

ROMANIA

Newsletter

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*National Agency
for Medicines and Medical Devices
of Romania*

Orders of the Minister of Health

Medicinal product batches recalled during the 2nd quarter of 2020

Applications for marketing authorisation/marketing authorisation renewal received during the 1st quarter of 2020

Centrally authorised medicinal products notified for marketing in Romania during the 1st quarter of 2020

Medicinal products authorised through centralised procedure, performed at the level of the European Medicines Agency (EMA), notified for marketing in Romania during the 1st quarter of 2020

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Order no. 561

of 3 April 2020

on amendment and supplementation of Annex to Order of the Minister of Health no. 85/2013 on approval of the Rules for implementation of provisions of Article 703 (1) and (2) of Law 95/2006 on healthcare reform on medicinal products for special needs

Published in: The Official Gazette no. 286 of 6 April 2020

On seeing the Approval report of the Medicinal Product Policy and Medical Devices Directorate No. NT 472 of 3 April 2020 and NAMMDR notification no. 53.611E of 25 March 2020, registered at the Ministry of Health with no. 15.966 of 25 March 2020,

taking into account provisions of:

- Article 703 (2) of Law 95/2006 on healthcare reform, republished, as further amended;

- Decree no. 195/2020 regarding the state of emergency established in Romania;

- Article 4 (3) point 1 of Law no. 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions;

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 I – Annex to Order of the Minister of Health no. 85/07.02.2013 on approval of the Norms for implementation of provisions of Article 703 (1) and (2) of Law No. 95/2006 on healthcare reform concerning medicinal products for special needs, published in the Official Gazette of Romania, Part I, no. 93 of 14 February 2013, as further amended and supplemented, is amended and shall read as follows:

1. A new Article, namely Article 11¹ is introduced after Article 11, as follows:

"Article 11¹ - (1) By waiver from the provisions of Article 10 (2), during the pandemic, the National Agency for Medicines and Medical Devices of Romania may issue an authorisation regarding the supply of medicines for special needs only for the medicinal products provided in the Protocol for the treatment of the SARS-Cov-2 virus infection, as approved through Order of the Minister of Health no. 487/2020, as amended, at the initiative of the Ministry of Health, through specialised commissions or directorates, pursuant to Article 703 (2) of Law 95/2006 on healthcare reform, as further amended and supplemented, for medicinal products both authorised and unauthorised for marketing in Romania.

(2) The National Agency for Medicines and Medical Devices of Romania issues the authorisation regarding the supply of medicinal products for special needs, in Romanian and English, based on the medical justification report issued by the specialised commissions within the Ministry of Health, within maximum 72 hours from the date of registration of the request sent by the Ministry of Health.

(3) The authorisation for supply of medicinal products for special needs shall be valid until the stock for which it was issued is exhausted, but no later than the expiry date of the authorisation.

(4) The medicinal products authorised in line with this Article shall be exempted from the legal provisions in force concerning the packaging / labelling of medicinal products authorised for placement on the market. "

2. Throughout the entire regulatory act, phrase "The National Agency for Medicines and Medical Devices" shall be replaced with "The National Agency for Medicines and Medical Devices of Romania".

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

Minister of Health,
Nelu Tătaru

ORDER

no. 672 of 23 April 2020

on approval of the list of medical devices required in order to ensure the prevention and treatment of conditions associated with the SARS-CoV-2 infection, whose distribution is temporarily suspended, and of measures required to ensure medicinal products at high risk of discontinuation on the national market

Published in: The Official Gazette no. 332 of 23 April 2020

On seeing Approval Report no. NT 1437/23.04.2020 of the Directorate for the policy of medicines and medical devices,

taking into account:

- Decree no. 195/2020 on establishment of the state of emergency on the Romanian territory and Decree no. 240/2020 on extension of the state of emergency on the Romanian territory;

- Article 5 (1) of Military Ordinance no. 1/2020 on certain first emergency measures concerning crowds and cross-border shipping of goods, with subsequent completions;

- Article 804 (21) and (3) of Law 95/2006 on healthcare reform, republished, as further amended;

- Article 4 (3) point 1 and (4) point 4 of Law no. 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions;

pursuant to Article 7 (4) of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health, as further amended and supplemented,

the minister of health hereby issues the following order:

Article 1 - (1) The list of medical devices required in order to ensure the prevention and treatment of conditions associated with the SARS-CoV-2 infection, whose distribution is temporarily suspended, provided in the Annex which is integral part of this Order, for a 6-month period from the date of entry into force of this Order.

(2) By waiver from provisions of paragraph (1), deliveries outside Romania of medical devices manufactured in Romania to commercial partners residing outside Romania with whom the Romanian economic operator has concluded a manufacturing or loan contract, medical devices in transit, as well as deliveries under contract in a joint public procurement launched at European Union level.

(3) In the situation provided in paragraph (2), the economic operator shall present to the customs office the following:

a) a copy of the license / certificate / authorisation for operation for the commercial partner based outside Romania, translated into an international language;

b) a statutory declaration according to which the delivered medical devices are not destined for the Romanian market and whose final destination is the country mentioned in the delivery documents;

c) the contract (copy) according to which the medical devices are delivered within a common public procurement launched at the level of the European Union.

(4) For delivery outside Romania of the medical devices provided under paragraph (2), in line with the provisions of Annex I to Commission Implementing Regulation (EU) 2020/402 of 14 March 2020 making the exportation of certain products subject to the production of an export authorisation, the authorisation shall be granted by the national authority responsible for implementation of the European Union's trade policy.

(5) The shipping of assemblies and subassemblies of medical devices, manufactured in Romania for external beneficiaries, is not subject to the interdiction provided under paragraph (1).

Article 2 - (1) The distribution, for a 6-month period, from the date of entry into force of this Order, of medicinal products included in the Protocol for the treatment of the SARS-Cov-2 virus infection, approved by Order of the Ministry of Health no. 487/2020, with subsequent amendments, as well as medicinal products with an increased risk of discontinuation for chronic pathologies in the context of the SARS-Cov-2 virus pandemic, provided in the Annex which is part of this Order.

(2) By waiver from the provisions of paragraph (1), the medicinal products provided in the Annex to this Order may be sent via intra-community delivery outside the territory of Romania under the following conditions:

a) the economic operator notifies the National Agency for Medicines and Medical Devices of Romania (NAMMDR) the intention to deliver outside Romania 7 working days before delivery, according to the Annex to Order of the Minister of Health no. 269/2017 on mandatory provision of medicinal product adequate and continuous stocks;

b) The NAMMDR analyses the request of the economic operator and may approve or reject its request in case of a discontinuation or risk of discontinuation on the national market. The NAMMDR considers the discontinuations communicated in the last two months by distributors, pharmacies or healthcare professionals. The NAMMDR also considers the situations in which the current stock does not cover the needs of patients in Romania;

c) the economic operator may also make the delivery if the NAMMDR does not comply with the request within a maximum of 7 working days from the receipt of its notification;

d) in case the economic operator's request is rejected, the NAMMDR communicates to him the reasons for the decision to reject the respective request;

e) the economic operator may contest within a maximum of two working days at the NAMMDR the decision of rejection in case it considers that the decision is unfounded, presenting in this respect the necessary arguments; the NAMMDR analyses the appeal of the economic operator and issues the final decision within a maximum of 5 working after receipt of the appeal.

(3) Medicinal products manufactured by manufacturers based in Romania, including those manufactured under contract, as well as medicinal products that transit the territory of Romania and which are destined for other markets outside Romania are exempted from the provisions of paragraphs (1) and (2).

(4) In the case of the medicinal products provided in paragraph (3), the manufacturer shall present to the customs office:

a) a copy of the manufacturing authorisation accompanied by Annex 8, approved by the NAMMDR, specifying the respective medicinal products. If the medicinal products are not provided in Annex 8, the manufacturer must provide a copy of the marketing authorisation / special needs import authorisation / import permit, translated into an international language, approved by the competent authority of the country of destination;

b) a statutory declaration, according to which the delivered medicinal products are not destined for the Romanian market and whose final destination is the country mentioned in the delivery documents.

(5) The medicinal products mentioned under paragraph (3) can only be exported if the NAMMDR approved the export declarations in line with Order of

the Minister of Public Health no. 894/2006 on approval of Regulations regarding export of medicinal products for human use, as further amended, and with Order of the Minister of Public Health no. 1809/2006 on approval of Norms concerning the approval of export declaration for medicinal products for human use in compliance with the provisions of this Order.

Article 3 - For the purpose of this order, the terms below have the following meaning:

- a) **export** - any delivery to third countries,
- b) **delivery outside the Romanian territory** - intra-community delivery and/or delivery to third countries;
- c) **distribution** - delivery or export outside the Romanian territory.

Article 4 - Noncompliance with the provisions of this Order shall be sanctioned according to the provisions of Article 875 (1) k) of Law 95/2006 on the healthcare reform, republished, as further amended and supplemented.

Article 5 - On this Order coming into force, Order of the Minister of Health no. 428/2020 on approval of the List of medical devices and healthcare materials to ensure prevention and treatment of diseases associated with the SARS-VOC-2 infection, whose distribution outside Romania is temporarily suspended, as well as of the measures to ensure medicines included in the CANAMED National Catalogue of the Prices of Medicinal Products Authorised for Marketing in Romania, published in the Official Gazette of Romania, Part I, no. 202 of March 12, 2020, as further amended and supplemented.

Article 6 - This Order shall be published in the Official Journal of Romania, Part I.

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This Order was notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

pp. the minister of health,

Romică-Andrei Baci,

Secretary of State

LIST

comprising the medical devices required in order to ensure prevention and treatment of conditions associated with the SARS-CoV-2 infection, whose distribution is temporarily suspended

I. Medical devices

No.	Medical device name
1.	Surgical masks for medical staff
2.	Surgical masks for patients
3.	Oxygen concentrator
4.	Pulse oximeter
5.	Oxygen supply regulator/distributor
6.	Thorpe tube flowmeter
7.	Heat-free humidifier
8.	Nasal cannulae
9.	Catheters
10.	Oxygen mask
11.	Venturi mask
12.	Patient ventilator for intensive care
13.	Laryngoscope for adults/children
14.	Laryngoscope for newborns
15.	Endotracheal tube without inflatable cuff
16.	Endotracheal tube with inflatable cuff
17.	Bougie type endotracheal tube introducer
18.	Stylet type endotracheal tube introducer
19.	Capnometer (CO2 detector)
20.	Manual resuscitators, adult (balloon ventilation)
21.	Manual resuscitators, child (balloon ventilation)
22.	Guedel airway, sterile, single use
23.	Nasopharyngeal probes
24.	Secretion aspirator
25.	Infusion kit
26.	Examination gloves, non-sterile
27.	Examination or surgical gloves, sterile
28.	Protective goggles

29.	Visors
30.	Medical clothing, jackets
31.	Medical clothing, trousers
32.	High-strength apron
33.	Gown
34.	SARS-CoV-2 infection diagnostic tests
35.	Means of transporting viruses/bacteria

II. Medicinal products

No.	International Non-proprietary Name	Pharmaceutical form	Strength
0	1	2	3
1	ACETILCISTEINUM	TABLETS	200 mg; 300 mg
2	ACICLOVIRUM	CAPSULES	200 mg; 400 mg
3	ACIDUM ACETYLSALICYLICUM	GASTRORESISTANT TABLETS	75 mg
4	ACIDUM TRANEXAMICUM	SOLUTION FOR INJECTION FOR I.V. AND ORAL ADMINISTRATION	500 mg/5 ml
5	ACIDUM VALPROICUM + SALTS	SOFT GASTRORESISTANT CAPSULES	150 mg; 200 mg; 300 mg; 500 mg
		PROLONGED-RELEASE TABLETS	300 mg; 500 mg
6	ADENOSINUM	SOLUTION FOR INJECTION/INFUSION	5 mg/ml
7	AMINOPHYLLINUM	SOLUTION FOR INJECTION	24 mg/ml
8	AMIODARONUM	SOLUTION FOR INJECTION	50 mg/ml
9	AMITRIPTYLINUM		
10	AMLODIPINUM	TABLETS	10 mg; 5 mg
11	AMOXICILLINUM + ACIDUM CLAVULANICUM	POWDER FOR SOLUTION FOR INJECTION/INFUSION	1000 mg/200 mg

12	AMPICILLINUM + SULBACTAM	POWDER FOR SOLUTION FOR INJECTION/INFUSION	1000 mg/500 mg
13	ATORVASTATINUM	FILM-COATED TABLETS	40 mg; 80 mg
14	ATRACURIUM	SOLUTION FOR INJECTION	10 mg/ml - 5 ml
		SOLUTION FOR INJECTION	50 mg/5 ml
		SOLUTION FOR INJECTION/INFUSION	10 mg/ml
15	ATROPINUM	SOLUTION FOR INJECTION	1 mg/ml
16	BACLOFENUM	TABLETS	10 mg; 20 mg
17	BENZYL PENICILLINUM	POWDER FOR SOLUTION FOR INJECTION	1000000 IU
		POWDER FOR SOLUTION FOR INJECTION	400000 IU
		POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	70 mg
18	BISOPROLOLUM	FILM-COATED TABLETS	5 mg
19	BUDESONIDUM	INHALATION POWDER	200 mcg/dose; 400 mcg/dose
		PROLONGED-RELEASE TABLETS	9 mg
		GASTRORESISTANT GRANULES	9 mg
20	BUPIVACAINUM	SOLUTION FOR INJECTION	0.5%
		SOLUTION FOR INJECTION	5 mg/ml
21	CALCII GLUCONAS	SOLUTION FOR INJECTION	94 mg/ml; 95 mg/ml
22	CANDESARTANUM CILEXETIL	TABLETS	8 mg; 16 mg

23	CARVEDILOLUM	FILM-COATED TABLETS	6.25 mg; 12.5 mg
		TABLETS	6.25 mg; 12.5 mg
24	CASPOFUNGINUM	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	50 mg; 70 mg
25	CEFEPIMUM	POWDER FOR SOLUTION FOR INJECTION /INFUSION	1 g
26	CEFIXIMUM	FILM-COATED TABLETS	200 mg; 400 mg;
		CAPSULES	200 mg; 100 mg
27	CEFOPERAZONUM	I.M./I.V. POWDER FOR SOLUTION FOR INJECTION/INFUSION	1 g; 2 g; 500 mg
28	CEFOTAXIMUM	I.M./I.V. POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	1 g; 2 g; 500 mg
29	CEFTAZIDIMUM	POWDER FOR SOLUTION FOR INJECTION/INFUSION	1 g; 2 g
30	CEFTRIAXONUM	POWDER FOR SOLUTION FOR INJECTION/INFUSION	250 mg; 500 mg; 1 g; 2 g;
		I.M./I.V. POWDER FOR SOLUTION FOR INJECTION	250 mg
31	CEFUROXIMUM	POWDER FOR SOLUTION FOR INJECTION	50 mg
		CAPSULES	250 mg
		TABLETS	250 mg; 500 mg
		FILM-COATED TABLETS	125 mg; 250 mg; 500 mg
		POWDER FOR SOLUTION FOR INJECTION/INFUSION	1.5 g

		GRANULES FOR ORAL SUSPENSION	125 mg/5 ml
		(I.M., I.V.) POWDER FOR SUSPENSION (I.M.)/SOLUTION FOR INJECTION	750 mg
32	CICLOSPORINUM	SOFT CAPSULES	25 mg; 50 mg
		EYE DROPS, EMULSION	1 mg/ml
33	CIPROFLOXACINUM	FILM-COATED TABLETS	100 mg; 250 mg; 500 mg; 750 mg
		CONCENTRATE FOR SOLUTION FOR INFUSION	100 mg/10 ml
		SOLUTION FOR INFUSION	2 mg/ml
		PROLONGED-RELEASE FILM-COATED TABLETS	500 mg; 1000 mg
34	CLARITHROMYCINUM	PROLONGED-RELEASE FILM-COATED TABLETS	500 mg
		FILM-COATED TABLETS	500 mg
		POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	500 mg
35	CLINDAMYCINUM	I.M., I.V. SOLUTION FOR INJECTION	300 mg/2 ml
		SOLUTION FOR INJECTION/INFUSION	150 mg/ml
		FILM-COATED TABLETS	600 mg
		CAPSULES	150 mg; 300 mg
36	CLONIDINUM	TABLETS	0.15 mg
37	CLOPIDOGRELUM	FILM-COATED TABLETS	75 mg
38	CODEINUM	TABLETS	15 mg

39	COLCHICINUM	TABLETS	1 mg
40	COMBINATIONS (CEFTAZIDIMUM + AVIBACTAMUM)	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	2 g/0.5 g
41	COMBINATIONS (CEFTOLOZANUM + TAZOBACTAMUM)	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	1 g/0.5 g
42	COMBINATIONS (COAGULATION FACTORS)	POWDER AND SOLVENT FOR SOLUTION FOR INFUSION	500 IU; 1000 IU
43	COMBINATIONS (SPIRONOLACTONUM + FUROSEMIDUM)	CAPSULES	50 mg/20 mg
44	COMBINATIONS (LEVOTHYROXINE SODIUM + SODIUM LIOTHYRONINE)	TABLETS	100 micrograms/ 20 micrograms
45	DEXAMETHASONUM SOLUTION FOR INJECTION		4 mg/ml; 8 mg/2 ml
46	DEKKETOPROFENUM	SOLUTION FOR INJECTION/CONCENTR ATE FOR SOLUTION FOR INFUSION	50 mg
		SOLUTION FOR INJECTION/INFUSION	50 mg/2 ml
47	DIAZEPAMUM	SOLUTION FOR INJECTION	10 mg/2 ml
		TABLETS	10 mg
		RECTAL SOLUTION	5 mg/2.5 ml; 10 mg/2.5 ml
48	DICLOFENACUM	SOLUTION FOR INJECTION	75 mg/3 ml
49	DIGOXINUM	SOLUTION FOR INJECTION	0.5 mg/2 ml
		TABLETS	0.25 mg
50	DILTIAZEMUM	TABLETS	60 mg
		PROLONGED- RELEASE CAPSULES	90 mg; 180 mg
51	DOBUTAMINUM	SOLUTION FOR INFUSION	250 mg
52	DOPAMINUM	CONCENTRATE FOR SOLUTION FOR INFUSION	5 mg/ml

53	DROPERIDOLUM	SOLUTION FOR INJECTION	2.5 mg/ml
54	ENOXAPARINUM	SOLUTION FOR INJECTION	2000 IU (20 mg)/0.2 ml
55	EPINEPHRINUM	SOLUTION FOR INJECTION	1 mg/ml
56	EPTACOG ALFA ACTIVATUM	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	50 KIU
57	ERDOSTEINUM	CAPSULES	300 mg
58	ERGOMETRINUM	SOLUTION FOR INJECTION	0.2 mg/ml
59	ERTAPENEMUM	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	1 g
60	ERYTHROMYCINUM	TABLETS	200 mg
		CUTANEOUS SOLUTION	4 g/30 ml
61	ETOMIDATUM	EMULSION FOR INJECTION	2 mg/ml
62	FENTANYLUM	SUBLINGUAL TABLETS	100 mcg; 200 mcg; 300 mcg; 400 mcg; 600 mcg; 800 mcg
		PLASTURE TRANSDERMIC	25 mcg/h; 50 mcg/h; 100 mcg/h
63	HUMAN FIBRINOGEN	POWDER FOR SOLUTION FOR INJECTION/INFUSION	1 g
64	FLUCONAZOLUM	SOLUTION FOR INFUSION	2 mg/ml
		POWDER FOR ORAL SUSPENSION	10 mg/ml
65	FLUMAZENILUM	SOLUTION FOR INJECTION	0.1 mg/ml
		SOLUTION FOR INJECTION/CONCENTRATE FOR SOLUTION FOR INFUSION	0.1 mg/ml
66	FUROSEMIDUM	SOLUTION FOR INJECTION	10 mg/ml; 20 mg/2 ml
		TABLETS	40 mg
67	GENTAMICINUM	SOLUTION FOR INJECTION	40 mg/ml; 80 mg/2 ml
		EYE DROPS, SOLUTION	3 mg/ml
68	GLUCOSUM	SOLUTION FOR INJECTION	3.3 g/10 ml

69	HALOPERIDOLUM	SOLUTION FOR INJECTION	5 mg/1 ml; 50 mg/ml
70	HEPARINUM	SOLUTION FOR INJECTION	5000 IU/ml
71	HYDROCORTISONUM	I.V. SOLUTION FOR INJECTION	25 mg/5 ml
		POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION	100 mg
72	IBUPROFENUM	SOLUTION FOR INFUSION	400 mg; 600 mg
		FILM-COATED TABLETS	400 mg; 600 mg
73	IDARUCIZUMABUM	SOLUTION FOR INJECTION/INFUSION	2.5 g/50 ml
74	IMIPENEMUM + CILASTATINUM	POWDER FOR SOLUTION FOR INFUSION	500 mg/500 mg
75	IPRATROPII BROMIDUM	PRESSURISED SOLUTION FOR INHALATION	20 micrograms/dose
76	IRBESARTANUM	TABLETS	150 mg; 300 mg
		FILM-COATED TABLETS	150 mg; 300 mg
77	ITRACONAZOLUM	CAPSULES	100 mg
78	KALII CHLORIDUM	CONCENTRATE FOR SOLUTION FOR INFUSION	150 mg/ml
79	KANAMYCINUM	EYE OINTMENT	10 mg/g
80	KETAMINUM	SOLUTION FOR INJECTION	50 mg/10 ml
81	KETOROLACUM TROMETHAMIN	SOLUTION FOR INJECTION	30 mg/ml; 30 mg/ml - 1 ml
82	LANDIOLOLUM	CONCENTRATE FOR SOLUTION FOR INJECTION	20 mg/2 ml

		POWDER FOR SOLUTION FOR INFUSION	300 mg
83	LEVOCETIRIZINUM	FILM-COATED TABLETS	5 mg
84	LEVOFLOXACINUM	SOLUTION FOR INFUSION	5 mg/ml
		FILM-COATED TABLETS	500 mg; 250 mg
85	LEVOTHYROXINUM	TABLETS	25 mcg; 50 mcg
		ORAL SOLUTION	25 mcg/5 ml; 50 mcg/5 ml
86	LIDOCAINUM	SOLUTION FOR INJECTION	1%
		SPRAY, SOLUTION	10%
87	LINEZOLIDUM	SOLUTION FOR INFUSION	2 mg/ml
		FILM-COATED TABLETS	600 mg
88	LORATADINUM	ORAL SUSPENSION	5 mg/5 ml
		SYRUP	1 mg/ml; 5 mg/5 ml
89	LORAZEPAMUM	SOLUTION FOR INJECTION	4 mg/ml
		TABLETS	1 mg
90	MAGNESII SULFAS	SOLUTION FOR INJECTION	250 mg/ml
91	MANNITOLUM	SOLUTION FOR INFUSION	20%
		SOLUTION FOR INFUSION	200 g/l
92	MEROPENEMUM	POWDER FOR SOLUTION FOR INJECTION/INFUSION	500 mg; 1000 mg
93	METAMIZOLUM NATRIUM	TABLETS	500 mg
		SOLUTION FOR INJECTION	1 g/2 ml
94	METFORMINUM	TABLETS	500 mg; 850 mg; 1000 mg
		FILM-COATED TABLETS	500 mg; 850 mg; 1000 mg

		PROLONGED- RELEASE TABLETS	500 mg
95	METHADONUM	CONCENTRATE FOR ORAL SOLUTION	10 mg/ml
		TABLETS	2.5 mg; 5 mg; 20 mg
96	METHOTREXATUM	CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION	100 mg/ml
		SOLUTION FOR INJECTION IN PRE- FILLED SYRINGE	10 mg/ml; 15 mg; 20 mg; 7.5 mg; 17.5 mg; 22.5 mg
		TABLETS	10 mg; 2.5 mg
97	METHYLPREDNISOLONUM	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION	125 mg; 500 mg
		TABLETS	16 mg; 32 mg
98	METHYLTHIONINII CHLORIDUM	SOLUTION FOR INJECTION	5 mg/ml
99	METOCLOPRAMIDUM	SOLUTION FOR INJECTION	1 mg/5 ml; 5 mg/ml
100	METOPROLOLUM	SOLUTION FOR INJECTION/INFUSION	5 mg/5 ml
		TABLETS	25 mg; 50 mg
101	METRONIDAZOLUM	SOLUTION FOR INFUSION	5 g/l; 5 mg/ml; 500 mg/100 ml
		OVULE	500 mg
		FILM-COATED TABLETS	250 mg
102	MICAFUNGINUM	POWDER FOR SOLUTION FOR INFUSION	50 mg; 100 mg
103	MIDAZOLAMUM	SOLUTION FOR INJECTION	5 mg/ml
104	MILRINONUM	SOLUTION FOR INJECTION	10 mg/10 ml
		CONCENTRATE FOR SOLUTION FOR INFUSION	1 mg/ml
105	MIVACURIUM	SOLUTION FOR INJECTION/INFUSION	20 mg/10 ml
106	MORPHYNUM	SOLUTION FOR INJECTION	20 mg/ml
		FILM-COATED TABLETS	10 mg
107	MOXIFLOXACINUM	SOLUTION FOR INFUSION	400 mg/250 ml
		FILM-COATED TABLETS	400 mg
108	MOXONIDINUM	FILM-COATED TABLETS	0.2 mg; 0.4 mg

109	NADROPARINUM	SOLUTION FOR INJECTION	2850 IU AFXa/0.3 ml; 3800IU AFXa/0.4 ml; 5700 IU AFXa/ 0.6 ml
110	NALOXONUM	SOLUTION FOR INJECTION/INFUSION	0.4 mg/ml
		SOLUTION FOR INJECTION	0.4 mg/ml
111	NATRII CHLORIDUM	CONCENTRATE FOR SOLUTION FOR INFUSION	5.85%
112	NATRII HYDROGENI CARBONAS	SOLUTION FOR INFUSION	8.4%
113	NEBIVOLOLUM	TABLETS	5 mg
114	NEFOPAMUM	SOLUTION FOR INJECTION	20 mg/2 ml
115	NICARDIPINUM	SOLUTION FOR INJECTION	10 mg/10 ml
116	NIMODIPINUM	SOLUTION FOR INFUSION	10 mg/50 ml
		FILM-COATED TABLETS	30 mg
117	NITROGLYCERINUM	SOLUTION FOR INFUSION	1 mg/ml
		PROLONGED-RELEASE TABLETS	2,6 mg
		SUBLINGUAL SPRAY	0.4 mg/dose
118	NORADRENALINUM	CONCENTRATE FOR SOLUTION FOR INFUSION	2 mg/ml
119	OMEPRAZOLUM	GASTRORESISTANT CAPSULES	20 mg; 40 mg
120	ONDANSETRONUM	SOLUTION FOR INJECTION/INFUSION	2 mg/ml
		SOLUTION FOR INJECTION	2 mg/ml - 4 ml
121	OSELTAMIVIRUM	CAPSULES	30 mg; 75 mg
122	OXYCODONUM	PROLONGED-RELEASE TABLETS	20 mg; 40 mg; 60 mg; 80 mg
123	PALONOSETRONUM	SOLUTION FOR INJECTION	250 mcg
		SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	250 mcg
124	PANTOPRAZOLUM	POWDER FOR SOLUTION FOR INJECTION	40 mg
		GASTRORESISTANT TABLETS	20 mg; 40 mg
125	PARACETAMOLUM	SOLUTION FOR INFUSION	10 mg/ml
		TABLETS	500 mg

126	PERINDOPRILUM	FILM-COATED TABLETS	5 mg; 10 mg
127	PETHIDINUM	SOLUTION FOR INJECTION	50 mg/ml
128	PHENYLEPHRINUM	SOLUTION FOR INJECTION	50 micrograms/ml
129	PHENYTOINUM	TABLETS	100 mg
		SOLUTION FOR INJECTION/INFUSION	50 mg/ml
		SOLUTION FOR INJECTION	250 mg/5 ml
130	PHYTOMENADIONUM	SOLUTION FOR INJECTION	10 mg/ml
131	PIPERACILLINUM + TAZOBACTAMUM	POWDER FOR SOLUTION FOR INFUSION	2 g/0.25 g; 4 g/0.50 g
132	PREGABALINUM	CAPSULES	300 mg; 75 mg; 150 mg
133	PROPAFENONUM	SOLUTION FOR INJECTION	70 mg/20 ml
134	PROPOFOLUM EMULSIE	INJECTION/INFUSION	10 mg/ml
135	PROTAMINI SULFAS	SOLUTION FOR INJECTION	10 mg/ml
136	PYRIDOSTIGMINI BROMIDUM	LOZENGES	60 mg
137	RANITIDINUM	SOLUTION FOR INJECTION	25 mg/ml - 2 ml
138	REMIFENTANILUM	POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION	1 mg
139	RIFAMPICINUM	CAPSULES	150 mg; 300 mg
140	RILMENIDINUM	TABLETS	1 mg
141	ROCURONIUM BROMIDE	SOLUTION FOR INJECTION	10 mg/ml
142	ROPIVACAINUM	SOLUTION FOR INJECTION	2 mg/ml; 10 mg/ml
143	ROSUVASTATINUM	FILM-COATED TABLETS	10 mg; 20 mg
144	SALBUTAMOLUM	PRESSURISED INHALATION, SOLUTION	100 mcg/dose
		SOLUTION FOR INJECTION	0.5 mg/ml
		SYRUP	2 mg/5 ml
145	SEVOFLURANUM	LIQUID INHALATION VAPOUR	
146	SPIRONOLACTONUM	CAPSULES	25 mg
		TABLETS	25 mg
		FILM-COATED TABLETS	25 mg
147	SUCRALFATUM	TABLETS	1 g

148	SUFENTANILUM CITRATUM	SOLUTION FOR INJECTION/INFUSION	5 micrograms/ml; 50 micrograms/ml
149	SUXAMETHONII CHLORIDUM	SOLUTION FOR INJECTION	0.1 g/5 ml
150	THIOPENTALUM	POWDER FOR SOLUTION FOR INJECTION	1 g; 500 mg
151	TICAGRELOR	FILM-COATED TABLETS	90 mg
152	TIGECYCLINUM	POWDER FOR SOLUTION FOR INFUSION	50 mg
153	TOBRAMYCINUM	SOLUTION FOR INHALATION	300 mg/5 ml
		EYE DROPS, SOLUTION	0.3%
		NEBULISER SOLUTION	300 mg
154	TRAMADOLUM	SOLUTION FOR INJECTION	50 mg/ml - 1 ml; 100 mg
		PROLONGED-RELEASE TABLETS	100 mg; 150 mg; 200 mg
155	TRIMEBUTINUM	TABLETS	100 mg
		FILM-COATED TABLETS	100 mg; 200 mg
		PROLONGED-RELEASE FILM-COATED TABLETS	300 mg
156	VACCIN BCG	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	0.05 mg/dose
157	VANCOMYCINUM	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	1000 mg; 500 mg
158	VASOPRESINUM (ARGIPRESINUM)	CONCENTRATE FOR SOLUTION FOR INFUSION	40 IU/2 ml
159	VERAPAMILUM	LOZENGES	40 mg; 80 mg
160	VORICONAZOLUM	POWDER FOR SOLUTION FOR INFUSION	POWDER FOR SOLUTION FOR INFUSION
		POWDER FOR ORAL SUSPENSION	POWDER FOR ORAL SUSPENSION

Medicinal product batches recalled during the 2nd quarter of 2020

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/MAH	Batch	Grounds for recall	Proposed action	Date of recall
1	Ranitidina ATB 150 mg	film-coated tablets	150 mg	ranitidine	Antibiotice SA	all batches	voluntary recall from the market, at pharmacy level, as a precautionary measure, of all batches blocked from sale following the identification of nitrosamine impurities	Voluntary recall and destruction	13.05.2020
2	Ranitidina Laropharm 150 mg	film-coated tablets	150 mg	ranitidine	Laropharm SRL	all batches	voluntary recall from the market, at pharmacy level, as a precautionary measure, of all batches blocked from sale following the identification of nitrosamine impurities	Voluntary recall and destruction	11.06.2020

Applications for marketing authorisation/marketing authorisation renewal received during the 1st quarter of 2020

10 applications for marketing authorisation/marketing authorisation renewal were received during the 1st quarter of 2020 for medicinal products belonging to the following therapeutic groups:

INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	ATC code	Status
SULFAMETOXAZOL + TRIMETOPRIM	BISEPTOL 120 mg tablets	tablets	120 mg	APC INSTYTUT SP. O.O. Al. Jerozolimskie 146C, Warsaw, POLAND	POLAND	J01 – antibacterials for systemic use	A
SULFAMETOXAZOL + TRIMETOPRIM	BISEPTOL 480 mg tablets	tablets	480 mg	APC INSTYTUT SP. Z O.O. Al. Jerozolimskie 146C, Warsaw, POLAND	POLAND	J01 – antibacterials for systemic use	A

PARACETAMOL + ASCORBIC ACID + PHENIRAMINE MALEATE	Sugar-free FERVEX “for adults” 500mg/200mg/25 mg granules for oral solution	granules for oral solution	500mg/ 200mg/25m g	UPSA S.A.S 3 Rue Joseph Monier Rueil Malmaison, 92500, FRANCE	FRANCE	N02 - Analgesics	A
BUDESONIDE, micronized	BUDECTON 200 µg inhalation powder, capsules	inhalation powder, capsules	200 µg	S.C. SLAVIA Pharm S.R.L. 44C Theodor Pallady, sector 3, Bucharest	ROMANIA	R03 - Drugs for obstructive airway diseases	A
CARBAZOCROM	ADRENOSTAZIN 1.5 mg solution for injection/infusion	solution for injection/infusi on	1.5 mg	TERAPIA SA 124 Fabricii Street, Cluj-Napoca, ROMANIA	ROMANIA	B02 – Other systemic haemostatics	R
CARBAMAZEPINE	CARBAMAZEPINĂ FARMEX 200 mg tablets	tablets	200 mg	S.C. FARMEX COMPANY S.R.L 30 Drumul Potcoavei, Pipera, Voluntari, Ilfov county, ROMANIA	ROMANIA	N03 - Antiepileptics	R

NORFLOXACIN	Norfloxacin Laropharm 400 mg film-coated tablets	film-coated tablets	400 mg	S.C. LAROPHARM S.R.L. 145A Șoseaua Alexandriei, Bragadiru, Ilfov county, ROMANIA	ROMANIA	J01 – antibacterials for systemic use	R
AMYLMETACRESOL ALCOHOL 2,4- DICHLOROBENZYL ALCOHOL	STREPSILS CU AROMĂ DE PRUNE 0.6mg/1.2mg lozenges	lozenges	0.6mg/1.2m g	RECKITT BENCKISER (ROMANIA) SRL 89-97 Grigore Alexandrescu, building A, floor 5, sector 1, Bucharest, ROMANIA	ROMANIA	R02 - Throat preparations	R
AMYLMETACRESOL ALCOHOL 2,4- DICHLOROBENZYL ALCOHOL	STREPSILS CU EUCALIPT 0.6mg/1.2mg lozenges	lozenges	0.6mg/1.2m g	RECKITT BENCKISER (ROMANIA) SRL 89-97 Grigore Alexandrescu, building A, floor 5, sector 1, Bucharest, ROMANIA	ROMANIA	R02 - Throat preparations	R

LORATADINE	LORATADINA SLAVIA 10 mg tablets	tablets	10 mg	SC SLAVIA PHARM SRL 44C Theodor Pallady, Sector 3, 032266, Bucharest, ROMANIA	ROMANIA	R06 – Antihistamines for systemic use	R
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Centrally authorised medicinal products notified for marketing in Romania during the 1st quarter of 2020

INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.		
ABACAVIRUM SULFATE	ABACAVIR AUROBINDO	film-coated tablets	300mg	AUROBINDO PHARMA SRL	ROMANIA	130 77	2020	01
ACICLOVIRUM	ACICLOVIR HYPERION	cream	50mg/g	HYPERION S.A.	ROMANIA	129 31	2020	01
ACIDUM FOLICUM	ACIFOL	film-coated tablets	5 mg	ZENTIVA S.A.	ROMANIA	129 35	2020	01
ACIDUM GADOTERICUM	DOTAGRAF	solution for injection in single dose vial	0.5mmoles /ml	BAYER AG	GERMANY	128 98	2020	01
ACIDUM GADOTERICUM	DOTAGRAF	solution for injection in multidose vial	0.5mmoles /ml	BAYER AG	GERMANY	128 99	2020	01
ALBENDAZOLUM	ALBENDAZOL LPH	film-coated tablets	200mg	LABORMED PHARMA S.A.	ROMANIA	129 41	2020	01
ALPRAZOLAMUM	FRONTIN	tablets	0.25mg	EGIS PHARMACEUTIC ALS PLC	HUNGARY	129 16	2020	01

ALPRAZOLAMUM	FRONTIN	tablets	0.5mg	EGIS PHARMACEUTIC ALS PLC	HUNGARY	129 17	2020	01
ALPRAZOLAMUM	FRONTIN	tablets	1mg	EGIS PHARMACEUTIC ALS PLC	HUNGARY	129 18	2020	01
ALPROSTADILUM	ALPROSTADIL ROMPHARM	powder for solution for infusion	20 µg	ROMPHARM COMPANY S.R.L.	ROMANIA	128 90	2020	01
AMIODARONUM HYDROCHLORIDE	AMIODARONA LPH	tablets	200mg	LABORMED PHARMA S.A.	ROMANIA	129 38	2020	01
AMISULPRIDUM	AMISULPRIDA LPH	tablets	200mg	LABORMED PHARMA S.A.	ROMANIA	129 93	2020	01
AMLODIPINUM	AMLODIPINA VIM SPECTRUM	tablets	5mg	VIM SPECTRUM S.R.L.	ROMANIA	129 06	2020	01
AMLODIPINUM	AMLODIPINA VIM SPECTRUM	tablets	10mg	VIM SPECTRUM S.R.L.	ROMANIA	129 07	2020	01
AMPICILLINUM	PAMECIL	powder for solution for injection/infusion	500 mg	MEDOCHÉMIE LTD	CYPRUS	130 27	2020	01
AMPICILLINUM	PAMECIL	powder for solution for injection/infusion	1 g	MEDOCHÉMIE LTD	CYPRUS	130 28	2020	01

ANIDULAFUNGINUM	ANIDULAFUNGINA MYLAN	powder for concentrate for solution for infusion	100mg	MYLAN IRELAND LIMITED	IRELAND	129 55	2020	01
HUMAN ANTITHROMBIN III	ATENATIV	powder and solvent for solution for infusion	50 UI/ml	OCTAPHARMA (IP) LTD.	BELGIUM	129 81	2020	01
ARIPIPRAZOLUM	ARIPIPRAZOL STADA	tablets	10mg	STADA M&D S.R.L.	AUSTRIA	130 53	2020	01
ARIPIPRAZOLUM	ARIPIPRAZOL STADA	tablets	15mg	STADA M&D S.R.L.	AUSTRIA	130 54	2020	01
ATORVASTATINUM	ATORVASTATINA AUROBINDO	film-coated tablets	10mg	AUROBINDO PHARMA LIMITED	MALTA	130 35	2020	01
ATORVASTATINUM	ATORVASTATINA AUROBINDO	film-coated tablets	20mg	AUROBINDO PHARMA LIMITED	MALTA	130 36	2020	01
ATORVASTATINUM	ATORVASTATINA AUROBINDO	film-coated tablets	40mg	AUROBINDO PHARMA LIMITED	MALTA	130 37	2020	01
ATORVASTATINUM	ATORVASTATINA AUROBINDO	film-coated tablets	80mg	AUROBINDO PHARMA LIMITED	MALTA	130 38	2020	01
AZITHROMYCINUM	AZITROMICINA ROMPHARM	powder for concentrate for	500mg	ROMPHARM COMPANY S.R.L.	ROMANIA	129 79	2020	01

		solution for infusion						
AZITHROMYCINUM DIHYDRATUM	AZIBIOT	film-coated tablets	500 mg	KRKA D.D. NOVO MESTO	SLOVENIA	130 84	2020	01
BENDAMUSTINUM	BENDAMUSTINA MYLAN	powder and solvent for solution for infusion	2.5mg/ml	MYLAN S.A.S.	FRANCE	129 56	2020	01
BETAHISTINUM DIHYDROCHLORIDE	BETAHISTINA MCC	tablets	8mg	MAGISTRA C&C S.R.L.	ROMANIA	129 14	2020	01
BETAHISTINUM DIHYDROCHLORIDE	BETAHISTINA MCC	tablets	24mg	MAGISTRA C&C S.R.L.	ROMANIA	129 15	2020	01
BICALUTAMIDUM	BICALUTAMIDA ACCORD	film-coated tablets	150mg	ACCORD HEALTHCARE POLSKA SP Z.O.O.	POLAND	130 76	2020	01
BORTEZOMIBUM	BORTEZOMIB SANDOZ	powder for solution for injection	2.5mg	SANDOZ S.R.L.	ROMANIA	130 23	2020	01
BORTEZOMIBUM	BORTEZOMIB SANDOZ	powder for solution for injection	1mg	SANDOZ S.R.L.	ROMANIA	129 63	2020	01
BORTEZOMIBUM	BORTEZOMIB SANDOZ	powder for solution for injection	3.5mg	SANDOZ S.R.L.	ROMANIA	129 64	2020	01

BORTEZOMIBUM	VORTEMYEL	powder for solution for injection	3.5mg	ALVOGEN IPCO S.A.R.L.	LUXEMBOU RG	129 01	2020	01
BORTEZOMIBUM	BORTEZOMIB GLENMARK	powder for solution for injection	3.5mg	GLENMARK PHARMACEUTIC ALS S.R.O.	THE CZECH REPUBLIC	129 60	2020	01
BROMHEXINUM HYDROCHLORIDE	CLORHIDRAT DE BROMHEXIN LAROPHRM	tablets	12mg	LAROPHARM S.R.L.	ROMANIA	130 04	2020	01
CANDESARTANUM CILEXETIL	CANDESARTAN CILEXETIL MCC	tablets	16mg	MAGISTRA C&C S.R.L.	ROMANIA	129 82	2020	01
CANDESARTANUM CILEXETIL	CANDESARTAN CILEXETIL MCC	tablets	32mg	MAGISTRA C&C S.R.L.	ROMANIA	129 83	2020	01
CANDESARTANUM CILEXETIL/ AMLOPIDINUM BESILATE	KANDOSSET	tablets	16mg/ 10mg	KRKA D.D. NOVO MESTO	SLOVENIA	129 00	2020	01
CARBAMAZEPINUM	CARBAMAZEPINA ARENA	tablets	200 mg	ARENA GROUP S.A.	ROMANIA	129 28	2020	01
CARBAMAZEPINUM	CARBAMAZEPINA ARENA	tablets	400 mg	ARENA GROUP S.A.	ROMANIA	129 29	2020	01
CARBAMAZEPINUM	CARBAMAZEPINA TERAPIA	tablets	200mg	TERAPIA S.A	ROMANIA	130 58	2020	01
CARBAZOCHROME	ADRENOSTAZIN	solution for injection/infusion	1.5mg	TERAPIA S.A	ROMANIA	130 65	2020	01

CARBOCISTEINUM	TRECID	syrup	100mg/ 5ml	BIOFARM S.A.	ROMANIA	130 64	2020	01
CEFTAZIDIMUM	CEFTRIZIDIMA APTAPHARMA	powder for solution for injection/infusion	1g	APTA MEDICA INTERNATIONA L	SLOVENIA	130 57	2020	01
CELECOXIBUM	CELECOXIB TERAPIA	capsules	100mg	TERAPIA S.A	ROMANIA	130 51	2020	01
CELECOXIBUM	CELECOXIB TERAPIA	capsules	200mg	TERAPIA S.A	ROMANIA	130 52	2020	01
CLOBETAZOLUM PROPIONATE	CLOBETAZOL ATB	ointment	0.5mg/g	ANTIBIOTICE S.A.	ROMANIA	130 62	2020	01
COMBINATIONS	ASPAMED	tablets		ARENA GROUP S.A.	ROMANIA	129 44	2020	01
COMBINATIONS	BANEOCIN	cutaneous powder		SANDOZ GmbH	AUSTRIA	130 83	2020	01
COMBINATIONS	HUMAGRIP	tablets and capsules		LAB. URGO	FRANCE	129 98	2020	01
COMBINATIONS	ZYMOGEN	gastroresistant lozenges		FELSIN FARM. S.R.L.	ROMANIA	130 25	2020	01
COMBINATIONS	OLIMEL N12E	emulsion for infusion		BAXTER HEALTHCARE S.A.	AUSTRIA	130 22	2020	01

COMBINATIONS	PHYSIONEAL 35 CLEAR-FLEX	solution for peritoneal dialysis	13.6 mg/ ml	BAXTER HEALTHCARE S.A.	ROMANIA	130 16	2020	01
COMBINATIONS	PHYSIONEAL 35 CLEAR-FLEX	solution for peritoneal dialysis	22.7 mg/ ml	BAXTER HEALTHCARE S.A.	ROMANIA	130 17	2020	01
COMBINATIONS	PHYSIONEAL 35 CLEAR-FLEX	solution for peritoneal dialysis	38.6 mg/ml	BAXTER HEALTHCARE S.A.	ROMANIA	130 18	2020	01
COMBINATIONS	PHYSIONEAL 40 CLEAR-FLEX	solution for peritoneal dialysis	13.6 mg/ ml	BAXTER HEALTHCARE S.A.	ROMANIA	130 19	2020	01
COMBINATIONS	PHYSIONEAL 40 CLEAR-FLEX	solution for peritoneal dialysis	22.7 mg/ ml	BAXTER HEALTHCARE S.A.	ROMANIA	130 20	2020	01
COMBINATIONS	PHYSIONEAL 40 CLEAR-FLEX	solution for peritoneal dialysis	38.6 mg/ ml	BAXTER HEALTHCARE S.A.	ROMANIA	130 21	2020	01
COMBINATIONS	BIPHOZYL	solution for hemofiltration and haemodialysis		GAMBRO LUNDIA AB	SWEDEN	129 65	2020	01
COMBINATIONS	PARAREMIN	tablets		POLISANO PHARMACEUTIC ALS S.A.	ROMANIA	129 94	2020	01

COMBINATIONS	EPICOCEL	oral suspension		EIPICO	EGYPT	129 39	2020	01
CROMOGLICATUM	ALERGOROM	eye/nasal drops, solution	20 mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	130 66	2020	01
DAPTOMYCINUM	DAPTOMICINA ACCORDPHARMA	powder for concentrate for solution for infusion/injection	350mg	ACCORD HEALTHCARE LTD.	POLAND	129 70	2020	01
DAPTOMYCINUM	DAPTOMICINA ACCORDPHARMA	powder for concentrate for solution for infusion/injection	500mg	ACCORD HEALTHCARE LTD.	POLAND	129 71	2020	01
DARUNAVIRUM PROPYLENE GLYCOLATUM	DARUNAVIR ACCORD	film-coated tablets	75mg	ACCORD HEALTHCARE LTD.	UK	130 07	2020	01
DARUNAVIRUM PROPYLENE GLYCOLATUM	DARUNAVIR ACCORD	film-coated tablets	150mg	ACCORD HEALTHCARE LTD.	UK	130 08	2020	01
DARUNAVIRUM PROPYLENE GLYCOLATUM	DARUNAVIR ACCORD	film-coated tablets	300mg	ACCORD HEALTHCARE LTD.	UK	130 09	2020	01
DARUNAVIRUM PROPYLENE GLYCOLATUM	DARUNAVIR ACCORD	film-coated tablets	400mg	ACCORD HEALTHCARE LTD.	UK	130 10	2020	01

DARUNAVIRUM PROPYLENE GLYCOLATUM	DARUNAVIR ACCORD	film-coated tablets	600mg	ACCORD HEALTHCARE LTD.	UK	130 11	2020	01
DARUNAVIRUM PROPYLENE GLYCOLATUM	DARUNAVIR ACCORD	film-coated tablets	800mg	ACCORD HEALTHCARE LTD.	UK	130 12	2020	01
DEFERASIROXUM	DEFERASIROX STADA	film-coated tablets	90mg	STADA M&D SRL	ROMANIA	129 50	2020	01
DEFERASIROXUM	DEFERASIROX STADA	film-coated tablets	180mg	STADA M&D SRL	ROMANIA	129 51	2020	01
DEFERASIROXUM	DEFERASIROX STADA	film-coated tablets	360mg	STADA M&D SRL	ROMANIA	129 52	2020	01
DEFERASIROXUM	DEFERASIROX ZENTIVA	dispersible tablets	125mg	ZENTIVA k.s.	THE CZECH REPUBLIC	129 47	2020	01
DEFERASIROXUM	DEFERASIROX ZENTIVA	dispersible tablets	250mg	ZENTIVA k.s.	THE CZECH REPUBLIC	129 48	2020	01
DEFERASIROXUM	DEFERASIROX ZENTIVA	dispersible tablets	500mg	ZENTIVA k.s.	THE CZECH REPUBLIC	129 49	2020	01
DEQUALINIUM CHLORIDE	FLUOMIZIN	vaginal tablets	10mg	PHARMASWISS CESKA REPUBLIKA s.r.o.	THE CZECH REPUBLIC	129 99	2020	01
DEXAMETHASONUM PHOSPHATE	DEXAMETAZONA FOSFAT KRKA	solution for injection	4mg/ml	KRKA D.D. NOVO MESTO	SLOVENIA	129 75	2020	01

DEXAMETHASONUM PHOSPHATE	DEXAMETAZONA FOSFAT KRKA	solution for injection	8mg/2ml	KRKA D.D. NOVO MESTO	SLOVENIA	129 76	2020	01
DEXKETOPROFENUM TROMETAMOL	DEXKETOPROFEN ROMPHARM	solution for injection	50mg/ 2 ml	ROMPHARM COMPANY S.R.L.	ROMANIA	129 62	2020	01
DIPIRIDAMOLUM	DIPIRIDAMOL ZENTIVA 25 mg	film-coated tablets	25 mg	ZENTIVA S.A.	ROMANIA	130 26	2020	01
DORZOLAMIDUM	DORZOPT	eye drops, solution	20 mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	130 68	2020	01
DORZOLAMIDUM HYDROCHLORIDE + TIMOLOL MALEATE	DUOKOPT	eye drops, solution	20mg/5mg	LAB THEA S.A.S	FRANCE	129 77	2020	01
DOXORUBICINUM HYDROCHLORIDE	SINDROXOCIN 2 mg/ml	powder for solution for infusion	2 mg/ml	TEVA PHARMACEUTIC ALS S.R.L.	ROMANIA	129 43	2020	01
DULOXETINUM	DULOXETINA AUROBINDO	gastroresistant capsules	30mg	AUROBINDO PHARMA LTD	MALTA	130 29	2020	01
DULOXETINUM	DULOXETINA AUROBINDO	gastroresistant capsules	60mg	AUROBINDO PHARMA LTD	MALTA	130 30	2020	01
DULOXETINUM HIDROCLORIDE	DULOXETINA STADA	gastroresistant capsules	30mg	STADA M&D SRL	ROMANIA	130 13	2020	01
DULOXETINUM HIDROCLORIDE	DULOXETINA STADA	gastroresistant capsules	60mg	STADA M&D SRL	ROMANIA	130 14	2020	01

DULOXETINUM HYDROCHLORIDE	DULOXETINA DR. REDDY'S	capsules	30mg	DR. REDDY'S LABORATORIES LTD.	ROMANIA	130 41	2020	01
DULOXETINUM HYDROCHLORIDE	DULOXETINA DR. REDDY'S	capsules	60mg	DR. REDDY'S LABORATORIES LTD.	ROMANIA	130 42	2020	01
DULOXETINUM HYDROCHLORIDUM	DULOXETINA SANDOZ	gastroresistant capsules	30mg	SANDOZ S.R.L.	ROMANIA	129 53	2020	01
DULOXETINUM HYDROCHLORIDUM	DULOXETINA SANDOZ	gastroresistant capsules	60mg	SANDOZ S.R.L.	ROMANIA	129 54	2020	01
DULOXETINUM HYDROCHLORIDE	DULSEVIA	gastroresistant capsules	30mg	KRKA D.D. NOVO MESTO	SLOVENIA	130 39	2020	01
DULOXETINUM HYDROCHLORIDE	DULSEVIA	gastroresistant capsules	60mg	KRKA D.D. NOVO MESTO	SLOVENIA	130 40	2020	01
DUTASTERIDUM	DUTASTERIDA CIPLA	capsules	0.5mg	CIPLA EUROPE NV	BELGIUM	130 33	2020	01
EXEMESTANUM	EXEMESTAN ALVOGEN	film-coated tablets	25mg	ALVOGEN IPCO S.A.R.L.	LUXEMBOURG	129 92	2020	01
FENILEFRINUM HYDROCHLORIDE	FENILEFRINA AGUETTANT	solution for injection/infusion	100 µg/ml	LABORATOIRE AGUETTANT	FRANCE	130 15	2020	01
FENOFIBRATUM	FENOFIBRAT TERAPIA	film-coated tablets	160 mg	TERAPIA S.A.	ROMANIA	130 63	2020	01
FENOFIBRATUM MICRONIZATUM	LIPOFIB	capsules	160 mg	TERAPIA S.A.	ROMANIA	130 69	2020	01

FOSFOMYCINUM	FOMICYT	powder for solution for infusion	40mg/ml	INFECTOPHARM ARZNEIMITTEL	GERMANY	130 34	2020	01
GEFITINIBUM	GEFITINIB FLOMI	film-coated tablets	250mg	FLOMI FARMA S.R.L.	ROMANIA	130 55	2020	01
GENTAMICINUM SULPHATE	GENTAMICINA KRKA	solution for injection	80 mg/ 2ml	KRKA D.D. NOVO MESTO	SLOVENIA	130 61	2020	01
HYDROCORTISONUM	HIDROCORTIZON FITERMAN	ointment	10 mg/g	FITERMAN PHARMA SRL	ROMANIA	129 08	2020	01
IBUPROFENUM	IBUPROFEN ARENA	capsules	400mg	ARENA GROUP S.A.	ROMANIA	129 19	2020	01
IBUPROFENUM	NUROFEN EXPRESS	lozenges	200mg	RECKITT BENCKISER ROMANIA	ROMANIA	129 30	2020	01
IBUPROFENUM	CALMOLIN ARENA	capsules	400mg	ARENA GROUP S.A.	ROMANIA	129 20	2020	01
IBUPROFENUM	IBUCALMIN	film-coated tablets	200mg	LAROPHARM S.R.L.	ROMANIA	130 82	2020	01
IBUPROFENUM/ PARACETAMOLUM	SYNOCAM	film-coated tablets	200/ 500mg	DR. REDDY'S LABORATORIES	ROMANIA	128 94	2020	01
INDAPAMIDUM	IMPAMID SR	prolonged-release tablets	1.5 mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	129 13	2020	01

INOSINUM	ISOPRINOSINE EWOPHARMA	powder for oral solution	1000 mg	EWOPHARMA INTERNATIONAL s.r.o.	SLOVAKIA	130 05	2020	01
IOD POVIDONUM	IODINA	cutaneous solution	100 mg/ml	TIS FARMACEUTIC S.A.	ROMANIA	129 36	2020	01
IRINOTECANUM HYDROCHLORIDE TRIHYDRATE	IRINOTECAN SUN	solution for infusion	1.5mg/ml	SUN PHARMACEUTI CAL INDUSTRIES EUROPE B.V.	HOLLAND	130 79	2020	01
KETOROLACUM TROMATAMINUM	KETOROLAC TROMETAMOL ROMPHARM	solution for injection	30mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	130 67	2020	01
LACTULOSUM	LACTECON	oral solution	667 g/l	MYLAN B.V.	HOLLAND	129 42	2020	01
LEVETIRACETAMUM	LEVETIRACETAM ACCORD	oral solution	100mg/ml	ACCORD HEALTHCARE POLSKA SP.ZO.O	POLAND	130 81	2020	01
LOSARTANUM POTASSIUM/ AMLODIPINUM BESYLATE	TENLORIS	film-coated tablets	50mg/5mg	KRKA D.D. NOVO MESTO	SLOVENIA	130 43	2020	01
LOSARTANUM POTASSIUM/	TENLORIS	film-coated tablets	50mg/ 10mg	KRKA D.D. NOVO MESTO	SLOVENIA	130 44	2020	01

AMLODIPINUM BESYLATE								
LOSARTANUM POTASSIUM/ AMLODIPINUM BESYLATE	TENLORIS	film-coated tablets	100mg/ 5mg	KRKA D.D. NOVO MESTO	SLOVENIA	130 45	2020	01
LOSARTANUM POTASSIUM/ AMLODIPINUM BESYLATE	TENLORIS	film-coated tablets	100mg/ 10 mg	KRKA D.D. NOVO MESTO	SLOVENIA	130 46	2020	01
LOVASTATINUM	MEDOSTATIN	tablets	40 mg	MEDOCHÉMIE LTD	CYPRUS	129 88	2020	01
METAMIZOLUM SODIUM	METAMIZOL FARMACOM	tablets	500mg	SC FARMACOM SA	ROMANIA	129 33	2020	01
METAMIZOLUM SODIUM	METAMIZOL KALCEKS	solution for injection	500mg/ml	AS KALCEKS	LITHUANIA	130 56	2020	01
METHADONUM	SINTALGON	tablets	2.5 mg	ZENTIVA S.A.	ROMANIA	129 91	2020	01
METOPROLOLUM TARTRATE	METOPROLOL VIM SPECTRUM	tablets	100mg	VIM SPECTRUM S.R.L.	ROMANIA	129 24	2020	01
METOPROLOLUM TARTRATE/IVABRADINE	ARPARIAL	film-coated tablets	25 mg/ 5 mg	LES LAB. SERVIER IND.	FRANCE	130 47	2020	01

METOPROLOLUM TARTRATE/IVABRADINE	ARPARIAL	film-coated tablets	50 mg/ 5 mg	LES LAB. SERVIER IND.	FRANCE	130 48	2020	01
METOPROLOLUM TARTRATE/IVABRADINE	ARPARIAL	film-coated tablets	25 mg/ 7.5 mg	LES LAB. SERVIER IND.	FRANCE	130 49	2020	01
METOPROLOLUM TARTRATE/IVABRADINE	ARPARIAL	film-coated tablets	50 mg/ 7.5 mg	LES LAB. SERVIER IND.	FRANCE	130 50	2020	01
METRONIDAZOLUM + CLOTRIMAZOLUM	ZIFEX DUO	ovules	500mg/ 200 mg	ANTIBIOTICE S.A.	ROMANIA	130 24	2020	01
METRONIDAZOLUM + NITRAT DE MICONAZOL	KLION-D	vaginal tablets	100mg/ 100mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	129 34	2020	01
NEVIRAPINUM	NEVIRAPINA SANDOZ	tablets	200mg	SANDOZ S.R.L.	ROMANIA	129 78	2020	01
NISTATINUM	NISTATINA ATB	ovules	1000000UI	ANTIBIOTICE S.A.	ROMANIA	130 59	2020	01
OFLOXACINUM	OFLOXIN	film-coated tablets	200 mg	ZENTIVA k.s.	THE CZECH REPUBLIC	129 87	2020	01
OLOPADINUM HYDROCHLORIDE	OLOPATADINA UNIMED PHARMA	eye drops, solution	1mg/ml	UNIMED PHARMA	SLOVAKIA	130 80	2020	01
OXALIPLATINUM	OXALIPLATIN EBEWE 5mg/ml	concentrate for solution for infusion	5mg/ml	EBEWE PHARMA Ges.m.b.H Nfg.KG	AUSTRIA	129 61	2020	01

PANCREATINUM	TRIFERMENT	Gastroresistant lozenges	325mg	BIOFARM S.A.	ROMANIA	129 95	2020	01
PAPAVERINUM HYDROCHLORIDE	PAPAVERINA ARENA	tablets	50 mg	ARENA GROUP S.A.	ROMANIA	130 01	2020	01
PAPAVERINUM HYDROCHLORIDE	PAPAVERINA ARENA	tablets	100 mg	ARENA GROUP S.A.	ROMANIA	130 02	2020	01
PARACETAMOLUM	PARACETAMOL LPH 500 mg	tablets	500 mg	LABORMED PHARMA S.A.	ROMANIA	129 21	2020	01
PARACETAMOLUM	PARACETAMOL INFOMED	solution for infusion	10 mg/ml	INFOMED FLUIDS S.R.L.	ROMANIA	130 78	2020	01
PARACETAMOLUM/ IBUPROFENUM	COMBIFEXIN	film-coated tablets	200/500mg	SANDOZ GmbH	AUSTRIA	128 96	2020	01
PAROXETINUM	PAXETIN	film-coated tablets	20 mg	TEVA PHARMA B.V.	HOLLAND	129 40	2020	01
PENTOXIFYLLINUM	ANGIOPENT RETARD 600 mg	prolonged-release film-coated tablets	600 mg	AC HELCOR SRL	ROMANIA	129 26	2020	01
PENTOXIFYLLINUM	ANGIOPENT RETARD 400 mg	prolonged-release film-coated tablets	400 mg	AC HELCOR SRL	ROMANIA	129 25	2020	01
PIROXICAMUM	PIROXICAM ARENA	tablets	20mg	ARENA GROUP S.A.	ROMANIA	129 09	2020	01
POSACONAZOLUM	GUDIVIN	gastroresistant tablets	100mg	EGIS PHARMACEUTIC ALS PLC	HUNGARY	129 66	2020	01

PRAMIPEXOLUM	PRAMIPEXOL ARENA	tablets	0.18mg	ARENA GROUP S.A.	ROMANIA	129 22	2020	01
PRAMIPEXOLUM	PRAMIPEXOL ARENA	tablets	0.7mg	ARENA GROUP S.A.	ROMANIA	129 23	2020	01
PREGABALINUM	PREGABALINA AUROBINDO	capsules	75mg	AVENTIS PHARMA	ROMANIA	128 91	2020	01
PREGABALINUM	PREGABALINA AUROBINDO	capsules	150mg	AVENTIS PHARMA	ROMANIA	128 92	2020	01
PREGABALINUM	PREGABALINA AUROBINDO	capsules	300mg	AVENTIS PHARMA	ROMANIA	128 93	2020	01
BIOLOGICAL PRODUCTS	ADACEL POLIO	suspension for injection in pre-filled syringe	2.5mcg	SANOFI PASTEUR	FRANCE	129 59	2020	01
BIOLOGICAL PRODUCTS	PNEUMOVAX 23	solution for injection in pre-filled syringe	0.5ml/ 25mcg	MERCK SHARP & DOHME ROMANIA SRL	ROMANIA	129 57	2020	01
BIOLOGICAL PRODUCTS	BOOSTRIX	powder and solvent for solution for injection		GLAXOSMITHK LINE (GSK) S.R.L.	ROMANIA	129 80	2020	01
BIOLOGICAL PRODUCTS	ACARIZAX	oral lyophilisate	12 SQ-HOM	ALK - ABELLO A/S	DENMARK	128 95	2020	01
PROPAFENONUM HYDROCHLORIDE	PROPANORM	film-coated tablets	300mg	PRO.MED.CS PRAHA a.s.	THE CZECH REPUBLIC	129 37	2020	01

PROPRANOLOLUM HYDROCHLORIDE	CLORHIDRAT DE PROPORANOLOL ARENA	tablets	10mg	ARENA GROUP S.A.	ROMANIA	129 27	2020	01
RABEPRAZOLUM SODIUM	RELITAZ	gastroresistant tablets	10mg	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	130 31	2020	01
RABEPRAZOLUM SODIUM	RELITAZ	gastroresistant tablets	20mg	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	130 32	2020	01
RAMIPRILUM	HARTIL	tablets	2.5mg	EGIS PHARMACEUTIC ALS PLC	HUNGARY	129 10	2020	01
RAMIPRILUM	HARTIL	tablets	5mg	EGIS PHARMACEUTIC ALS PLC	HUNGARY	129 11	2020	01
RAMIPRILUM	HARTIL	tablets	10mg	EGIS PHARMACEUTIC ALS PLC	HUNGARY	129 12	2020	01
RILMENIDINE	HYPERBIS	tablets	1mg	ANPHARM PRZEDSIĘBIORST WO FARMACEUTYCZ NE S.A.	FRANCE	130 06	2020	01
RIVAROXABANUM	XANIRVA	film-coated tablets	2.5 mg	ZENTIVA S.A.	ROMANIA	129 02	2020	01

RIVAROXABANUM	XANIRVA	film-coated tablets	10 mg	ZENTIVA S.A.	ROMANIA	129 03	2020	01
RIVAROXABANUM	XANIRVA	film-coated tablets	15 mg	ZENTIVA S.A.	ROMANIA	129 04	2020	01
RIVAROXABANUM	XANIRVA	film-coated tablets	20 mg	ZENTIVA S.A.	ROMANIA	129 05	2020	01
SALMETEROLUM XINOFOATE + FLUTICAZONUM PROPIONATE	AIRFLUSAL FORSPIRO	inhalation powder	50µg/ 250µg/ dose	SANDOZ S.R.L.	ROMANIA	129 46	2020	01
SALMETEROLUM XINOFOATE + FLUTICAZONUM PROPIONATE	AIRFLUSAL FORSPIRO	inhalation powder	50µg/ 500µg/ dose	SANDOZ S.R.L.	ROMANIA	129 45	2020	01
SALMETEROLUM XINOFOATE + FLUTICAZONUM PROPIONATE	BREFULL AIRMASTER	inhalation powder	50/ 100 mcg	WELLNEX GmbH	UK	130 70	2020	01
SALMETEROLUM XINOFOATE + FLUTICAZONUM PROPIONATE	BREFULL AIRMASTER	inhalation powder	50/ 250 mcg	WELLNEX GmbH	UK	130 71	2020	01
SALMETEROLUM XINOFOATE + FLUTICAZONUM PROPIONATE	BREFULL AIRMASTER	inhalation powder	50/ 500 mcg	WELLNEX GmbH	UK	130 72	2020	01

SALMETEROLUM XINOFOATE + FLUTICAZONUM PROPIONATE	PAVTIDE DISKUS	inhalation powder	50mcg/ 100mcg	GLAXOSMITHK LINE SRL	ROMANIA	129 72	2020	01
SALMETEROLUM XINOFOATE + FLUTICAZONUM PROPIONATE	PAVTIDE DISKUS	inhalation powder	50mcg/ 250mcg	GLAXOSMITHK LINE SRL	ROMANIA	129 73	2020	01
SALMETEROLUM XINOFOATE + FLUTICAZONUM PROPIONATE	PAVTIDE DISKUS	inhalation powder	50mcg/ 500mcg	GLAXOSMITHK LINE SRL	ROMANIA	129 74	2020	01
SALMETEROLUM XINOFOATE + FLUTICAZONUM PROPIONATE	CAMPONA AIRMASTER	inhalation powder (capsules)	50/100 mg	WELLNEX GmbH	GERMANY	130 73	2020	01
SALMETEROLUM XINOFOATE + FLUTICAZONUM PROPIONATE	CAMPONA AIRMASTER	inhalation powder (capsules)	50/250 mg	WELLNEX GmbH	GERMANY	130 74	2020	01
SALMETEROLUM XINOFOATE + FLUTICAZONUM PROPIONATE	CAMPONA AIRMASTER	inhalation powder (capsules)	50/500 mg	WELLNEX GmbH	GERMANY	130 75	2020	01
SILUBINUM	SILIMARINA BIOFARM	tablets	150mg	BIOFARM S.A.	ROMANIA	129 32	2020	01

SITAGLIPTINUM	MAYSIGLU	film-coated tablets	25mg	KRKA D.D. NOVO MESTO	SLOVENIA	129 84	2020	01
SITAGLIPTINUM	MAYSIGLU	film-coated tablets	50mg	KRKA D.D. NOVO MESTO	SLOVENIA	129 85	2020	01
SITAGLIPTINUM	MAYSIGLU	film-coated tablets	100mg	KRKA D.D. NOVO MESTO	SLOVENIA	129 86	2020	01
SULFADIAZINUM	REGEN AG	cream	10mg/g	FITERMAN PHARMA SRL	ROMANIA	129 90	2020	01
TENOFOVIRUM DISOPROXILUM SUCCINATUM	EMTRICITABINA/ TENOFOVIR DISOPROXIL STADA	film-coated tablets	200mg/ 245mg	STADA M&D SRL	ROMANIA	129 58	2020	01
TRAMADOLUM CLORHIDRATUM	TRAMACALM	capsules	50 mg	AC HELCOR SRL	ROMANIA	130 00	2020	01
TRAMADOLUM HCl / PARACETAMOLUM	PALGOTAL	film-coated tablets	75mg/ 650mg	ZENTIVA k.s.	THE CZECH REPUBLIC	128 97	2020	01
TROXERUTINUM	TROXERUTIN FITERMAN	gel	20mg/g	FITERMAN PHARMA SRL	ROMANIA	129 89	2020	01
VARDENAFILUM	STAREXON	film-coated tablets	5 mg	ZENTIVA S.A.	ROMANIA	129 67	2020	01
VARDENAFILUM	STAREXON	film-coated tablets	10 mg	ZENTIVA S.A.	ROMANIA	129 68	2020	01
VARDENAFILUM	STAREXON	film-coated tablets	20 mg	ZENTIVA S.A.	ROMANIA	129 69	2020	01

VERAPAMILUM HYDROCHLORIDE	CORDAMIL	tablets	40mg	AC HELCOR PHARMA SRL	ROMANIA	129 96	2020	01
VERAPAMILUM HYDROCHLORIDE	CORDAMIL	tablets	80mg	AC HELCOR PHARMA SRL	ROMANIA	129 97	2020	01
VINBLASTINE	SULFAT DE VINBLASTINA TEVA	solution for injection	1mg/ml	TEVA PHARMACEUTIC AL S.R.L	ROMANIA	130 03	2020	01

Medicinal products authorised through centralised procedure, performed at the level of the European Medicines Agency (EMA), notified for marketing in Romania during the 1st quarter of 2020

INN	Trade name		Strength	MAH	Holding country	MA no.		
AZACITIDINUM	AZACITIDINE ACCORD 25 mg/ml	powder for suspension for injection	25mg/ml	ACCORD HEALTHCARE S.L.U.	SPAIN	1413	2020	01
AZACITIDINUM	AZACITIDINE BETAPHARM 25 mg/ml	powder for suspension for injection	25mg/ml	BETAPHARM ARZNEIMITTEL GMBH	GERMANY	1416	2020	01
BROLUCIZUMABUM	BEOVU 120 mg/ml	solution for injection in pre-filled syringe	120mg/ml	NOVARTIS EUROPHARM LIMITED	IRELAND	1417	2020	01
GIVOSIRANUM	GIVLAARI 189 mg/ml	solution for injection	189mg/ml	ALNYLAM NETHERLANDS B.V.	HOLLAND	1428	2020	01
IMIPENEMUM + CILASTATINUM + RELEBACTAMUM	RECARBRIO 500 mg/ 500 mg/250 mg	powder for solution for infusion	500mg/ 500mg/ 250mg	MERCK SHARP & DOHME B.V.	HOLLAND	1420	2020	01
POLATUZUMAB VEDOTIN	POLIVY 140mg	powder for concentrate for solution for infusion	20mg/ml	ROCHE REGISTRATION GMBH	GERMANY	1388	2020	01

SIPONIMOD	MAYZENT 0.25 mg	film-coated tablets	0.25mg	NOVARTIS EUROPHARM LTD	IRELAND	1414	2020	01
SIPONIMOD	MAYZENT 0.25 mg	film-coated tablets	0.25mg	NOVARTIS EUROPHARM LTD	IRELAND	1414	2020	02
SIPONIMOD	MAYZENT 0.25 mg	film-coated tablets	0.25mg	NOVARTIS EUROPHARM LTD	IRELAND	1414	2020	04
SIPONIMOD	MAYZENT 2 mg	film-coated tablets	2mg	NOVARTIS EUROPHARM LTD	IRELAND	1414	2020	03
SIPONIMOD	MAYZENT 2 mg	film-coated tablets	2mg	NOVARTIS EUROPHARM LTD	IRELAND	1414	2020	05
SIPONIMOD	MAYZENT 2 mg	film-coated tablets	2mg	NOVARTIS EUROPHARM LTD	IRELAND	1414	2020	06
TAFAMIDIS	VYNDAQEL	soft capsules	61mg	PFIZER EUROPE MA EEIG	BELGIUM	717	2020	03