

ROMANIA

Newsletter

Year 21, No. 2 (82), 2nd Quarter 2019

*National Agency
for Medicines
and Medical Devices*

Orders of the Minister of Health

Medicinal product batches recalled/withdrawn in the 2nd quarter 2019

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD in the 1st quarter 2019

Medicinal products authorised for marketing in the 1st quarter 2019

Centrally authorised medicinal products notified for marketing in Romania in the 1st quarter 2019

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TABLE OF CONTENTS

Orders of the Minister of Health

ORDER no. 522 of 4 April 2019 for amendment of Order of the Minister of Health no. 1.173/2010 on set up and operation of the group of experts responsible for technical standpoints on documents under EU debate, also ensuring representation in meetings of EU working entities4

Medicinal product batches recalled/withdrawn in the 2nd quarter 20197

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD in the 1st quarter 20199

Medicinal products authorised for marketing in the 1st quarter 201910

Centrally authorised medicinal products notified for marketing in Romania in the 1st quarter 201923

**ORDER No. 522
of 4 April 2019**

for amendment of Order of the Minister of Health no. 1.173/2010 on set up and operation of the group of experts responsible for technical standpoints on documents under EU debate, also ensuring representation in meetings of EU working entities

Published in: Official Journal of Romania No. 276 of 11 April 2019

On seeing Approval Report no. S8 4.536/4.04.2019 of the Ministry of Health Directorate for Press Relations, European Affairs and International Relations,

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 – Order of the Minister of Health no. 1.173/2010 on set up and operation of the group of experts responsible for technical standpoints on documents under EU debate, also ensuring representation in meetings of EU working entities, as amended, published in: Official Journal of Romania, Part I, No. 649 of 20 September 2019, is hereby amended as follows:

1. Article 5 (28), a) is hereby amended as follows:

"28. a) Drinking water:

Co-ordinator: Ileana Văcaru, MD - Alba County Public Health Directorate

Alternate: Edit Vartic, MD - National Public Health Institute

Technical Group:

- Ioana-Rodica Lupşa, MD - National Public Health Institute
- chem. Gabriela Brînzei - National Public Health Institute
- chem. eng. Nicoleta Lemne - National Public Health Institute
- chem. Dana Rusea - National Public Health Institute
- biol. Liliana Neagu - National Public Health Institute
- Ileana Anca Badea, MD - Argeş County Public Health Directorate

- Ioan Chirilă, MD - National Public Health Institute".

2. Article 5 (35), a) - e) are hereby amended as follows:

"a) Medicinal products for human use:

Co-ordinator: Marius Daniel Şişu – president of the National Agency for Medicines and Medical Devices (NAMMD)

Technical Group:

- Simona Bădoi, MD - NAMMD
- Cristiana Octaviana Ilie, MD - NAMMD
- Roxana Ştefania Stroe, MD - NAMMD
- pharm. Victoriţa Ivaşcu - NAMMD
- biol. Mirela Tavakol - NAMMD
- pharm. Anca Crupariu - NAMMD
- pharm. Monica Daniela Lazăr – Ministry of Health

b) Biological products for human use:

Co-ordinator: biol. Mirela Tavakol - NAMMD

Technical Group:

- biol. Gianina Andrei - NAMMD
- Roxana Ştefania Stroe, MD - NAMMD

c) Pharmacovigilance:

Co-ordinator: Roxana Ştefania Stroe, MD - NAMMD

Technical Group:

- pharm. Roxana Dondera - NAMMD
- Camelia Lazăr, MD - NAMMD

d) Falsified medicines:

Co-ordinator: Marius Daniel Şişu - NAMMD president

Technical Group:

- Cristina Gavrilă, Legal Advisor - NAMMD
- Adina Pîrvu, MD - NAMMD

e) Clinical trials:

Co-ordinator: Marius Daniel Şişu - NAMMD president

Technical Group:

- Mirela Viţă, MD – NAMMD
- Adina Pîrvu, MD - NAMMD
- Cristina Gavrilă, Legal Advisor - NAMMD".

3. Article 5, 36 - 38 are hereby amended as follows:

"36. Medical devices:

Co-ordinators:

- Marius Daniel Şişu – NAMMD president
- eng. Ioana Țene - NAMMD

Technical Group:

- eng. Oana Arsenescu - NAMMD
- eng. Cristina Durle - NAMMD
- eng. Rodica Marinela Chifor - NAMMD
- subeng. Margareta Mihalache - NAMMD
- eng. Mihaela Buzatu - NAMMD

- eng. Mihaela Grigore - NAMMD
- eng. Georgeta Herța - NAMMD
- eng. Cristina Vulcăneanu - NAMMD
- eng. Adrian Pacioaga - NAMMD

37. Assessment of health technologies:

Co-ordinator: Dan Octavian Alexandrescu, MD - Secretary of state, Ministry of Health

Technical Group:

- Roxana Ștefania Stroe, MD - NAMMD
- pharm. Felcia Ciulu Costinescu - NAMMD
- Cristina Gavrilă, Legal Advisor - NAMMD

38. Patient access to innovative therapies:

Co-ordinator: Dan Octavian Alexandrescu, MD - Secretary of state, Ministry of Health

Technical Group:

- Adrian-Stelian Dumitru - Ministry of Health
- Costin Iliuță - Ministry of Health
- Simona Bădoi, MD - NAMMD
- biol. Mirela Tavakol - NAMMD
- Cristina Gavrilă, Ministry of Health - NAMMD".

Art. II - This order is published in the Official Journal of Romania, Part I.

p. Minister of Health,
Tiberius-Marius Brădățan,
Secretary of State

Medicinal product batches recalled/withdrawn in the 2nd quarter 2019

No.	Product recalled/ withdrawn	Pharm. form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall/withdrawal	Action proposed	Recall/ Withdrawal date
1	MILLIGEST	lozenges		combinations (Search Results Featured snippet from the web Image result for ethinyl oestradiol)	Gedeon Richter PLC, Hungary	Z91001B	recall triggered by a quality nonconformity for a different product batch (one 22- instead of 21- lozenges containing blister), nonconformity potentially affecting the batch in question as well; the MAH has applied for CA's approval for repackaging of the withdrawn batch after verification of each package; the NAMMD resolution is provided after assessment requested by the competent authority.	Voluntary withdrawal and potential batch repackaging (on NAMMD approval)	11.04.2019
2	CITROLIN	mouthwash		various	Pharco Impex 93 SRL	all marketed batches	recall triggered by a quality nonconformity found by a user (breaking of the plastic lid on opening the vial); in addition, plus noncompliance was found authorisation conditions for the same product (as per Annex I to MA no. 4618/2004/01, i/e the package shall consist of a polyethylene terephthalate vial closed with aluminium lid)	Recall and destruction	11.04.2019
3	NIFEDIPIN RETARD TERAPIA, 20 mg	prol. release tabl.	20 mg	nifedipine	Terapia SA	1186324	recall triggered by out-of-specification result for the "Dissolution" parameter	Recall and destruction	24.04.2019
4	SOLPADEINE EXTRA 500 mg/12.8 mg/ 30 mg	efferv. tabl.	500 mg/ 12.8 mg/ 30 mg	combinations	Glaxosmithkline Ltd, Ireland/Hipocrate 2000 SRL	1284660104, 1284660105	recall triggered by a quality nonconformity notified by patients (qualitative and quantitative composition not compliant with MA no. 9796/2017/01-07)	Recall and destruction	24.04.2019
5	NUTRIFLEX OMEGA SPECIAL	emuls. for infusion		combinations (1000 ml aminoacid solution, 500 ml lipidic emulsion, 1000 ml glucose solution)	B.Braun Melsungen AG, Germany	173848052, 182828051	potential out-of-specification result for the glucose solution chamber	Voluntary recall and destruction	24.04.2019

No.	Product recalled/ withdrawn	Pharm. form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall/withdrawal	Action proposed	Recall/ Withdrawal date
6	GYNOZOL 200	vaginal caps.	200 mg	miconazole	Pharco Impex 93 SRL	all marketed batches	recall triggered by missing submission to the Min. of Health of documentation required for product inclusion in the CaNaMed Index, the 2019 ed.	Voluntary recall and destruction	14.06.2019
7	GYNOZOL 400	vaginal caps.	400 mg	miconazole	Pharco Impex 93 SRL	all marketed batches	recall triggered by missing submission to the Min. of Health of documentation required for product inclusion in the CaNaMed Index, the 2019 ed.	Voluntary recall and destruction	14.06.2019
8	VITAMINA E 400 mg	soft caps.	400mg	tocopherol	Pharco Impex 93 SRL	all marketed batches	recall triggered by missing submission to the Min. of Health of documentation required for product inclusion in the CaNaMed Index, the 2019 ed.	Voluntary recall and destruction	14.06.2019
9	VITAMINA A 50000 IU	soft caps.	50000 IU	retinol	Pharco Impex 93 SRL	all marketed batches	recall triggered by missing submission to the Min. of Health of documentation required for product inclusion in the CaNaMed Index, the 2019 ed.	Voluntary recall and destruction	14.06.2019

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD in the 1st quarter 2019

During the 1st quarter 2019, 24 marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been submitted:

COD ATC
A07 - ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTI-INFECTIVE AGENTS
A09 - DIGESTIVES, INCLUDING ENZYMES
B01 - ANTITHROMBOTIC AGENTS
C03 - DIURETICS
J01 - ANTIBACTERIALS FOR SYSTEMIC USE
J02 - ANTIMYCOTICS FOR SYSTEMIC USE
M01 - ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
M02 - TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAINS
N02 - ANALGESICS
N03 - ANTIEPILEPTICS
P01 - ANTIPROTOZOALS
R02 - THROAT PREPARATIONS
R05 - COUGH AND COLD PREPARATIONS

Medicinal products authorised for marketing in the 1st quarter 2019

INN	Trade name	Pharm. form	Strength	MAH	Country	MA No.	MA Date	ATC Code
ATAZANAVIRUM	ATAZANAVIR ALVOGEN 150 mg	caps.	150mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	11319	11.01.2019	J05AE08
ATAZANAVIRUM	ATAZANAVIR ALVOGEN 200 mg	caps.	200mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	11320	11.01.2019	J05AE08
ATAZANAVIRUM	ATAZANAVIR ALVOGEN 300 mg	caps.	300mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	11321	11.01.2019	J05AE08
IBUPROFENUM	IBUPROFEN AUROBINDO 600 mg	film coated tabl.	600 mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	11330	16.01.2019	M01AE01
SITAGLIPTINUM	SITAGLIPTINA BIOGARAN 100 mg	film coated tabl.	100mg	BIOGARAN	FRANCE	11329	16.01.2019	A10BH01
SITAGLIPTINUM	SITAGLIPTINA BIOGARAN 50 mg	film coated tabl.	50mg	BIOGARAN	FRANCE	11328	16.01.2019	A10BH01
SITAGLIPTINUM	SITAGLIPTINA BIOGARAN 25 mg	film coated tabl.	25mg	BIOGARAN	FRANCE	11327	16.01.2019	A10BH01
COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	CO-ROSWERA 5 mg/10 mg	film coated tabl.	5mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	11331	18.01.2019	C10BA06
COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	CO-ROSWERA 10 mg/10 mg	film coated tabl.	10mg/ 10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	11332	18.01.2019	C10BA06
COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	CO-ROSWERA 15 mg/10 mg	film coated tabl.	15mg/ 10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	11333	18.01.2019	C10BA06
COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	CO-ROSWERA 20 mg/10 mg	film coated tabl.	20mg/ 10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	11334	18.01.2019	C10BA06

INN	Trade name	Pharm. form	Strength	MAH	Country	MA No.	MA Date	ATC Code
COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	CO-ROSWERA 40 mg/10 mg	film coated tabl.	40mg/ 10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	11335	18.01.2019	C10BA06
HUMAN NORMAL IMMUNOGLOBULIN FOR INTRAVASCULAR ADMINISTRATION	OCTAGAM 50 mg/ml	sol. for inf.	50mg/ml	OCTAPHARMA (IP) SPRL	BELGIUM	11338	18.01.2019	J06BA02
CEFIXIMUM	CEFIXIMA NECTAR 200 mg	film coated tabl.	200mg	NECTAR LIFESCIENCES UK LIMITED	UK	11336	18.01.2019	J01DD08
CEFIXIMUM	CEFIXIMA NECTAR 200 mg	film coated tabl.	200mg	NECTAR LIFESCIENCES UK LIMITED	UK	11336	18.01.2019	J01DD08
CEFIXIMUM	CEFIXIMA NECTAR 400 mg	film coated tabl.	400mg	NECTAR LIFESCIENCES UK LIMITED	UK	11337	18.01.2019	J01DD08
COMBINATIONS (CANDESARTANUM CILEXETIL+ AMLODIPINUM)	TILAMCAR 8 mg/5 mg	caps.	8mg/5mg	SWYSSI AG	GERMANY	11344	21.01.2019	C09DB07
COMBINATIONS (CANDESARTANUM CILEXETIL+ AMLODIPINUM)	TILAMCAR 8 mg/10 mg	caps.	8mg/10mg	SWYSSI AG	GERMANY	11345	21.01.2019	C09DB07
COMBINATIONS (CANDESARTANUM CILEXETIL+ AMLODIPINUM)	TILAMCAR 16 mg/5 mg	caps.	16mg/5mg	SWYSSI AG	GERMANY	11346	21.01.2019	C09DB07
COMBINATIONS (CANDESARTANUM CILEXETIL+ AMLODIPINUM)	TILAMCAR 16 mg/10 mg	caps.	16mg/ 10mg	SWYSSI AG	GERMANY	11347	21.01.2019	C09DB07

INN	Trade name	Pharm. form	Strength	MAH	Country	MA No.	MA Date	ATC Code
ACIDUM ALENDRONICUM+ COLECALCIFEROLUM	ACID ALENDRONIC/ COLECALCIFEROL MYLAN 70 mg/ 5600 IU	tabl.	70mg/ 5600UI	MYLAN S.A.S.	FRANCE	11352	22.01.2019	M05BB03
ACIDUM ALENDRONICUM+ COLECALCIFEROLUM	ACID ALENDRONIC/ COLECALCIFEROL MYLAN 70 mg/ 2800 IU	tabl.	70mg/ 2800UI	MYLAN S.A.S.	FRANCE	11351	22.01.2019	M05BB03
KETOPROFENUM	KETIFEXIN 25 mg	granule for oral sol. in sachet	25mg	MIDAS PHARMA GMBH	GERMANY	11353	23.01.2019	M01AE03
KETOPROFENUM	KETIFEXIN 50 mg	granules for oral sol. in sachet	50mg	MIDAS PHARMA GMBH	GERMANY	11354	23.01.2019	M01AE03
ENTECAVIRUM	ENTECAVIR KRKA 0.5 mg	film coated tabl.	0.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	11361	25.01.2019	J05AF10
ENTECAVIRUM	ENTECAVIR KRKA 1 mg	film coated tabl.	1mg	KRKA, D.D., NOVO MESTO	SLOVENIA	11362	25.01.2019	J05AF10
IBUPROFENUM	AUROFEN 200 mg	film coated tabl.	200mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	11365	25.01.2019	M01AE01
IBUPROFENUM	AUROFEN 400 mg	film coated tabl.	400mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	11366	25.01.2019	M01AE01
TIOTROPIUM	TIOTROPIU MYLAN 18 µgrams	inhal. powder caps.	18 µgrams	MYLAN S.A.S.	FRANCE	11370	25.01.2019	A10BH02
DESLORATADINUM	DASERGIN 5 mg	film coated tabl.	5mg	HCS BVBA	BELGIUM	11371	25.01.2019	R06AX27
TENOFOVIRUM DISOPROXIL	TENOFOVIR DISOPROXIL ACCORDPHARMA 245 mg	film coated tabl.	245mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	11373	30.01.2019	J05AF07

INN	Trade name	Pharm. form	Strength	MAH	Country	MA No.	MA Date	ATC Code
GEFITINIBUM	GEFITINIB ACCORD 250 mg	film coated tabl.	250mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	11374	30.01.2019	L01XE02
GLIMEPIRIDUM	GLIMEPIRIDA ACCORD 6 mg	tabl.	6mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	11375	30.01.2019	A10BB12
GLIMEPIRIDUM	GLIMEPIRIDA ACCORD 6 mg	tabl.	6mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	11375	30.01.2019	A10BB12
SALMETEROLUM+ FLUTICASONUM	SALMETEROL/ FLUTICAZONA APC INSTYTUT 50 µgrams/ 500 µgrams	single dose inhal. powder	50µgrams/ 500µgrams	CELON PHARMA S.A.	POLAND	11377	30.01.2019	R03AK06
SALMETEROLUM+ FLUTICASONUM	SALMETEROL/ FLUTICAZONA APC INSTYTUT 50 µgrams/ 500 µgrams	single dose inhal. powder	50µgrams/ 500µgrams	CELON PHARMA S.A.	POLAND	11377	30.01.2019	R03AK06
VILDAGLIPTINUM	VILDAGLIPTINA FLOMI 50 mg	tabl.	50mg	FLOMI FARMA SRL	ROMANIA	11378	30.01.2019	A10BH02
ESOMEPRAZOLUM	ESOMEPRAZOL TERAPIA 20 mg	gastrores. caps.	20mg	TERAPIA SA	ROMANIA	11407	31.01.2019	A02BC05
ESOMEPRAZOLUM	ESOMEPRAZOL TERAPIA 40 mg	gastrores. caps.	40mg	TERAPIA SA	ROMANIA	11408	31.01.2019	A02BC05
FEBUXOSTATUM	FEBUXOSTAT AUROBINDO 80 mg	film coated tabl.	80mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	11409	31.01.2019	M04AA03
FEBUXOSTATUM	FEBUXOSTAT AUROBINDO 120 mg	film coated tabl.	120mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	11410	31.01.2019	M04AA03
METFORMINUM	SIOFOR 500 mg	prol. release tabl.	500mg	BERLIN - CHEMIE AG	GERMANY	11413	31.01.2019	A10BA02

INN	Trade name	Pharm. form	Strength	MAH	Country	MA No.	MA Date	ATC Code
METFORMINUM	SIOFOR 750 mg	prol. release tabl.	750mg	BERLIN - CHEMIE AG	GERMANY	11414	31.01.2019	A10BA02
METFORMINUM	SIOFOR 1000 mg	prol. release tabl.	1000mg	BERLIN - CHEMIE AG	GERMANY	11415	31.01.2019	A10BA02
ATOMOXETINUM	ATOMOXETINA ACCORD 10 mg	caps.	10mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	11379	31.01.2019	N06BA09
ATOMOXETINUM	ATOMOXETINA ACCORD 18 mg	caps.	18mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	11380	31.01.2019	N06BA09
ATOMOXETINUM	ATOMOXETINA ACCORD 25 mg	caps.	25mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	11381	31.01.2019	N06BA09
ATOMOXETINUM	ATOMOXETINA ACCORD 40 mg	caps.	40mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	11382	31.01.2019	N06BA09
ATOMOXETINUM	ATOMOXETINA ACCORD 60 mg	caps.	60mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	11383	31.01.2019	N06BA09
ATOMOXETINUM	ATOMOXETINA ACCORD 80 mg	caps.	80mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	11384	31.01.2019	N06BA09
ATOMOXETINUM	ATOMOXETINA ACCORD 100 mg	caps.	100mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	11385	31.01.2019	N06BA09
BORTEZOMIBUM	BORTEZOMIB STADA 2.5 mg/ml	sol. for inj.	2.5mg/ml	STADA M&D SRL	ROMANIA	11423	18.02.2019	L01XX32
BORTEZOMIBUM	BORTEZOMIB MSN 3.5 mg	powder for sol. for inj.	3.5mg	VIVANTA GENERICS S.R.O.,	CZECH REP.	11424	18.02.2019	L01XX32
DARUNAVIRUM	DARUNAVIR FLOMI 400 mg	film coated tabl.	400mg	FLOMI FARMA S.R.L.	ROMANIA	11420	18.02.2019	J05AE10
DARUNAVIRUM	DARUNAVIR FLOMI 600 mg	film coated tabl.	600mg	FLOMI FARMA S.R.L.	ROMANIA	11421	18.02.2019	J05AE10

INN	Trade name	Pharm. form	Strength	MAH	Country	MA No.	MA Date	ATC Code
DARUNAVIRUM	DARUNAVIR FLOMI 800 mg	film coated tabl.	800mg	FLOMI FARMA S.R.L.	ROMANIA	11422	18.02.2019	J05AE10
HOMEOPATHIC MEDICINAL PRODUCTS	ENGYSTOL	tabl.		BIOLOGISCHE HEILMITTEL HEEL GMBH	GERMANY	11430	18.02.2019	XRNIT
PARACETAMOLUM	PROSINUS 150 mg/5 ml	oral sol.	150mg/5ml	S.C. FITERMAN PHARMA S.R.L.	ROMANIA	11431	18.02.2019	N02BE01
COMBINATIONS	FERVEX "pentru adulti" cu aroma de zmeura	gran. for oral sol.	500mg/ 200mg/ 25mg	UPSA SAS	FRANCE	11432	18.02.2019	N02BE51
CALCII CHLORIDUM	CALRECIA 100 mmol/l	sol. for inf.	100mmol/l	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	GERMANY	11452	27.02.2019	B05XA07
BORTEZOMIBUM	BORTEZOMIB KRKA 1 mg	powder for sol. for inj.	1mg	KRKA, D.D., NOVO MESTO	SLOVENIA	11456	27.02.2019	L01XX32
BORTEZOMIBUM	BORTEZOMIB KRKA 3.5 mg	powder for sol. for inj.	3.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	11457	27.02.2019	L01XX32
ERLOTINIBUM	ERLOTINIB TERAPIA 25 mg	film coated tabl.	25mg	TERAPIA SA	ROMANIA	11468	28.02.2019	L01XE03
ERLOTINIBUM	ERLOTINIB TERAPIA 100 mg	film coated tabl.	100mg	TERAPIA SA	ROMANIA	11469	28.02.2019	L01XE03
ERLOTINIBUM	ERLOTINIB TERAPIA 150 mg	film coated tabl.	150mg	TERAPIA SA	ROMANIA	11470	28.02.2019	L01XE03
METYRAPONUM	METOPIRONE 250 mg	soft caps.	250mg	LABORATOIRE HRA PARMA	FRANCE	11476	11.03.2019	V04CD01
ANIDULAFUNGINUM	ANIDULAFUNGINA SANDOZ 100 mg	powder for conc. for sol. for inf.	100mg	S.C. SANDOZ SRL	ROMANIA	11478	11.03.2019	J02AX06
COMBINATIONS (PIOGLITAZONUM + METFORMINUM)	PIOGLITAZONA/ METFORMIN FLOMI 15 mg/850 mg	film coated tabl.	15mg/ 850mg	FLOMI FARMA S.R.L.	ROMANIA	11480	11.03.2019	A10BD05
DIENOGESTUM	ZAFRILLA 2 mg	tabl.	2mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	11486	11.03.2019	G03DB08

INN	Trade name	Pharm. form	Strength	MAH	Country	MA No.	MA Date	ATC Code
ACIDUM ALENDRONICUM+ COLECALCIFEROLUM	ACID ALENDRONIC/ COLECALCIFEROL ACCORD 70 mg/2800 IU	tabl.	70mg/ 2800UI	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	11487	11.03.2019	M05BB03
ACIDUM ALENDRONICUM+ COLECALCIFEROLUM	ACID ALENDRONIC/ COLECALCIFEROL ACCORD 70 mg/5600 IU	tabl.	70mg/ 5600UI	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	11488	11.03.2019	M05BB03
CINACALCETUM	CINACALCET PHARMAZAC 30 mg	film coated tabl.	30mg	PHARMAZAC S.A.	GREECE	11493	12.03.2019	H05BX01
CINACALCETUM	CINACALCET PHARMAZAC 60 mg	film coated tabl.	60mg	PHARMAZAC S.A.	GREECE	11494	12.03.2019	H05BX01
CINACALCETUM	CINACALCET PHARMAZAC 90 mg	film coated tabl.	90mg	PHARMAZAC S.A.	GREECE	11495	12.03.2019	H05BX01
IVABRADINUM	APREDONAV 5 mg	film coated tabl.	5mg	MEDOCHEMIE LTD.	CYPRUS	11501	13.03.2019	C01EB17
IVABRADINUM	APREDONAV 7.5 mg	film coated tabl.	7.5mg	MEDOCHEMIE LTD.	CYPRUS	11502	13.03.2019	C01EB17
SUFENTANILUM CITRATUM	SOFENTIL 5 µgrams/ml	sol. for inj./inf.	5µgrams/ml	MEDOCHEMIE LTD.	CYPRUS	11503	13.03.2019	N01AH03
SUFENTANILUM CITRATUM	SOFENTIL 50 µgrams/ml	sol. for inj./inf.	50µgrams/ml	MEDOCHEMIE LTD.	CYPRUS	11504	13.03.2019	N01AH03
COMBINATIONS	SMOFKABIVEN LOW OSMO PERIPHERAL	emulsion inf.	100mg/ml	S.C. FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	11510	18.03.2019	B05BA10
FULVESTRANTUM	FULVESTRANT EVER PHARMA 250 mg	sol. for inj. in pre-filled syringe	250mg	EVER VALINJECT GMBH	AUSTRIA	11512	18.03.2019	L02BA03
FEBUXOSTATUM	FORURE 80 mg	film coated tabl.	80mg	EGIS PHARMACEUTICAL PLC	HUNGARY	11516	18.03.2019	M04AA03
FEBUXOSTATUM	FORURE 120 mg	film coated tabl.	120mg	EGIS PHARMACEUTICAL PLC	HUNGARY	11517	18.03.2019	M04AA03
ULIPRISTALUM	FEMKE 30 mg	film coated	30mg	MYLAN S.A.S.	FRANCE	11518	18.03.2019	G03AD02

INN	Trade name	Pharm. form	Strength	MAH	Country	MA No.	MA Date	ATC Code
ACETATUM		tabl.						
FLURBIPROFENUM	FARINGO INTENSIV 8.75 mg/dose	oromucosal spray, sol	8.75	TERAPIA S.A.	ROMANIA	11527	20.03.2019	R02AX01
BETAHISTINUM	DICLORHIDRAT DE BETAHISTINA ACCORD 24 mg	tabl.	24 mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	11531	20.03.2019	N07CA01
COMBINATIONS (AMLODIPINA+ VALSARTAN+HCT)	VALTRICOM 5 mg/160 mg/12.5 mg	film coated tabl.	5mg/160mg/1 2.5mg	KRKA D.D. NOVO MESTO	SLOVENIA	11545	28.03.2019	C09DX01
COMBINATIONS (AMLODIPINA+ VALSARTAN+HCT)	VALTRICOM 10 mg/160 mg/12.5 mg	film coated tabl.	0mg/160mg/12 .5mg	KRKA D.D. NOVO MESTO	SLOVENIA	11546	28.03.2019	C09DX01
COMBINATIONS (AMLODIPINA+ VALSARTAN+HCT)	VALTRICOM 5 mg/160 mg/25 mg	film coated tabl.	5mg/160mg/2 5mg	KRKA D.D. NOVO MESTO	SLOVENIA	11547	28.03.2019	C09DX01
COMBINATIONS (AMLODIPINA+ VALSARTAN+HCT)	VALTRICOM 10 mg/160 mg/25 mg	film coated tabl.	0mg/160mg/25 mg	KRKA D.D. NOVO MESTO	SLOVENIA	11548	28.03.2019	C09DX01
COMBINATIONS (AMLODIPINA+ VALSARTAN+HCT)	VALTRICOM 10 mg/320 mg/25 mg	film coated tabl.	0mg/320mg/25 mg	KRKA D.D. NOVO MESTO	SLOVENIA	11549	28.03.2019	C09DX01
FENTANYLUM	FENTANIL YES PHARMACEUTICALS 200 µgrams	lozenges with integrated oromucosal applicator	200 µgrams	YES PHARMACEUTICALS DEVELOPMENT SERVICES GMBH	GERMANY	11550	28.03.2019	N02AB03
FENTANYLUM	FENTANIL YES PHARMACEUTICALS 400 µgrams	lozenges with integrated oromucosal applicator	400 µgrams	YES PHARMACEUTICALS DEVELOPMENT SERVICES GMBH	GERMANY	11551	28.03.2019	N02AB03
FENTANYLUM	FENTANIL YES PHARMACEUTICALS 600 µgrams	lozenges with integrated oromucosal applicator	600 µgrams	YES PHARMACEUTICALS DEVELOPMENT SERVICES GMBH	GERMANY	11552	28.03.2019	N02AB03

INN	Trade name	Pharm. form	Strength	MAH	Country	MA No.	MA Date	ATC Code
FENTANYLUM	FENTANIL YES PHARMACEUTICALS 800 µgrams	lozenges with integrated oromucosal applicator	800 µgrams	YES PHARMACEUTICALS DEVELOPMENT SERVICES GMBH	GERMANY	11553	28.03.2019	N02AB03
FENTANYLUM	FENTANIL YES PHARMACEUTICALS 1200 µgrams	lozenges with integrated oromucosal applicator	1200 µgrams	YES PHARMACEUTICALS DEVELOPMENT SERVICES GMBH	GERMANY	11554	28.03.2019	N02AB03
FENTANYLUM	FENTANIL YES PHARMACEUTICALS 1600 µgrams	lozenges with integrated oromucosal applicator	1600 µgrams	YES PHARMACEUTICALS DEVELOPMENT SERVICES GMBH	GERMANY	11555	28.03.2019	N02AB03
ANAGRELIDUM	ANAGRELIDA NORDIC 0.5 mg	tabl.	0.5mg	NORDIC GROUP B.V.	NETHERLANDS	11556	28.03.2019	L01XX35
ANAGRELIDUM	ANAGRELIDA NORDIC 0.75 mg	tabl.	0.75mg	NORDIC GROUP B.V.	NETHERLANDS	11557	28.03.2019	L01XX35
ANAGRELIDUM	ANAGRELIDA NORDIC 1,0 mg	tabl.	1mg	NORDIC GROUP B.V.	NETHERLANDS	11558	28.03.2019	L01XX35
OMEPRAZOLUM	OMECOD 10 mg	gastrores. caps.	10mg	ESTEVE PHARMACEUTICALS, S.A.	SPAIN	11559	28.03.2019	A02BC01
OMEPRAZOLUM	OMECOD 20 mg	gastrores. caps.	20mg	ESTEVE PHARMACEUTICALS, S.A.	SPAIN	11560	28.03.2019	A02BC01
OMEPRAZOLUM	OMECOD 40 mg	gastrores. caps.	40mg	ESTEVE PHARMACEUTICALS, S.A.	SPAIN	11561	28.03.2019	A02BC01
FULVESTRANTUM	FULVESTRANT ACCORD 250 mg	sol. for inj. in pre-filled syringe	250mg	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	11563	28.03.2019	L02BA03
SILDENAFILUM	AZURVIG 25 mg/ml	oral susp.	25mg/ml	FARMALIDER S.A.	SPAIN	11564	28.03.2019	G04BE03
ANIDULAFUNGINUM	ANIDULAFUNGINA ACCORD 100 mg	powder for conc. for sol. for inf.	100mg	ACCORD HEALTHCARE	POLAND	11565	28.03.2019	J02AX06

INN	Trade name	Pharm. form	Strength	MAH	Country	MA No.	MA Date	ATC Code
VACCIN PNEUMOCOCCIC POLIZAHARIDIC	PNEUMOVAX 23	sol. for inj. in pre-filled syringe		MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	11566	28.03.2019	J07AL
TOPIRAMATUM	TOPIRAMAT ARENA 25 mg	film coated tabl.	25mg	ARENA GROUP SRL	ROMANIA	11567	28.03.2019	N03AX11
TOPIRAMATUM	TOPIRAMAT ARENA 50 mg	film coated tabl.	50mg	ARENA GROUP SRL	ROMANIA	11568	28.03.2019	N03AX11
TOPIRAMATUM	TOPIRAMAT ARENA 100 mg	film coated tabl.	100mg	ARENA GROUP SRL	ROMANIA	11569	28.03.2019	N03AX11
TOLPERISONUM	MYDERISON 50 mg	film coated tabl.	50mg	S.C. BIO EEL S.R.L.	ROMANIA	11570	28.03.2019	M03BX04
TOLPERISONUM	MYDERISON 150 mg	film coated tabl.	150mg	S.C. BIO EEL S.R.L.	ROMANIA	11571	28.03.2019	M03BX04
FOSFOMYCINUM	FOSFOMICINA MIDAS 3g	powder for oral sol.	3g	MIDAS PHARMA GMBH	GERMANY	11576	28.03.2019	J01XX01
ACIDUM ASCORBICUM	VITAMINA C MESFARMA 100 mg/ml	sol inj./inf.	100mg/ml	MESFARMA SRL	ROMANIA	11595	29.03.2019	A11GA01
PREGABALINUM	PREGABALINA VIVANTA 75 mg	caps.	75mg	VIVANTA GENERICS S.R.O.	CZECH REP.	11601	29.03.2019	N03AX16
PREGABALINUM	PREGABALINA VIVANTA 150 mg	caps.	150mg	VIVANTA GENERICS S.R.O.	CZECH REP.	11602	29.03.2019	N03AX16
PREGABALINUM	PREGABALINA VIVANTA 300 mg	caps.	300mg	VIVANTA GENERICS S.R.O.	CZECH REP.	11603	29.03.2019	N03AX16
COMBINATIONS (GESTODENUM+ ETINILESTRADIOLUM)	KARISSA ZILNIC 75 µgrams/ 20 µgrams	lozenges	75µgrams/ 20µgrams	GEDEON RICHTER ROMANIA S.A.	ROMANIA	11584	29.03.2019	G03AA10
POSACONAZOLUM	POSACONAZOL FLOMI 40 mg/ml	oral susp.	40mg/ml	FLORA FARM SRL	ROMANIA	11578	29.03.2019	J02AC04
PARACETAMOLUM	PARACETAMOL ACCORD 500 mg	eff. tabl.	500mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	11579	29.03.2019	N02BE01

INN	Trade name	Pharm. form	Strength	MAH	Country	MA No.	MA Date	ATC Code
COMBINATIONS	GNAK 50 mg/ml	sol. for inf.	50mg/ml	BAXTER HEALTHCARE SRL	ROMANIA	11581	29.03.2019	B05BB02
SUGAMMADEXUM	SUGAMMADEX MEDICHEM 100 mg/ml	sol. for inj.	100mg/ml	MEDICHEM S.A.	SPAIN	11583	29.03.2019	V03AB35
COMBINATIONS (TELMISARTANUM+ HYDROCHLOROTHIAZIDUM)	TELHYCAR 80 mg/12.5 mg	tabl.	80mg/ 12.5mg	SWYSSI AG.	GERMANY	11599	29.03.2019	C09DA07
COMBINATIONS (TELMISARTANUM+ HYDROCHLOROTHIAZIDUM)	TELHYCAR 80 mg/25 mg	tabl.	80mg/25mg	SWYSSI AG.	GERMANY	11600	29.03.2019	C09DA07
KETOPROFENUM	SPRANTIFEN 25 mg	film coated tabl.	25mg	DOMPE FARMACEUTICI S.P.A.	ITALY	11609	29.03.2019	M01AE03

Centrally authorised medicinal products notified for marketing in Romania in the 1st quarter 2019

INN	Trade name	Pharm. form	Strength	MAH	Country	MAH No	MA date	ATC Code
BRIGATINIBUM	ALUNBRIG 30 mg	film coated tabl.	30mg	TAKEDA PHARMA A/S	DENMARK	1264	22.11.2018	L01XE43
BRIGATINIBUM	ALUNBRIG 90 mg	film coated tabl.	90mg	TAKEDA PHARMA A/S	DENMARK	1264	22.11.2018	L01XE43
BRIGATINIBUM	ALUNBRIG 180 mg	film coated tabl.	180mg	TAKEDA PHARMA A/S	DENMARK	1264	22.11.2018	L01XE43
DORAVIRINUM	PIFELTRO 100 mg	film coated tabl.	100mg	MERCK SHARP & DOHME B.V.	NETHERLANDS	1332	22.11.2018	J05AG06
DORAVIRINUM+ LAMIVUDINUM+ TENOFVIRUM DISOPROXIL	DELSTRIGO 100 mg/300 mg/ 245 mg	film coated tabl.	100mg/300mg/ 245mg	MERCK SHARP & DOHME B.V.	NETHERLANDS	1333	22.11.2018	J05AG24
COMBINATIONS (GLICOPIRONIUM + FORMOTEROLUM)	BEVESPI AEROSPHERE 7.2 µgrams/5 µgrams µ	pressurised inhalation, susp.	7.2µgrams/5µgrams ms	ASTRAZENECA AB	SWEDEN	1339	20.12.2018	R03AL07
NATRII ZIRCONII CYCLOSILICAS	LOKELMA 5 g	powder for oral susp.	5g	ASTRA ZENECA AB	SWEDEN	1173	22.03.2018	V03AE10
NATRII ZIRCONII CYCLOSILICAS	LOKELMA 10 g	powder for oral susp.	10g	ASTRA ZENECA AB	SWEDEN	1173	22.03.2018	V03AE10
TRASTUZUMABUM	HERZUMA 420 mg	powder for conc. for sol. for inf.	420mg	CELLTRION HEALTHCARE HUNGARY KFT.	HUNGARY	1257	09.02.2018	L01XC03
DUPILUMABUM	DUPIXENT 300 mg	sol. for inj. in pre-filled syringe	300mg	SANOFI-AVENTIS GROUPE	FRANCE	1229	28.09.2017	D11AH05
BARICITINIBUM	OLUMIANT 2 mg	film coated tabl.	2mg	ELI LILLY NEDERLAND B.V.	NETHERLANDS	1170	13.02.2017	L04AA37
LETERMOVIRUM	PREVYMIS 240 mg	conc. for sol. for inf.	240mg	MERCK SHARP & DOHME B.V.	NETHERLANDS	1245	08.01.2018	J05AX18
INSULINUM GLARGINE	TOUJEO 300 Units/ml DOUBLESTAR	sol. for inj. in pre-filled pen	300units/ml	SANOFI - AVENTIS DEUTSCHLAND GMBH	GERMANY	133	24.04.2015	A10AE04