN 15000 IU	powder and solvent for solution for injection	15000 IU	bleomicina	Parasfarma SL SPAIN (solvent), Nilppon Kayaku Co.Ltd.Japan (fl cu bleomicin)/Mylan Pharmaceuticals SL	J8J4	The presence of glass particles in the powder was signaled	Recall	09.05.2017
15	ALBIOMIN 50g/l, 200g/l	solution for infusion	50g/l, 200g/l	albumina umana	Biotest Pharma GmbH Germany	1133044	Product possibly contaminated with ethylene glycol	Recall	09.05.2017
16	SEVO-ANESTERAN	liquid for inhalation vapours		sevofluran	Rompharm Company SRL	1617101	Some vials have a connecting ring with a valve fixed backward on the vial's opening, so that the valve and the ring do not match. Thus, the vials cannot be connected to the medical device for administration	Recall, check of all vials and marketing of corresponding vials only	15.05.2017
17	SINECOD 7.5mg/5ml	syrup	7.5mg/5ml	butamirat	Novartis Consumer Health GmbH, GERMANY/GSK Consumer Healthcare SRL Romania	M02647A, M03693A, N03483A, N05151A, P01933A, P02959B, P04920A, P05753A, R02075A, R03174A	Product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval of (on 04.05.2015) of amendments to MA no. 5314/2005/01	Voluntary recall and destruction	17.05.2017
18	DERMODRIN	ointment	20 mg/g	Diphenhydramine	Pharmazeutische Fabrik Montavit GES. M.B.H., Austria	1097, 1103, 1108	Product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following reauthorisation (on 08.05.2015)	Voluntary recall and destruction	17.05.2017

19	OTOCALM	ear drops	6.25g/ 1.5g/ 100 ml	combinations	Pharco Egipt/Pharco Impex 93 SRL	toate seriile	product whose MA validity has expired, as of 28.03.2016	Voluntary recall and destruction	22.05.201 7
20	REUPROFEN 400 mg	film-coated tablets	400 mg	ibuprofen	AC Helcor SRL	2480115	Out-of-specification results for parameter „Chemically related substances, g%, other impurities"	Recall and destruction	24.05.201 7
21	INKONTAN 15 mg	film-coated tablets	15 mg	trospium	Pharmazeutische Fabrik Montavit GES. M.B.H., Austria	61781, 62137, 63238, 63674, 64299, 64715, 65685, 66753, 66754,	Product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following reauthorisation (on 25.05.2015)	Voluntary recall and destruction	06.06.201 7
22	INKONTAN 30 mg	film-coated tablets	30 mg	trospium	Pharmazeutische Fabrik Montavit GES. M.B.H., Austria	61602, 62143, 63250, 63618, 65358, 66994, 66994a	Product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following reauthorisation (on 25.05.2015)	Voluntary recall and destruction	06.06.201 7
23	HYCANTIN 1 mg	capsules	1 mg	topotecam	GSK Manufacturing SPA ITALY/ Novartis Europharm Ltd Great Britain	5501, 4504B, 5503, 5503A, 5505, 5506A, 5506, 5506B	product whose CIM code validity W531777001 has expired as of 01.05.2017	Voluntary recall and destruction	12.06.201 7
24	REVOLADE 25mg	film-coated tablets	25 mg	eltrombopag	Glaxo Operations UK Ltd/ Novartis Europharm Ltd Great Britain	F48V, YR2X, LU9K, RR4B	product whose CIM code validity W55492002 has expired as of 01.05.2017	Voluntary recall and destruction	12.06.201 7

25	REVOLADE 50mg	film-coated tablets	50mg	eltrombopag	Glaxo Operations UK Ltd/ Novartis Europharm Ltd Great Britain	RB4F, FT9S, J56F, UD6Y	product whose CIM code validity W55493002 has expired as of 01.05.2017	Voluntary recall and destruction	12.06.201 7
26	TAFINLAR 50mg	capsules	50 mg	dabrafenib	Glaxo Wellcome SA SPAIN/ Novartis Europharm Ltd Great Britain	YM9P	product whose CIM code validity W60246002 has expired as of 01.05.2017	Voluntary recall and destruction	12.06.201 7
27	TAFINLAR 75 mg	capsules	75 mg	dabrafenib	Glaxo Wellcome SA SPAIN/ Novartis Europharm Ltd Great Britain	M83U, RD6N, U94S, U94T, WP5B	product whose CIM code validity W60247002 has expired as of 01.05.2017	Voluntary recall and destruction	12.06.201 7
28	VOTRIENT 400 mg	film-coated tablets	400 mg	pazopanib	Glaxo Operations UK Ltd/ Novartis Europharm Ltd Great Britain	MY2A, P64U, TL7M, TA5T, VN2D	product whose CIM code validity W55765002 has expired as of 01.05.2017	Voluntary recall and destruction	12.06.201 7
29	OMERAN 20 mg	gastroresistant capsules	20 mg	omeprazol	Laboratorios Linconsa SA SPAIN/ GSK SRL Romania	LC21804, LC21812, LC24320, LC24336, LC25065, LC24986, LC25394, LC25393, LC25202, LC5054	Product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval (on 28.04.2015) of amendments to MA no. 7785/2006/02	Voluntary recall and destruction	12.06.201 7
30	OROFAR 1 mg/ 1 mg	orodispersible tablets	1 mg/ 1mg	combinations	Kemwell AB Suedia/GSK Consumer Healthcare SRL, Romania	ORA15011, ORA15012, ORA15048, ORA15049, ORA15072, ORA15073, ORA15074	Product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following reauthorisation (on 28.05.2015)	Voluntary recall and destruction	15.06.201 7

31	PROPRA- NOLOL 40 mg	tablets	40 mg	propranolol	Sintofarm SA	W0317008	Lack of two blisters from the secondary packaging in 7 units comerciale	Voluntary recall and repackaging	15.06.2017
32	MAALOX 35mg/40mg/ ml	oral suspension	35mg/ 40mg/ml	combinations	TAKEDA GmbH Germany	267999	out-of-specification results for parameters: "contains Methyl 4-hydroxybenzoate "	Voluntary recall and destruction	15.06.2017
33	MUCOSOLV AN 15 mg	oral gum	15 mg	ambroxol	Boehringer Ingelheim Int GmbH Germany	toate seriile	out-of-specification results during stability trials performed on batches which have not been imported in Romania	Voluntary recall (as a precaution) and destruction	22.06.2017
34	WARTEC 1.5 mg/g	cream	1.5 mg/g	podophyllotoxin	Stiefel Lab (Ireland)Ltd/ GSK SRL Romania	893R	Product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval of (29.05.2015) of amendments to MA no. 7372/2006/01-02	Voluntary recall and destruction	22.06.2017
35	TEZEO HCT 80mg/25mg	tablets	80mg/ 25mg	combinations (telmisartan+ hydrochlorothiazide)	Zentiva S.A. Romania/Zentiva K.S. Czech Republic	2630216	product whose out-of-specification results were obtained during stability trials performed under normal conditions	Voluntary recall (as a precaution) and destruction	22.06.2017
36	CATHEJELL cu LIDOCAINA	urethral gel		combinations	Pharmazeutische Fabrik Montavit GES. M.B.H., Austria	2951	Certain secondary packages do not have the batch and shelf life imprinted	Voluntary recall and destruction	23.06.2017

37	FORTUM 1g	powder for solution for injection	1 g	ceftazidim	Glaxo WellcomeUK Ltd Great Britain	U952, V086, V155, V532	product whose MA validity has expired as of 15.06.2016	Voluntary recall and destruction	28.06.2017
38	IRBESARTAN HF 150 mg	film-coated tablets	150 mg	irbesartan	Stada Arzneimittel AG GERMANY/ Stada Hemofarm SRL Romania	44420	Product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following reauthorisation	Voluntary recall and destruction	29.06.2017
39	IRBESARTAN HF 300 mg	film-coated tablets	300 mg	irbesartan	Stada Arzneimittel AG GERMANY/ Stada Hemofarm SRL Romania	44537	Product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following reauthorisation	Voluntary recall and destruction	29.06.2017

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 1st quarter of 2017

During the 1st quarter of 2017, **179** marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

A02 - DRUGS FOR ACID RELATED DISORDERS
A05 – BILE AND LIVER THERAPY
A07 - ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS
A09 - DIGESTIVES, INCL. ENZYMES
A10 - DRUGS USED IN DIABETES
A12 - MINERAL SUPPLEMENTS
B01 - ANTITHROMBOTIC AGENTS
B02 – ANTIHEMORRHAGICS
B03 - ANTIANEMIC PREPARATIONS
BO6.- OTHER HEMATOLOGICAL AGENTS
C01 – CARDIAC THERAPY
C02.- ANTIHYPERTENSIVES
C03 - DIURETICS
C07 - BETA BLOCKING AGENTS
C08 - CALCIUM CHANNEL BLOCKERS
C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
D01 – ANTIFUNGALS FOR DERMATOLOGICAL USE
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
J06 – IMMUNE SERA AND IMMUNOGLOBULINS
L01 - ANTINEOPLASTIC AGENTS
L02 - ENDOCRINE THERAPY
L04- IMMUNOSUPPRESSANTS
M01 - ANTI-INFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
M05 - DRUGS FOR TREATMENT OF BONE DISEASES
N02 - ANALGESICS
N03 - ANTIEPILEPTICS
N04 - ANTI-PARKINSON DRUGS
N05 - PSYCHOLEPTICS
N06 - PSYCHOANALEPTICS
R03 - DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

R05 - COUGH AND COLD PREPARATIONS
R07 – OTHER RESPIRATORY SYSTEM PRODUCTS
S01 - OPHTHALMOLOGICALS
V01 - ALLERGENS
V03 - ALL OTHER THERAPEUTIC PRODUCTS
XRN – HOMEOPATHIC MEDICINAL PRODUCTS

Medicinal products authorised for marketing during the 1st quarter of 2017

INN	Invented name	Pharmaceutical form	Strength	MAH	Country	MA number		
ABACAVIRUM+ LAMIVUDINUM	ABACAVIR/ LAMIVUDINA SANDOZ 600 mg/300mg	film-coated tablets	600mg/ 300mg	SANDOZ S.R.L.	ROMANIA	9615	2017	01
ACID OMEGA-3- ESTERI ETILICI 90	OMACOR 1000 mg	soft capsules	1000mg	PRONOVA BIOPHARMA NORGE AS	NORWAY	9639	2017	01
ACIDUM ACETYLSALICYLICUM	THROMBO ASS 50 mg	gastroresistant tablets	50mg	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	9657	2017	01
ACIDUM ACETYLSALICYLICUM	THROMBO ASS 100 mg	gastroresistant tablets	100mg	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	9659	2017	01
ACIDUM ACETYLSALICYLICUM	THROMBO ASS 75 mg	gastroresistant tablets	75mg	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	9658	2017	01
ACIDUM ACETYLSALICYLICUM	ASPITOR CARDIO 75 mg	gastroresistant tablets	75mg	TORRENT PHARMA S.R.L.	ROMANIA	9700	2017	01
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC SANDOZ 75 mg	gastroresistant tablets	75mg	SANDOZ S.R.L.	ROMANIA	9721	2017	01

ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC SANDOZ 100 mg	gastroresistant tablets	100mg	SANDOZ S.R.L.	ROMANIA	9722	2017	01
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC KRKA 75 mg	gastroresistant tablets	75mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9753	2017	01
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC KRKA 100 mg	gastroresistant tablets	100mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9754	2017	01
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC KRKA 160 mg	gastroresistant tablets	160mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9755	2017	01
ACIDUM ACETYLSALICYLICUM	VASOPIRIN 75 mg	gastroresistant tablets	75mg	PHARMASWISS CESKA REPUBLIKA S.R.O.	THE CZECH REPUBLIC	9631	2017	01
ACIDUM ACETYLSALICYLICUM	VASOPIRIN 100 mg	gastroresistant tablets	100mg	PHARMASWISS CESKA REPUBLIKA S.R.O.	THE CZECH REPUBLIC	9632	2017	01
ACIDUM GADOTERICUM	DOTAGRAF 0.5 mmol/ml	solution for injection in multidose vial	0.5mmol/ml	BAYER PHARMA AG	GERMANY	9788	2017	01
ACIDUM GADOTERICUM	DOTAGRAF 0.5 mmol/ml	solution for injection in single dose vial	0.5mmol/ml	BAYER PHARMA AG	GERMANY	9787	2017	01
ACIDUM IBANDRONICUM	HOLMEVIS 50 mg	film-coated tablets	50mg	EGIS PHARMACEUTICALS PLC	HUNGARY	9840	2017	01
ACIDUM IBANDRONICUM	HOLMEVIS 1 mg/1 ml	concentrate for solution for infusion	1mg/1ml	EGIS PHARMACEUTICALS PLC	HUNGARY	9837	2017	01

ACIDUM IBANDRONICUM	HOLMEVIS 2 mg/2 ml	concentrate for solution for infusion	2mg/2ml	EGIS PHARMACEUTICALS PLC	HUNGARY	9838	2017	01
ACIDUM IBANDRONICUM	HOLMEVIS 6 mg/6 ml	concentrate for solution for infusion	6mg/6ml	EGIS PHARMACEUTICALS PLC	HUNGARY	9839	2017	01
ACIDUM MEFENAMICUM	VIDAN 500 mg	film-coated tablets	500mg	VIANEX S.A.	GREECE	9616	2017	01
ACITRETINUM	NEOTIGASON 10 mg	capsules	10mg	ACTAVIS GROUP PTC EHF	ICELAND	9699	2017	01
ALPROSTADILUM	ALPROSTADIL "REMEDIA" 500 µg	concentrate for solution for infusion	500µg	FARMACEUTICA REMEDIA DISTRIBUTION& LOGISTICS S.R.L.	ROMANIA	9608	2017	01
AMBROXOLUM	AMBROXOL-RICHTER 30 mg/5 ml	syrup	30mg/5ml	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9749	2017	01
AMBROXOLUM	FLAVAMED 60 mg	effervescent tablets	60mg	BERLIN-CHEMIE AG (MENARINI GROUP)	GERMANY	9646	2017	01
AMISULPRIDUM	SOLIAN 200 mg	tablets	200mg	SANOFI-AVENTIS FRANCE	FRANCE	9817	2017	01
AMLODIPINUM	AMLOHEXAL 5 mg	tablets	5mg	HEXAL AG	GERMANY	9758	2017	01
AMLODIPINUM	AMLOHEXAL 10 mg	tablets	10mg	HEXAL AG	GERMANY	9759	2017	01
AMOXICILLINUM	MOXILEN 500 mg	capsules	500mg	MEDOCHEMIE LTD.	CYPRUS	9697	2017	01
AMOXICILLINUM	DUOMOX 250 mg	tablets for oral dispersion	250mg	ASTELLAS PHARMA EUROPE B.V.	HOLLAND	9595	2017	01

AMOXICILLINUM	DUOMOX 500 mg	tablets for oral dispersion	500mg	ASTELLAS PHARMA EUROPE B.V.	HOLLAND	9596	2017	01
AMOXICILLINUM	DUOMOX 750 mg	tablets for oral dispersion	750mg	ASTELLAS PHARMA EUROPE B.V.	HOLLAND	9597	2017	01
AMOXICILLINUM	DUOMOX 1000 mg	tablets for oral dispersion	1000mg	ASTELLAS PHARMA EUROPE B.V.	HOLLAND	9598	2017	01
ATOMOXETINUM	BITINEX 10 mg	capsules	10mg	EGIS PHARMACEUTICALS P.L.C.	HUNGARY	9714	2017	01
ATOMOXETINUM	BITINEX 18 mg	capsules	18mg	EGIS PHARMACEUTICALS P.L.C.	HUNGARY	9715	2017	01
ATOMOXETINUM	BITINEX 25 mg	capsules	25mg	EGIS PHARMACEUTICALS P.L.C.	HUNGARY	9716	2017	01
ATOMOXETINUM	BITINEX 40 mg	capsules	40mg	EGIS PHARMACEUTICALS P.L.C.	HUNGARY	9717	2017	01
ATOMOXETINUM	BITINEX 60 mg	capsules	60mg	EGIS PHARMACEUTICALS P.L.C.	HUNGARY	9718	2017	01
ATOMOXETINUM	BITINEX 80 mg	capsules	80mg	EGIS PHARMACEUTICALS P.L.C.	HUNGARY	9719	2017	01
ATOMOXETINUM	BITINEX 100 mg	capsules	100mg	EGIS PHARMACEUTICALS P.L.C.	HUNGARY	9720	2017	01

ATOMOXETINUM	ATOMOXETINA SANDOZ 10 mg	capsules	10mg	SANDOZ S.R.L.	ROMANIA	9670	2017	01
ATOMOXETINUM	ATOMOXETINA SANDOZ 18 mg	capsules	18mg	SANDOZ S.R.L.	ROMANIA	9671	2017	01
ATOMOXETINUM	ATOMOXETINA SANDOZ 25 mg	capsules	25mg	SANDOZ S.R.L.	ROMANIA	9672	2017	01
ATOMOXETINUM	ATOMOXETINA SANDOZ 40 mg	capsules	40mg	SANDOZ S.R.L.	ROMANIA	9673	2017	01
ATOMOXETINUM	ATOMOXETINA SANDOZ 60 mg	capsules	60mg	SANDOZ S.R.L.	ROMANIA	9674	2017	01
ATOMOXETINUM	ATOMOXETINA SANDOZ 80 mg	capsules	80mg	SANDOZ S.R.L.	ROMANIA	9675	2017	01
BENDAMUSTINUM	BENDAMUSTINA KABI 2.5 mg/ml	powder for concentrate for solution for infusion	2.5mg/ml	FRESENIUS KABI ONCOLOGY PLC.	GREAT BRITAIN	9853	2017	01
BENZYDAMINUM	TANTUM VERDE CU AROMA FROMMAIE 3 mg	lozenges	3mg	ANGELINI PHARMA ÖSTERREICH GMBH	AUSTRIA	9814	2017	01
BENZYDAMINUM	TANTUM VERDE 1.5 mg/ml	gargling solution	1.5mg/ml	ANGELINI PHARMA ÖSTERREICH GMBH	AUSTRIA	9734	2017	01
BETAHISTINUM	VERTIMED 8 mg	tablets	8mg	MEDOCHEMIE LTD.	CYPRUS	9723	2017	01
BETAHISTINUM	VERTIMED 16 mg	tablets	16mg	MEDOCHEMIE LTD.	CYPRUS	9724	2017	01
BETAHISTINUM	VERTIMED 24 mg	tablets	24mg	MEDOCHEMIE LTD.	CYPRUS	9725	2017	01
BETAMETHASONUM	DIPROPHOS	suspension for injection	7mg/ml	MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	9844	2017	01

BISOPROLOLUM	BISOPROLOL FUMARAT AUROBINDO 5 mg	film-coated tablets	5mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	9601	2017	01
BISOPROLOLUM	BISOPROLOL FUMARAT AUROBINDO 10 mg	film-coated tablets	10mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	9602	2017	01
BISOPROLOLUM	BISOPROLOL FUMARAT SANDOZ 5 mg	film-coated tablets	5mg	SANDOZ S.R.L.	ROMANIA	9739	2017	01
BISOPROLOLUM	BISOPROLOL FUMARAT SANDOZ 10 mg	film-coated tablets	10mg	SANDOZ S.R.L.	ROMANIA	9740	2017	01
BORTEZOMIBUM	BORTEZOMIB SANDOZ 3.5 mg	powder for solution for injection	3.5mg	SANDOZ S.R.L.	ROMANIA	9756	2017	01
BORTEZOMIBUM	BORTEZOMIB HETERO 3.5 mg	powder for solution for injection	3.5mg	HETERO EUROPE S.L.	SPAIN	9691	2017	01
BORTEZOMIBUM	BORTEZOMIB KOANAA 3.5 mg	powder for solution for injection	3.5mg	KOANAA HEALTHCARE LIMITED	GREAT BRITAIN	9692	2017	01
BRINZOLAMIDUM	BRINZOLAMIDA SANDOZ 10 mg/ml	eye drops, suspension	10mg/ml	SANDOZ S.R.L.	ROMANIA	9708	2017	01
CARBOCISTEINUM	RHINATHIOL 100 mg/5 ml PENTRU COPII	syrup	100 mg/5 ml	SANOFI ROMANIA S.R.L.	ROMANIA	9827	2017	01
CASPOFUNGINUM	CASPOFUNGINA MYLAN 50 mg	powder for concentrate for solution for infusion	50mg	MYLAN S.A.S.	FRANCE	9741	2017	01
CASPOFUNGINUM	CASPOFUNGINA MYLAN 70 mg	powder for concentrate for solution for infusion	70mg	MYLAN S.A.S.	FRANCE	9742	2017	01

CASPOFUNGINUM	CASPOFUNGINA ZENTIVA 50 mg	powder for concentrate for solution for infusion	50mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	9797	2017	01
CASPOFUNGINUM	CASPOFUNGINA ZENTIVA 70 mg	powder for concentrate for solution for infusion	70mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	9798	2017	01
CASPOFUNGINUM	CASPOFUNGINA ATB 50 mg	powder for concentrate for solution for infusion	50mg	ANTIBIOTICE S.A.	ROMANIA	9764	2017	01
CASPOFUNGINUM	CASPOFUNGINA ATB 70 mg	powder for concentrate for solution for infusion	70mg	ANTIBIOTICE S.A.	ROMANIA	9765	2017	01
CASPOFUNGINUM	DALVOCANS 50 mg	powder for concentrate for solution for infusion	50mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	9689	2017	01
CASPOFUNGINUM	DALVOCANS 70 mg	powder for concentrate for solution for infusion	70mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	9690	2017	01
CASPOFUNGINUM	CASPOFUNGINA RATIOPHARM 50 mg	powder for concentrate forsolution for infusion	50mg	RATIOPHARM GMBH	GERMANY	9850	2017	01
CASPOFUNGINUM	CASPOFUNGINA RATIOPHARM 70 mg	powder for concentrate forsolution for infusion	70mg	RATIOPHARM GMBH	GERMANY	9851	2017	01
CEFALEXINUM	OSPEXIN 1000 mg	film-coated tablets	1000mg	SANDOZ GMBH	AUSTRIA	9816	2017	01

CEFALEXINUM	OSPEXIN 500 mg	film-coated tablets	500mg	SANDOZ GMBH	AUSTRIA	9815	2017	01
CEFIXIMUM	CEFIXIMA AUROBINDO 200 mg	film-coated tablets	200mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	9576	2017	01
CEFIXIMUM	CEFIXIMA AUROBINDO 400 mg	film-coated tablets	400mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	9577	2017	01
CEFUROXIMUM	CEFUROXIMA PANPHARMA 1.5 g	powder for solution for infusion i.v.	1.5g	PANPHARMA	FRANCE	9663	2017	01
CEFUROXIMUM	CEFUROXIMA PANPHARMA 750 mg	powder for suspension for injection i.m./solution for injection i.v.	750mg	PANPHARMA	FRANCE	9662	2017	01
CINACALCETUM	CINACALCET ACCORD 30 mg	film-coated tablets	30mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9676	2017	01
CINACALCETUM	CINACALCET ACCORD 60 mg	film-coated tablets	60mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9677	2017	01
CINACALCETUM	CINACALCET ACCORD 90 mg	film-coated tablets	90mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9678	2017	01
CLARITHROMYCINUM	CLARITROMICINA AUROBINDO 250 mg	film-coated tablets	250mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	9769	2017	01
CLARITHROMYCINUM	CLARITROMICINA AUROBINDO 500 mg	film-coated tablets	500mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	9770	2017	01
CLOBETASOLUM	CLOBETAZOL ATB 0.5 mg/g	cream	0.5mg/g	ANTIBIOTICE S.A.	ROMANIA	9832	2017	01

CLOPIDOGRELUM	CLOPIDIX 75 mg	film-coated tablets	75mg	STADA HEMOFARM SRL	ROMANIA	9593	2017	01
CLOTRIMAZOLUM	CANESTEN GYN UNO 500 mg	soft vaginal capsules	500 mg	BAYER S.R.L.	ROMANIA	9603	2017	01
COMBINATIONS	MOBILAT	cream		STADA ARZNEIMITTEL AG	GERMANY	9618	2017	01
COMBINATIONS	MOBILAT	gel		STADA ARZNEIMITTEL AG	GERMANY	9617	2017	01
COMBINATIONS	TOTHEMA	oral solution		LABORATOIRE INNOTECH INTERNATIONAL	FRANCE	9694	2017	01
COMBINATIONS	DALERON COLD3	film-coated tablets		KRKA, D.D., NOVO MESTO	SLOVENIA	9823	2017	01
COMBINATIONS	SARIDON	tablets		BAYER S.R.L.	ROMANIA	9813	2017	01
COMBINATIONS	FERRETAB 50 mg+0.5 mg	prolonged-release capsules	50mg+0.5mg	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	9701	2017	01
COMBINATIONS	COLDREX JUNIOR 250 mg/100 mg/5 mg	film-coated tablets	250mg/ 100mg/5mg	HIPOCRATE 2000 S.R.L.	ROMANIA	9709	2017	01
COMBINATIONS	OROFAR 2 mg/ml+1.5 mg/ml	oromucosal spray, solution	2mg/ml+ 1.5mg/ml	GLAXOSMITHKLINE CONSUMER HEALTHCARE S.R.L.	ROMANIA	9619	2017	01
COMBINATIONS	VIBROCIL 2.5 mg/0.25 mg/ml	nasal spray, solution	2.5mg/ 0.25 mg/ml	GLAXOSMITHKLINE CONSUMER HEALTHCARE S.R.L.	ROMANIA	9848	2017	01
COMBINATIONS	COLDREX JUNIOR HOTREM	powder for oral suspension	300mg+ 20mg+5mg	HIPOCRATE 2000 S.R.L.	ROMANIA	9664	2017	01

	300 mg+20 mg+5 mg							
COMBINATIONS	RINOFLUIMUCIL 10 mg+5 mg/ml	nasal spray, solution	10mg+ 5mg/ml	ZAMBON S.P.A.	ITALY	9693	2017	01
COMBINATIONS	SEPTOLETE	lozenges		KRKA D.D. NOVO MESTO	SLOVENIA	9635	2017	01
COMBINATIONS	SEPTOLETE D	lozenges		KRKA D.D. NOVO MESTO	SLOVENIA	9636	2017	01
COMBINATIONS	RUBJOVIT	eye drops, solution		SIFI S.P.A.	ITALY	9696	2017	01
COMBINATIONS	COLDREX HONEY & LEMON 750 mg+60 mg+10 mg	powder for oral suspension	750mg+ 60mg+10mg	HIPOCRATE 2000 S.R.L.	ROMANIA	9710	2017	01
COMBINATIONS	COLDREX 500 mg+25 mg+5 mg	film-coated tablets	500mg+ 25mg+5mg	HIPOCRATE 2000 S.R.L.	ROMANIA	9665	2017	01
COMBINATIONS	ZIFEX COMPLEX	ovules		ANTIBIOTICE S.A.	ROMANIA	9599	2017	01
COMBINATIONS	SOLPADEINE EXTRA 500 mg/12.8 mg/30 mg	effervescent tablets	500mg/ 12.8mg/ 30mg	HIPOCRATE 2000 S.R.L.	ROMANIA	9796	2017	01
COMBINATIONS (ETINILESTRADIOLUM + DROSPIRENONUM)	DROSETIL 0.02 mg/3 mg	film-coated tablets	0.02mg/3mg	EXELTIS MAGYARORSZAG KFT	HUNGARY	9679	2017	01
COMBINATIONS (ETINILESTRADIOLUM + DROSPIRENONUM)	DROSETIL 0.03 mg/3 mg	film-coated tablets	0.03mg/3mg	EXELTIS MAGYARORSZAG KFT	HUNGARY	9680	2017	01
COMBINATIONS (PARACETAMOLUM + ACIDUM ASCORBICUM)	DALERON C 500 mg/20 mg	granules for oral solution	500mg/ 20mg	KRKA, D.D. NOVO MESTO	SLOVENIA	9822	2017	01
COMBINATIONS (PARACETAMOLUM+ ACIDUM ASCORBICUM)	DALERON C JUNIOR 120mg/10mg	granules for oral solution	120mg/ 10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9828	2017	01

COMBINATIONS (AMLODIPINUM+ VALSARTANUM)	BEVACOMB 5 mg/80mg	film-coated tablets	5mg/80mg	ACTAVIS GROUP PTC EHF	ICELAND	9726	2017	01
COMBINATIONS (AMLODIPINUM+ VALSARTANUM)	BEVACOMB 5 mg/160mg	film-coated tablets	5mg/ 160mg	ACTAVIS GROUP PTC EHF	ICELAND	9727	2017	01
COMBINATIONS (AMLODIPINUM+ VALSARTANUM)	BEVACOMB 10 mg/160mg	film-coated tablets	10mg/ 160mg	ACTAVIS GROUP PTC EHF	ICELAND	9728	2017	01
COMBINATIONS (BISOPROLOLUM+ HYDROCHLOROTHIAZIDUM)	LODOZ 10 mg/6.25mg	film-coated tablets	10 mg/ 6.25mg	MERCK KGAA	GERMANY	9843	2017	01
COMBINATIONS (BISOPROLOLUM+ HYDROCHLOROTHIAZIDUM)	LODOZ 5mg/6.25mg	film-coated tablets	5mg/ 6.25mg	MERCK KGAA	GERMANY	9842	2017	01
COMBINATIONS (BISOPROLOLUM+ HYDROCHLOROTHIAZIDUM)	LODOZ 2.5mg/6.25mg	film-coated tablets	2.5mg/ 6.25mg	MERCK KGAA	GERMANY	9841	2017	01
COMBINATIONS (CANDESARTANUM CILEXETIL+ AMLODIPINUM)	FRAMSYL	capsules	8mg/5mg	SANDOZ S.R.L.	ROMANIA	9566	2017	01
COMBINATIONS (CANDESARTANUM CILEXETIL+ AMLODIPINUM)	FRAMSYL	capsules	16mg/5mg	SANDOZ S.R.L.	ROMANIA	9567	2017	01
COMBINATIONS (CANDESARTANUM CILEXETIL+ AMLODIPINUM)	FRAMSYL	capsules	8mg/10mg	SANDOZ S.R.L.	ROMANIA	9568	2017	01
COMBINATIONS (CANDESARTANUM CILEXETIL+ AMLODIPINUM)	FRAMSYL	capsules	16mg/10mg	SANDOZ S.R.L.	ROMANIA	9569	2017	01
COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	CARIVALAN 6.25 mg/5 mg	film-coated tablets	6.25mg/ 5mg	LES LABORATOIRES SERVIER	FRANCE	9781	2017	01

COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	CARIVALAN 6.25 mg/7.5 mg	film-coated tablets	6.25mg/ 7.5mg	LES LABORATOIRES SERVIER	FRANCE	9782	2017	01
COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	CARIVALAN 12.5 mg/5 mg	film-coated tablets	12.5mg/ 5mg	LES LABORATOIRES SERVIER	FRANCE	9783	2017	01
COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	CARIVALAN 12.5 mg/7.5 mg	film-coated tablets	12.5mg/ 7.5mg	LES LABORATOIRES SERVIER	FRANCE	9784	2017	01
COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	CARIVALAN 25 mg/5 mg	film-coated tablets	25mg/5mg	LES LABORATOIRES SERVIER	FRANCE	9785	2017	01
COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	CARIVALAN 25 mg/7.5 mg	film-coated tablets	25mg/ 7.5mg	LES LABORATOIRES SERVIER	FRANCE	9786	2017	01
COMBINATIONS (DESOGESTRELUM+ ETINILESTRADIOLUM)	NOVYNETTE 0.15 mg+0.02 mg	film-coated tablets	0.15mg+ 0.02mg	GEDEON RICHTER PLC.	HUNGARY	9812	2017	01
COMBINATIONS (DESOGESTRELUM+ ETINILESTRADIOLUM)	DESORELLE 0.15 mg+0.03 mg	film-coated tablets	0.15mg+ 0.03mg	GEDEON RICHTER PLC.	HUNGARY	9811	2017	01
COMBINATIONS (DIENOGESTUM+ ETINILESTRADIOLUM)	LISA 2 mg/0.03 mg	film-coated tablets	2mg/ 0.03mg	LABORATORIOS LEON FARMA, S.A.	SPAIN	9578	2017	01
COMBINATIONS (ETINILESTRADIOLUM + DROSPIRENONUM)	DROSPIRENONA/ETINILE STRADIOL SANDOZ 0.02mg+3mg	film-coated tablets	0.02mg+ 3mg	SANDOZ S.R.L.	ROMANIA	9757	2017	01
COMBINATIONS (FLUOCINOLONUM+ DEXPANTHENOLUM)	FLUOCINOLON D FITERMAN 0.25 mg+50 mg/g	cream	0.25mg+ 50mg/g	FITERMAN PHARMA S.R.L.	ROMANIA	9831	2017	01
COMBINATIONS (FLUOCINOLONUM+ GENTAMICINUM)	FLUOCINOLON G FITERMAN 0.25 mg/+1 mg/g	cream	0.25mg/+ 1mg/g	FITERMAN PHARMA S.R.L.	ROMANIA	9830	2017	01

COMBINATIONS (GESTODENUM+ ETINILESTRADIOLUM)	MINELLA 60 micrograms/15micrograms	film-coated tablets	60micrograms/ 15micrograms	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9801	2017	01
COMBINATIONS (LATANOPROSTUM+ TIMOLOLUM)	LATANOPROST/TIMOLOL SANDOZ 50 micrograms/5 mg/ml	eye drops, solution	50micrograms/ 5mg/ml	SANDOZ S.R.L.	ROMANIA	9600	2017	01
COMBINATIONS (LEVONORGESTRELUM+ ETINILESTRADIOLUM)	ARIADNE 125 micrograms/30 micrograms	lozenges	125micrograms/ 30micrograms	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9643	2017	01
COMBINATIONS (OXICODONUM+ NALOXONUM)	TARGIN 60 mg/30 mg	prolonged- release tablets	60mg/ 30mg	MUNDIPHARMA GESELLSCHAFT M.B.H.	AUSTRIA	9735	2017	01
COMBINATIONS (OXICODONUM+ NALOXONUM)	TARGIN 80 mg/40 mg	prolonged- release tablets	80mg/ 40mg	MUNDIPHARMA GESELLSCHAFT M.B.H.	AUSTRIA	9736	2017	01
COMBINATIONS (PARACETAMOLUM + CODEINUM)	SOLPADEINE DUO 500 mg/12.8 mg	film-coated tablets	500mg/ 12.8mg	HIPOCRATE 2000 S.R.L.	ROMANIA	9795	2017	01
COMBINATIONS (PARACETAMOLUM+ CAFEINUM)	SOLPADEINE PLUSCAF 500 mg/65 mg	effervescent tablets	500mg/ 65mg	HIPOCRATE 2000 S.R.L.	ROMANIA	9649	2017	01
COMBINATIONS (PARACETAMOLUM+ PHENYLEPHRINUM)	THERAFLU SINUS RACEALA SI GRIPA 650 mg/10 mg	powder for oral solution	650mg/ 10mg	GLAXOSMITHKLINE CONSUMER HEALTHCARE S.R.L.	ROMANIA	9763	2017	01
COMBINATIONS (PARACETAMOLUM+ PHENYLEPHRINUM)	TANTUMGRIP CU GUST DE PORTOCALA 600 mg/10 mg	powder for oral solution	600mg/ 10mg	ANGELINI PHARMA ÖSTERREICH GMBH	AUSTRIA	9706	2017	01
COMBINATIONS (PARACETAMOLUM+ PHENYLEPHRINUM)	TANTUMGRIP CU GUST FROMMAIE SI MIERE 600 mg/10 mg	powder for oral solution	600mg/ 10mg	ANGELINI PHARMA ÖSTERREICH GMBH	AUSTRIA	9705	2017	01
COMBINATIONS (PARACETAMOLUM+ PHENYLEPHRINUM)	TANTUMGRIP CU GUST FROMMAIE 600 mg/10 mg	powder for oral solution	600mg/ 10mg	ANGELINI PHARMA ÖSTERREICH GMBH	AUSTRIA	9704	2017	01
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	PERINDOPRIL TOSILAT/INDAPAMIDA TEVA 10 mg/2.5 mg	film-coated tablets	10mg/ 2.5mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9743	2017	01

COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	EGIRAMLON 2.5 mg/2.5 mg	capsules	2.5mg/ 2.5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	9580	2017	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	EGIRAMLON 5 mg/5 mg	capsules	5mg/5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	9581	2017	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	EGIRAMLON 5 mg/10mg	capsules	5mg/10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	9582	2017	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	EGIRAMLON 10 mg/5 mg	capsules	10mg/5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	9583	2017	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	EGIRAMLON 10 mg/10 mg	capsules	10mg/ 10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	9584	2017	01
COMBINATIONS (ROSUVASTATINUM+ VALSARTAMUM)	VALAROX 10 mg/80 mg	film-coated tablets	10mg/ 80mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9604	2017	01
COMBINATIONS (ROSUVASTATINUM+ VALSARTAMUM)	VALAROX 20 mg/80 mg	film-coated tablets	20mg/ 80mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9605	2017	01
COMBINATIONS (ROSUVASTATINUM+ VALSARTAMUM)	VALAROX 10 mg/160 mg	film-coated tablets	10mg/ 160mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9606	2017	01
COMBINATIONS (ROSUVASTATINUM+ VALSARTAMUM)	VALAROX 20 mg/160 mg	film-coated tablets	20mg/ 160mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9607	2017	01
COMBINATIONS (TELMISARTANUM+ AMLODIPINUM)	TELASSMO 40 mg/5 mg	tablets	40mg/5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9684	2017	01
COMBINATIONS (TELMISARTANUM+ AMLODIPINUM)	TELASSMO 40 mg/10 mg	tablets	40mg/ 10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9685	2017	01
COMBINATIONS (TELMISARTANUM+ AMLODIPINUM)	TELASSMO 80 mg/5 mg	tablets	80mg/5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9686	2017	01

COMBINATIONS (TELMISARTANUM+ AMLODIPINUM)	TEASSMO 80 mg/10 mg	tablets	80mg/ 10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9687	2017	01
COMBINATIONS (TRAMADOLUM+ PARACETAMOLUM)	ZALDIAR 37.5 mg/325 mg	film-coated tablets	37.5mg/ 325mg	STADA ARZNEIMITTEL AG	GERMANY	9695	2017	01
COMBINATIONS(ACIDUM ACETYLSALICYLICUM+ ACIDU ASCORBIC	ASPIRIN PLUS C FORTE 800 mg/480 mg	effervescent tablets	800mg/ 480mg	BAYER S.R.L.	ROMANIA	9799	2017	01
DARUNAVIRUM	DARUNAVIR TEVA 400 mg	film-coated tablets	400mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9737	2017	01
DARUNAVIRUM	DARUNAVIR TEVA 600 mg	film-coated tablets	600mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9738	2017	01
DESMOPRESSINUM	MINIRIN 0.1 mg	tablets	0.1mg	FERRING GMBH	GERMANY	9845	2017	01
DESMOPRESSINUM	MINIRIN 0.2 mg	tablets	0.2mg	FERRING GMBH	GERMANY	9846	2017	01
DICLOFENACUM	ALMIRAL 75mg/3ml	solution for injection	75mg/3ml	MEDOCHEMIE LTD.	CYPRUS	9748	2017	01
DICLOFENACUM	DICLOFENAC SODIC 100 mg	suppositories	100mg	MAGISTRA C&C S.R.L.	ROMANIA	9653	2017	01
DOXYCYCLINUM	DOXICICLINA ARENA 100 mg	capsules	100mg	ARENA GROUP S.A.	ROMANIA	9747	2017	01
DUTASTERIDUM	AVATERID 0.5 mg	soft capsules	0.5mg	GALENICUM HEALTH S.L.	SPAIN	9579	2017	01
DUTASTERIDUM	DUTRYS 0.5 mg	soft capsules	0.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9780	2017	01
ERLOTINIBUM	ERLOTINIB TEVA 25 mg	film-coated tablets	25mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9640	2017	01
ERLOTINIBUM	ERLOTINIB TEVA 100 mg	film-coated tablets	100mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9641	2017	01

ERLOTINIBUM	ERLOTINIB TEVA 150 mg	film-coated tablets	150mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	9642	2017	01
EVEROLIMUS	CERTICAN 0.5 mg	tablets	0.5mg	NOVARTIS PHARMA GMBH	GERMANY	9626	2017	01
EVEROLIMUS	CERTICAN 0.25 mg	tablets	0.25mg	NOVARTIS PHARMA GMBH	GERMANY	9625	2017	01
EVEROLIMUS	CERTICAN 0.75 mg	tablets	0.75mg	NOVARTIS PHARMA GMBH	GERMANY	9627	2017	01
EVEROLIMUS	CERTICAN 1 mg	tablets	1mg	NOVARTIS PHARMA GMBH	GERMANY	9628	2017	01
EVEROLIMUS	CERTICAN 0.25 mg	tablets for oral dispersion	0.25mg	NOVARTIS PHARMA GMBH	GERMANY	9630	2017	01
EVEROLIMUS	CERTICAN 0.1 mg	tablets for oral dispersion	0.1mg	NOVARTIS PHARMA GMBH	GERMANY	9629	2017	01
EZETIMIBUM	EZOLETA 10 mg	tablets	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9633	2017	01
EZETIMIBUM	EZETIMIB TORRENT 10 mg	tablets	10mg	TORRENT PHARMA S.R.L.	ROMANIA	9634	2017	01
FAMOTIDINUM	FAMODIN 40	film-coated tablets	40mg	AC HELCOR PHARMA S.R.L.	ROMANIA	9703	2017	01
FAMOTIDINUM	FAMODIN 20	film-coated tablets	20mg	AC HELCOR PHARMA S.R.L.	ROMANIA	9702	2017	01
FELODIPINUM	SISTAR 5 mg	modified-release tablets	5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9791	2017	01

FELODIPINUM	SISTAR 10 mg	modified-release tablets	10mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9792	2017	01
FEXOFENADINUM	ALLEGRA 120 mg	film-coated tablets	120mg	SANOFI ROMANIA S.R.L.	ROMANIA	9776	2017	01
FINASTERIDUM	PROPECIA 1 mg	film-coated tablets	1mg	MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	9711	2017	01
FLUCONAZOLUM	FUNGOLON 100 mg	capsules	100mg	BALKANPHARMA RAZGRAD AD	BULGARIA	9821	2017	01
FLURBIPROFENUM	DOLIPS CU AROMA DE PORTOCALA 8.75mg	lozenges	8.75mg	SANDOZ S.R.L.	ROMANIA	9589	2017	01
FLUTAMIDUM	FLUTASIN 250 mg	tablets	250mg	ACTAVIS S.R.L.	ROMANIA	9819	2017	01
FOSINOPRILUM	MONOPRIL 10 mg	tablets	10mg	PHARMASWISS CESKÁ REPUBLIKA S.R.O.	THE CZECH REPUBLIC	9760	2017	01
FOSINOPRILUM	MONOPRIL 20 mg	tablets	20mg	PHARMASWISS CESKÁ REPUBLIKA S.R.O.	THE CZECH REPUBLIC	9761	2017	01
GELATINUM	GELASPAN 40 mg/ml	solution for infusion	40mg/ml	B. BRAUN MELSUNGEN AG	GERMANY	9645	2017	01
GLIQUIDONUM	GLURENORM 30 mg	tablets	30mg	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	9794	2017	01
HEPARINOIDUM	HIRUDOID 3 mg/g	gel	3mg/g	STADA ARZNEIMITTEL AG	GERMANY	9773	2017	01
HEPARINOIDUM	HIRUDOID 3 mg/g	cream	3mg/g	STADA ARZNEIMITTEL AG	GERMANY	9774	2017	01

HOMEOPATE	ARNIGEL 70 mg/g	gel	70mg/g	BOIRON	FRANCE	9829	2017	01
HOMEOPATE	MASTODYNON	tablets		BIONORICA SE	GERMANY	9793	2017	01
HOMEOPATE	REMENS	sublingual tablets		RICHARD BITTNER AG	AUSTRIA	9647	2017	01
HOMEOPATE	REMENS	oral drops, solution		RICHARD BITTNER AG	AUSTRIA	9648	2017	01
IDARUBICINUM	IDARUBICINA ACCORD 5 mg/5 ml	solution for injection	5mg/5ml	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9744	2017	01
IDARUBICINUM	IDARUBICINA ACCORD 10 mg/10 ml	solution for injection	10mg/10ml	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9745	2017	01
IDARUBICINUM	IDARUBICINA ACCORD 20 mg/20 ml	solution for injection	20mg/20ml	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9746	2017	01
IMATINIBUM	IMATINIB KOANAA 100 mg	film-coated tablets	100mg	KOANAA HEALTHCARE LIMITED	GREAT BRITAIN	9590	2017	01
IMATINIBUM	IMATINIB KOANAA 400 mg	film-coated tablets	400mg	KOANAA HEALTHCARE LIMITED	GREAT BRITAIN	9591	2017	01
INDAPAMIDUM	RAWEL SR 1.5 mg	prolonged-release tablets	1.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	9654	2017	01
INDOMETACINUM	INDOMETACIN MCC 50 mg	suppositories	50mg	MAGISTRA C&C S.R.L.	ROMANIA	9818	2017	01
IVABRADINUM	FELOCORD 5 mg	film-coated tablets	5mg	TERAPIA S.A.	ROMANIA	9623	2017	01
IVABRADINUM	FELOCORD 7.5 mg	film-coated tablets	7.5mg	TERAPIA S.A.	ROMANIA	9624	2017	01

IVABRADINUM	RAENOM 5 mg	film-coated tablets	5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9612	2017	01
IVABRADINUM	RAENOM 7.5 mg	film-coated tablets	7.5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9613	2017	01
IVABRADINUM	IVABRADINA SANDOZ 5 mg	film-coated tablets	5mg	SANDOZ S.R.L.	ROMANIA	9681	2017	01
IVABRADINUM	IVABRADINA SANDOZ 7.5 mg	film-coated tablets	7.5mg	SANDOZ S.R.L.	ROMANIA	9682	2017	01
LATANOPROSTUM	MONOPOST 50 micrograms/ml	eye drops, solution	50micrograms/ml	LABORATOIRES THEA	FRANCE	9594	2017	01
LERCANIDIPINUM	LERCANIDIPINA TORRENT 10 mg	film-coated tablets	10mg	TORRENT PHARMA S.R.L.	ROMANIA	9807	2017	01
LERCANIDIPINUM	LERCANIDIPINA TORRENT 20 mg	film-coated tablets	20mg	TORRENT PHARMA S.R.L.	ROMANIA	9807	2017	01
LEVAMISOLUM	DECARIS 150 mg	tablets	150mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9611	2017	01
LEVAMISOLUM	DECARIS 50 mg	tablets	50mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9610	2017	01
LEVETIRACETAMUM	LEVETIRACETAM TERAPIA 250 mg	film-coated tablets	250mg	TERAPIA S.A.	ROMANIA	9650	2017	01
LEVETIRACETAMUM	LEVETIRACETAM TERAPIA 500 mg	film-coated tablets	500mg	TERAPIA S.A.	ROMANIA	9651	2017	01
LEVETIRACETAMUM	LEVETIRACETAM TERAPIA 1000 mg	film-coated tablets	1000mg	TERAPIA S.A.	ROMANIA	9652	2017	01
LEVOFLOXACINUM	OFTAQUIX 5 mg/ml	eye drops, solution	5mg/ml	SANTEN OY	FINLAND	9806	2017	01

LEVOMETHADONUM	LEVO-METHASAN 5 mg/ml	concentrate for oral solution	5mg/ml	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	9777	2017	01
LINEZOLIDUM	LINEZOLID KRKA 2 mg/ml	solution for infusion	2mg/ml	KRKA, D.D., NOVO MESTO	SLOVENIA	9707	2017	01
LOPERAMIDUM	LOPEDIUM 2 mg	capsules	2mg	HEXAL AG	GERMANY	9656	2017	01
LOPINAVIRUM+ RITONAVIRUM	LOPINAVIR/RITONAVIR ACCORD 200 mg/50 mg	film-coated tablets	200mg/50mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9800	2017	01
LOSARTANUM	TALOSAN 50 mg	film-coated tablets	50mg	TERAPIA S.A.	ROMANIA	9637	2017	01
LOSARTANUM	TALOSAN 100 mg	film-coated tablets	100mg	TERAPIA S.A.	ROMANIA	9638	2017	01
MACROGOLUM	GOLAX 10 mg	Powder for oral solution (sachet)	10mg	PHAROS PHARMACEUTICAL ORIENTED SERVICES LTD	GREECE	9614	2017	01
METAMIZOLUM NATRIUM	ALINDOR 500 mg	tablets	500mg	LAROPHARM S.R.L.	ROMANIA	9847	2017	01
METHOTREXATUM	METORTHTRIT 10 mg/ml	solution for injection in pre-filled syringe	10mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	9688	2017	01
METHYLDOPUM	DOPEGYT 250 mg	tablets	250mg	EGIS PHARMACEUTICALS PLC	HUNGARY	9698	2017	01
METOPROLOLUM	METOPROLOL VIM	tablets	50mg	VIM SPECTRUM S.R.L.	ROMANIA	9775	2017	01

	SPECTRUM 50 mg							
MIRTAZAPINUM	PHARMATAZ 30 mg	film-coated tablets	30mg	ACTAVIS GROUP HF.	ICELAND	9820	2017	01
MYCOPHENOLATUM	ACID MICOFENOLIC SANDOZ 180 mg	gastroresistant tablets	180mg	SANDOZ S.R.L.	ROMANIA	9729	2017	01
MYCOPHENOLATUM	ACID MICOFENOLIC SANDOZ 360 mg	gastroresistant tablets	360mg	SANDOZ S.R.L.	ROMANIA	9730	2017	01
NAPROXENUM	ETRIXENAL 100 mg/g	gel	100mg/g	PROENZI S.R.O.	THE CZECH REPUBLIC	9789	2017	01
NITRAZEPAMUM	NITRAZEPAM - RICHTER 5 mg	tablets	5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9762	2017	01
OMEPRAZOLUM	OMEPRAZOL-RICHTER 20 mg	gastroresistant capsules	20mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	9620	2017	01
OMEPRAZOLUM	OMEPRAZOL SANDOZ 40 mg	powder for solution for infusion	40mg	SANDOZ S.R.L.	ROMANIA	9622	2017	01
ONDANSETRONUM	ONDANSETRON AUROBINDO 2 mg/ml	solution for injection/infusion	2mg/ml	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	9849	2017	01
OXACILLINUM	OXACILINA ATB 500 mg	capsules	500mg	ANTIBIOTICE SA	ROMANIA	9772	2017	01
OXACILLINUM	OXACILINA ATB 250 mg	capsules	250mg	ANTIBIOTICE SA	ROMANIA	9771	2017	01
PARACETAMOLUM	PARACETAMOL SINTOFARM 250 mg	suppositories	250mg	SINTOFARM S.A.	ROMANIA	9732	2017	01
PARACETAMOLUM	PARACETAMOL SINTOFARM 125 mg	suppositories	125mg	SINTOFARM S.A.	ROMANIA	9731	2017	01
PARACETAMOLUM	PARACETAMOL SINTOFARM 500 mg	suppositories	500mg	SINTOFARM S.A.	ROMANIA	9733	2017	01

PARACETAMOLUM	PARACETAMOL SLAVIA 500 mg	tablets	500mg	SLAVIA PHARM S.R.L.	ROMANIA	9609	2017	01
PARACETAMOLUM	PARACETAMOL ROMPHARM 10 mg/ml	solution for infusion	10mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	9621	2017	01
PAROXETINUM	ARKETIS 20 mg	tablets	20mg	MEDOCHEMIE LTD.	CYPRUS	9667	2017	01
PAROXETINUM	ARKETIS 10 mg	tablets	10mg	MEDOCHEMIE LTD.	CYPRUS	9666	2017	01
PAROXETINUM	ARKETIS 30 mg	tablets	30mg	MEDOCHEMIE LTD.	CYPRUS	9668	2017	01
PAROXETINUM	ARKETIS 40 mg	tablets	40mg	MEDOCHEMIE LTD.	CYPRUS	9669	2017	01
PHENOXYMETHYLPENI- CILLINUM	OSPEN 500	film-coated tablets	500000 IU	SANDOZ GMBH	AUSTRIA	9750	2017	01
PHENOXYMETHYLPENI- CILLINUM	OSPEN 1000	film-coated tablets	1000000 IU	SANDOZ GMBH	AUSTRIA	9751	2017	01
PHENOXYMETHYLPENI- CILLINUM	OSPEN 1500	film-coated tablets	1500000 IU	SANDOZ GMBH	AUSTRIA	9752	2017	01
PLANTE	DIFRAREL 100 mg/5 mg	lozenges	100mg/ 5mg	BIOCODEX	FRANCE	9713	2017	01
PLANTE	DIFRAREL E 50 mg/50 mg	lozenges	50mg/ 50mg	BIOCODEX	FRANCE	9712	2017	01
PLANTE, COMBINATIONS	BRONCHOSTOP	syrup		KWIZDA PHARMA GMBH	AUSTRIA	9852	2017	01
PREGABALINUM	PREGABALINA TERAPIA 125 mg	capsules	125mg	TERAPIA S.A.	ROMANIA	9802	2017	01
PREGABALINUM	PREGABALINA TERAPIA 175 mg	capsules	175mg	TERAPIA S.A.	ROMANIA	9803	2017	01
PREGABALINUM	PREGABALINA TERAPIA	capsules	250mg	TERAPIA S.A.	ROMANIA	9804	2017	01

	250 mg							
PREGABALINUM	PREGABALINA TERAPIA 275 mg	capsules	275m	TERAPIA S.A.	ROMANIA	9805	2017	01
QUETIAPINUM	QUETIAPINA ACCORD 150 mg	prolonged- release tablets	150mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9809	2017	01
RITONAVIRUM	RITONAVIR ACCORD 100 mg	film-coated tablets	100mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9768	2017	01
RUPATADINUM	TAMALIS 10 mg	tablets	10mg	J. URIACH Y COMPANIA, S.A.	SPAIN	9660	2017	01
RUPATADINUM	TAMALIS 1 mg/ml	oral solution	1mg/ml	J. URIACH Y COMPANIA, S.A.	SPAIN	9661	2017	01
SALMETEROLUM+ FLUTICASONUM	SERETIDE DISKUS 50 micrograms/100 micrograms	inhalation powder	50micrograms/ 100micrograms	GLAXO WELLCOME UK LIMITED	GREAT BRITAIN	9570	2017	01
SALMETEROLUM+ FLUTICASONUM	SERETIDE DISKUS 50 micrograms/250 micrograms	inhalation powder	50micrograms/ 250micrograms	GLAXO WELLCOME UK LIMITED	GREAT BRITAIN	9571	2017	01
SALMETEROLUM+ FLUTICASONUM	SERETIDE DISKUS 50 micrograms/500 micrograms	inhalation powder	50micrograms/ 500micrograms	GLAXO WELLCOME UK LIMITED	GREAT BRITAIN	9572	2017	01
SALMETEROLUM+ FLUTICASONUM	PAVTIDE DISKUS 50 micrograms/100 micrograms	inhalation powder	50micrograms/ 100micrograms	GLAXOSMITHKLINE (GSK) S.R.L.	ROMANIA	9573	2017	01
SALMETEROLUM+ FLUTICASONUM	PAVTIDE DISKUS 50 micrograms/250 micrograms	inhalation powder	50micrograms/ 250micrograms	GLAXOSMITHKLINE (GSK) S.R.L.	ROMANIA	9574	2017	01
SALMETEROLUM+ FLUTICASONUM	PAVTIDE DISKUS 50 micrograms/500 micrograms	inhalation powder	50micrograms/ 500micrograms	GLAXOSMITHKLINE (GSK) S.R.L.	ROMANIA	9575	2017	01
SILDENAFILUM	BALCOGA 20 mg	film-coated tablets	20mg	SANDOZ S.R.L.	ROMANIA	9767	2017	01
TADALAFILUM	QIZERZ 20 mg	film-coated	20mg	SANDOZ S.R.L.	ROMANIA	9778	2017	01

		tablets						
TADALAFILUM	REVESTAD 20 mg	film-coated tablets	20mg	STADA M&D S.R.L.	ROMANIA	9810	2017	01
TADALAFILUM	GEROCILAN 2.5 mg	film-coated tablets	2.5mg	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	9833	2017	01
TADALAFILUM	GEROCILAN 5 mg	film-coated tablets	5mg	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	9834	2017	01
TADALAFILUM	GEROCILAN 10 mg	film-coated tablets	10mg	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	9835	2017	01
TADALAFILUM	GEROCILAN 20 mg	film-coated tablets	20mg	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	9836	2017	01
TC - TETROFOSMINUM	MYOVIEW 230 micrograms	kit for radiopharmaceutical preparation	230mg	GE HEALTHCARE LIMITED	GREAT BRITAIN	9655	2017	01
TENOFOVIRUM DISOPROXIL	TENOFOVIR DISOPROXIL SANDOZ 245 mg	film-coated tablets	245mg	SANDOZ S.R.L.	ROMANIA	9644	2017	01
TERLIPRESSINUM	ACETAT DE TERLIPRESINA EVER PHARMA 0.2 mg/ml	solution for injection	0.2mg/ml	EVER VALINJECT GMBH	AUSTRIA	9592	2017	01
TIOTROPIUM	SPIRIVA 18 micrograms	capsules with inhalation powder	18micrograms	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	9766	2017	01

TOPIRAMATUM	TOPIRAMAT ACTAVIS 25 mg	film-coated tablets	25mg	ACTAVIS S.R.L.	ROMANIA	9824	2017	01
TOPIRAMATUM	TOPIRAMAT ACTAVIS 50 mg	film-coated tablets	50mg	ACTAVIS S.R.L.	ROMANIA	9825	2017	01
TOPIRAMATUM	TOPIRAMAT ACTAVIS 100 mg	film-coated tablets	100mg	ACTAVIS S.R.L.	ROMANIA	9826	2017	01
TOPOTECAMUM	TOPOTECAN EBEWE 1 mg/ml	concentrate for solution for infusion	1mg/ml	EBEWE PHARMA GES.M.B.H. NFG. KG	AUSTRIA	9779	2017	01
TROXERUTINUM	TROXSAL 20mg/g	gel	20mg/g	SLAVIA PHARM SRL	ROMANIA	9790	2017	01
VINORELBINUM	VINORELBINA ACCORD 10 mg/ml	concentrate for solution for infusion	10mg/ml	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	9683	2017	01

Medicinal products authorised through centralised procedure by the EMA, notified for marketing in Romania during the 1st quarter of 2017

INN	Invented name	Pharmaceutical form	MAH	Country	MA number	INN		
BARICITINIB	OLUMIANT 4 mg	film-coated tablets	4mg	ELI LILLY NEDERLAND B.V.	HOLLAND	1170	2017	12
COMBINATIONS (INSULINE GLARGINE+ LIXISENATIDUM)	SULIQUA 100 units/ml+ 50 micrograms/ml	solution for injection in pre- filled pen	100units/ml+ 50micrograms/ml	SANOFI - AVENTIS GROUPE	FRANCE	1157	2017	02
COMBINATIONS (INSULINE GLARGINE+ LIXISENATIDUM)	SULIQUA 100 units/ml+33 micrograms/ml	solution for injection in pre- filled pen	100units/ml+ 33micrograms/ml	SANOFI - AVENTIS GROUPE	FRANCE	1157	2017	04
DARUNAVIRUM	DARUNAVIR MYLAN 600 mg	film-coated tablets	600mg	MYLAN S.A.S.	FRANCE	1140	2017	31
DARUNAVIRUM	DARUNAVIR MYLAN 800 mg	film-coated tablets	800mg	MYLAN S.A.S.	FRANCE	1140	2017	39
TENOFOVIRUM ALAFENAMIDA	VEMLIDY 25 mg	film-coated tablets	25mg	GILEAD SCIENCES INTERNATIONAL LTD	GREAT BRITAIN	1154	2017	01
TOFACITINIB	XELJANZ 5 mg	film-coated tablets	5mg	PFIZER LIMITED	GREAT BRITAIN	1178	2017	03