

ROMANIA

Newsletter

Year 25, No. 4 (100), 4th quarter of 2023

*National Agency
for Medicines and Medical Devices
of Romania*

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The Newsletter of the National Agency for Medicines and Medical Devices of Romania contains the following:

– information of public interest communicated ex officio, provided in Article 5 paragraph 2 of Law no. 544/2001:

a) The ruling provisions regulating the organisation and operation of the NAMMDR are the following:

Law no. 134 of 12 July 2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions, as further amended and supplemented;

Order no. 1412 of 13 September 2019 on approval of the organisational structure of the National Agency for Medicines and Medical Devices of Romania;

Order no. 1522 of 9 October 2019 on approval of the Regulation for organisation and operation of the National Agency for Medicines and Medical Devices of Romania.

Order of the Minister of Health no. 857/2022 on approval of the Regulation for the organisation and operation of the National Agency for Medicines and Medical Devices of Romania;

Order of the Minister of Health no. 2318/2021 on approval of the organisational structure of the National Agency for Medicines and Medical Devices of Romania.

b) The public institution's organisation chart, attributions of each department, working programme, audience programme:

Regulation for organisation and operation of the National Agency for Medicines and Medical Devices of Romania

c) Names and surnames of the persons of the public institution's management, responsible for the dissemination of public information

d) The institution's contact data

e) Audiences

Business hours

f) Financial sources, budget and the balance sheet

Budget and funding source

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g) The institution's programmes and strategies

h) Public documents and NAMMDR managed/generated documents

**i) Challenge of decisions and associated forms for administrative complaint
(refusal and failure to comply with legal deadlines)**

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Government decisions

Government Decision no. 1.005/2023 on approval of the National Strategy for the prevention and limitation of healthcare-related infections and combating the phenomenon of antimicrobial resistance in Romania for the period 2023—2030

Orders

Order of the Minister of Health no. 3362/2023 on approval of the List of Romanian standards that adopt the harmonised European standards in the field of medical devices falling under the scope of Regulation (EU) 2017/745, as well as of the List of Romanian standards that adopt the harmonised European standards in the field of in vitro diagnostic medical devices, falling under the scope of Regulation (EU) 2017/746

Order of the Minister of Health no. 3277 of 22 September 2023 on amendment of Order of the Minister of Health no. 3969/2022 on approval of the Methodological Rules for assessment, designation and notification of the bodies assessing medical device compliance, as well as for monitoring and reassessment of notified bodies

Order of the Minister of Health no. 3753/2023 on approval of the methodological rules regarding the introduction on the market of in vitro diagnostic medical devices and registration of economic operators into the European Database on Medical Devices (Eudamed), as well as into the national database and exemption from compliance assessment procedures

Order of the Minister of Health no. 3876/2023 on amendment and supplementation of certain regulatory acts concerning medical devices and in vitro diagnostic medical devices

Regulations

Commission Implementing Regulation (EU) 2023/2713 of 5 December 2023 designating European Union reference laboratories in the field of in vitro diagnostic medical devices

Medicinal product batches recalled during the 4th quarter of 2023

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/MAH	Batch	Grounds for recall	Proposed action	Date of recall
1	RINOFUG 1 mg/ml nasal drops, solution	nasal drops, solution	1mg/ml	NAPHAZOLINUM	MEDUMAN S.A., ROMANIA	3201022	Out-of-specification results	Recall upon request of the NAMMDR	15.12.2023
2	NEXIUM 10mg gastroresistant granules for oral suspension, sachet	gastroresistant granules for oral suspension	10 mg	ESOMEPRAZOLUM	ASTRAZENECA AB , SWEDEN	all batches on the market	Termination of MA validity in Romania	Voluntary recall	15.12.2023
3	DOBUTAMINA ADMEDA 250 mg solution for infusion	solution for infusion	250 mg	DOBUTAMINUM	ADMEDA ARZNEIMITTEL GMBH, GERMANY	20504C-RO 20505C-RO	Out-of-specification results	Voluntary recall	04.12.2023

**Applications for marketing authorisation/marketing authorisation renewal
received during the 3rd quarter of 2023**

In the 3rd quarter of 2023, 17 marketing authorisation/marketing authorisation renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

AUTHORISATION	RENEWAL
J01 - ANTIBACTERIAL DRUGS	A05 – BILE AND LIVER THERAPY
J01 - ANTIBACTERIAL DRUGS	A11 - VITAMINS
J01 - ANTIBACTERIAL DRUGS	V10 – THERAPEUTIC RADIOPHARMACEUTICALS
J01 - ANTIBACTERIAL DRUGS	G03 – SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM
J01 - ANTIBACTERIAL DRUGS	N03 – ANTIEPILEPTIC DRUGS
J01 - ANTIBACTERIAL DRUGS	N03 – ANTIEPILEPTIC DRUGS
N02B – OTHER ANALGESICS AND ANTIPYRETICS	B01A – ANTITHROMBOTIC AGENTS
J01 - ANTIBACTERIAL DRUGS	R02A – THROAT ANTISEPTICS
	V03A – ALL OTHER THERAPEUTIC PRODUCTS

Medicinal products authorised for marketing during the 3rd quarter of 2023

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.		
1	ALBENDAZOLUM	VERMIGAL NOVO 200 mg	film-coated tablets	200mg	BIOFARM S.A.	ROMANIA	15088	2023	01
2	ALLOPURINOLUM	MILURIT 150 mg	tablets	150mg	EGIS PHARMACEUTIC ALS PLC.	HUNGARY	15061	2023	01
3	ALLOPURINOLUM	MILURIT 200 mg	tablets	200mg	EGIS PHARMACEUTIC ALS PLC.	HUNGARY	15062	2023	01
4	AMBROXOLUM	AMBROGAL 20 mg	tablets	20mg	GALENKA INTERNATIONA L KFT.	HUNGARY	15106	2023	01
5	BECLOMETASONUM	SOPROBEC 50 micrograms per dose	pressurised solution for inhalation	50micrograms/ dose	GLENMARK PHARMACEUTIC ALS S.R.O.	THE CZECH REPUBLIC	15115	2023	01
6	BECLOMETASONUM	SOPROBEC 100 micrograms per dose	pressurised solution for inhalation	100micrograms/ dose	GLENMARK PHARMACEUTIC ALS S.R.O.	THE CZECH REPUBLIC	15116	2023	01

7	BECLOMETASONUM	SOPROBEC 200 micrograms per dose	pressurised solution for inhalation	200micrograms/ dose	GLENMARK PHARMACEUTIC ALS S.R.O.	THE CZECH REPUBLIC	15117	2023	01
8	BECLOMETASONUM	SOPROBEC 250 micrograms per dose	pressurised solution for inhalation	250micrograms/ dose	GLENMARK PHARMACEUTIC ALS S.R.O.	THE CZECH REPUBLIC	15118	2023	01
9	BENZYDAMINUM	FARINGOCALM MIERE SI PORTOCALA	tablets	3mg	TERAPIA S.A.	ROMANIA	15095	2023	01
10	BENZYDAMINUM	FARINGOCALM LAMAIE 3 mg	tablets	3mg	TERAPIA S.A.	ROMANIA	15096	2023	01
11	BIMATOPROSTUM	ELYMBUS 0.1 mg/g	eye gel in single dose	0.1mg/g	LABORATOIRES THEA	FRANCE	15105	2023	01
12	BORTEZOMIBUM	BORTEZOMIB STADA 2.5 mg/ml	solution for injection	2.5mg/ml	STADA M&D SRL	ROMANIA	15113	2023	01
13	CEFALEXINUM	CEFALEXINA ARENA 500 mg	capsules	500mg	ARENA GROUP S.A.	ROMANIA	15050	2023	01
14	CEFALEXINUM	CEFALEXINA ARENA 250 mg	capsules	250mg	ARENA GROUP S.A.	ROMANIA	15049	2023	01

15	CLINDAMYCINUM	CLINDAMICINA NORIDEM 150 mg/ml	solution for injection/infusion	150mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	15074	2023	01
16	COMBINATIONS	SEPTOLETE OMNI LAMAIE SI MIERE 3 mg/1 mg	tablets	3mg/1mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15124	2023	01
17	COMBINATIONS	SEPTOLETE OMNI LAMAIE SI SOC 3 mg/1 mg	tablets	3mg/1mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15125	2023	01
18	COMBINATIONS	KIDTRAYZE	concentrate for solution for infusion		FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	15079	2023	01
19	COMBINATIONS (AMLODIPINA+ VALSARTAN+HCT)	VALTRICOM 5 mg/160 mg/12.5 mg	film-coated tablets	5mg/160mg/ 12.5mg	KRKA D.D., NOVO MESTO	SLOVENIA	15138	2023	01
20	COMBINATIONS (AMLODIPINA+ VALSARTAN+HCT)	VALTRICOM 10 mg/160 mg/12.5 mg	film-coated tablets	10mg/160mg/ 12.5mg	KRKA D.D., NOVO MESTO	SLOVENIA	15139	2023	01
21	COMBINATIONS (AMLODIPINA+ VALSARTAN+HCT)	VALTRICOM 5 mg/160 mg/25 mg	film-coated tablets	5mg/160mg/ 25mg	KRKA D.D., NOVO MESTO	SLOVENIA	15140	2023	01
22	COMBINATIONS (AMLODIPINA+ VALSARTAN+HCT)	VALTRICOM 10 mg/160 mg/25 mg	film-coated tablets	10mg/160mg/ 25mg	KRKA D.D., NOVO MESTO	SLOVENIA	15141	2023	01

23	COMBINATIONS (AMLODIPINA+ VALSARTAN+HCT)	VALTRICOM 10 mg/320 mg/25 mg	film-coated tablets	10mg/320mg/ 25mg	KRKA D.D., NOVO MESTO	SLOVENIA	15142	2023	01
24	COMBINATIONS (AZELASTINUM+ FLUTICASONUM)	AZEFLU 137 micrograms/ 50 micrograms/dose	spray nazal, sol.	137micrograms/ 50micrograms/ dose	VIATRIS LIMITED	IRELAND	15056	2023	01
25	COMBINATIONS (BRIMONIDINUM+ TIMOLOLUM)	BRIMONIDINA/ TIMOLOL ROMPHARM 2 mg/ml + 5 mg/ml	eye drops, solution	2mg/ml+ 5mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	15053	2023	01
26	COMBINATIONS (BUDESONIDUM+ FORMOTEROLUM)	AIRBUFO FORSPIRO 160 micrograms/ 4.5 micrograms	inhalation powder, single dose	160micrograms/ 4.5micrograms	SANDOZ PHARMACEUTIC ALS S.R.L.	ROMANIA	15093	2023	01
27	COMBINATIONS (BUDESONIDUM+ FORMOTEROLUM)	AIRBUFO FORSPIRO 320 micrograms/ 9 micrograms	inhalation powder, single dose	320 micrograms /9 micrograms	SANDOZ PHARMACEUTIC ALS S.R.L.	ROMANIA	15094	2023	01
28	COMBINATIONS (CANDESARTANUM CILEXETIL+ AMLODIPINUM)	KANDOSET 8 mg/ 5 mg	tablets	8mg/5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15108	2023	01
29	COMBINATIONS (CANDESARTANUM CILEXETIL+ AMLODIPINUM)	KANDOSET 16 mg/ 5 mg	tablets	16mg/5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15109	2023	01

30	COMBINATIONS (CANDESARTANUM CILEXETIL+ AMLODIPINUM)	TILAMCAR 8 mg/5 mg	capsules	8mg/5mg	SWYSSI AG	GERMANY	15084	2023	01
31	COMBINATIONS (CANDESARTANUM CILEXETIL+ AMLODIPINUM)	TILAMCAR 8 mg/10mg	capsules	8mg/10mg	SWYSSI AG	GERMANY	15085	2023	01
32	COMBINATIONS (CANDESARTANUM CILEXETIL+ AMLODIPINUM)	TILAMCAR 16 mg/5 mg	capsules	16mg/5mg	SWYSSI AG	GERMANY	15086	2023	01
33	COMBINATIONS (CANDESARTANUM CILEXETIL+ AMLODIPINUM)	TILAMCAR 16 mg/10 mg	capsules	16mg/10mg	SWYSSI AG	GERMANY	15087	2023	01
34	COMBINATIONS (CARBON MONOXIDE+ HELIUM)	PNEUMOXON 0.25%/10%	compressed medicinal gas	0.25%/10%	MESSER ROMANIA GAZ S.R.L.	ROMANIA	15143	2023	01
35	COMBINATIONS (CARBON MONOXIDE+ HELIUM)	PULMOPRODIFF 0.25%/18%	compressed medicinal gas	0.25%/18%	MESSER ROMANIA GAZ S.R.L.	ROMANIA	15144	2023	01

36	COMBINATIONS (LATANOPROSTUM+ TIMOLOLUM)	FIXANPOST 50 micrograms/ml+ 5 mg/ml	eye drops, solution in single- dose recipient	50micrograms/ ml+5mg/ml	LABORATOIRES THEA	FRANCE	15097	2023	01
37	COMBINATIONS (LATANOPROSTUM+ TIMOLOLUM)	FIXANPOST 50 micrograms/ml + 5 mg/ml	eye drops, solution	50micrograms/ ml+5 mg/ml	LABORATOIRES THEA	FRANCE	15098	2023	01
38	COMBINATIONS (PARACETAMOLUM + CHLORPHENAMINUM)	FERVEX RACEALA SI GRIPA 500 mg/4 mg	film-coated tablets	500mg/4mg	UPSA SAS	FRANCE	15119	2023	01
39	COMBINATIONS (SOLIFENACINUM SUCCINATE+ TAMSULOSINUM)	MINGERLAN 6 mg/0.4 mg	modified-release tablets	6mg/0.4mg	G.L. PHARMA GMBH	AUSTRIA	15111	2023	01
40	COMBINATIONS (TRAVOPROSTUM+ TIMOLOLUM)	KIVIZIDIALE 40 micrograms/ml+ 5 mg/ml	eye drops, solution	40micrograms/ ml+5mg/ml	BAUSCH + LOMB IRELAND LIMITED	IRELAND	15063	2023	01
41	DAPAGLIFLOZINUM	DAFORBIS 5 mg	film-coated tablets	5mg	ARRIELLO S.R.O.	THE CZECH REPUBLIC	15100	2023	01
42	DAPAGLIFLOZINUM	DAFORBIS 10 mg	film-coated tablets	10mg	ARRIELLO S.R.O.	THE CZECH REPUBLIC	15101	2023	01

43	DEXAMETHASONUM	DEXAMETAZONA MEDOCHEMIE 4 mg/ml	solution for injection/infusion	4mg/ml	MEDOCHEMIE ROMANIA S.R.L.	ROMANIA	15080	2023	01
44	DEXAMETHASONUM	DEXAMETAZONA ZENTIVA 4 mg	tablets	4mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15104	2023	01
45	DIOSMINUM (COMBINATIONS)	FLAXIOS 500 mg	film-coated tablets	500mg	MEDREG S.R.O.	THE CZECH REPUBLIC	15102	2023	01
46	DROPERIDOLUM	DROPERIDOL SINETICA 0.5 mg/ml	solution for injection	0.5mg/ml	SINETICA GMBH	GERMANY	15126	2023	01
47	DROTAVERINUM	NO-SPA FORTE 80 mg	film-coated tablets	80mg	OPELLA HEALTHCARE ROMANIA S.R.L.	ROMANIA	15083	2023	01
48	ESOMEPRAZOLUM	ESOMEPRAZOL TERAPIA 20 mg	gastroresistant capsules	20mg	TERAPIA S.A.	ROMANIA	15069	2023	01
49	ESOMEPRAZOLUM	ESOMEPRAZOL TERAPIA 40 mg	gastroresistant capsules	40mg	TERAPIA S.A.	ROMANIA	15070	2023	01
50	EVEROLIMUS	EVEROLIMUS KRKA 2.5 mg	tablets	2.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15120	2023	01
51	EVEROLIMUS	EVEROLIMUS KRKA 5 mg	tablets	5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15121	2023	01

52	EVEROLIMUS	EVEROLIMUS KRKA 10 mg	tablets	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15122	2023	01
53	FLURBIPROFENUM	FARINGO INTENSIV 8.75 mg/dose	oromucosal spray, solution	8.75mg/dose	TERAPIA S.A.	ROMANIA	15099	2023	01
54	GEFITINIBUM	GEFITINIB LABORMED 250 mg	film-coated tablets	250mg	LABORMED PHARMA S.A.	ROMANIA	15137	2023	01
55	HOMEOPATE	ZEEL	ointment		BIOLOGISCHE HEILMITTEL HEEL GMBH	GERMANY	15107	2023	01
56	IBUPROFENUM	NUROFEN SR 300 mg	prolonged-release tablets	300mg	RECKITT BENCKISER (ROMANIA) S.R.L.	ROMANIA	15078	2023	01
57	IBUPROFENUM	IBUPROM PENTRU COPII 100 mg/5 ml	oral suspension	100mg/5ml	TWOJA FARMACJA SP. Z O.O.	POLAND	15081	2023	01
58	IBUPROFENUM	IBUPROM FORTE PENTRU COPII 200 mg/5 ml	oral suspension	200mg/5ml	TWOJA FARMACJA SP. Z O.O.	POLAND	15082	2023	01

59	HUMAN NORMAL IMMUNOGLOBULIN FOR INTRAVENOUS ADMINISTRATION	OCTAGAM 50 mg/ml	solution for infusion	50mg/ml	OCTAPHARMA (IP) SPRL	BELGIUM	15114	2023	01
60	HUMAN CYTOMEGALOVIRUS IMMUNOGLOBULIN	CYTOTECT CP BIOTEST 100 U/ml	solution for infusion	100IU/ml	BIOTEST PHARMA GMBH	GERMANY	15130	2023	01
61	IVABRADINUM	APREDONAV 5 mg	film-coated tablets	5mg	MEDOCHEMIE LTD.	CYPRUS	15128	2023	01
62	IVABRADINUM	APREDONAV 7.5 mg	film-coated tablets	7.5mg	MEDOCHEMIE LTD.	CYPRUS	15129	2023	01
63	KETOPROFENUM	KETIFEXIN 25 mg	granules for oral solution, sachet	25mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15150	2023	01
64	KETOPROFENUM	KETIFEXIN 50 mg	granules for oral solution, sachet	50mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15151	2023	01
65	LENALIDOMIDUM	LENALIDOMIDA DR. REDDY'S 5 mg	capsules	5mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	15089	2023	01

66	LENALIDOMIDUM	LENALIDOMIDA DR. REDDY'S 10 mg	capsules	10mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	15090	2023	01
67	LENALIDOMIDUM	LENALIDOMIDA DR. REDDY'S 15 mg	capsules	15mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	15091	2023	01
68	LENALIDOMIDUM	LENALIDOMIDA DR. REDDY'S 25 mg	capsules	25mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	15092	2023	01
69	LEVOCARNITINUM	CARNIL 1 g/10 ml	oral solution	100mg/ml	ANFARM HELLAS S.A.	GREECE	15071	2023	01
70	LOPERAMIDUM	LOPERAMID LPH 2 mg	orodispersible tablets	2mg	LABORMED PHARMA S.A.	ROMANIA	15123	2023	01
71	LOPERAMIDUM	LOPERAMIDA GRINDEKS 2 mg	capsules	2mg	AS GRINDEKS	LATVIA	15110	2023	01
72	METAMIZOLUM NATRIUM	METAMIZOL MEDREG 500 mg	tablets	500mg	MEDREG S.R.O.	THE CZECH REPUBLIC	15051	2023	01
73	METFORMINUM	SIOFOR 500 mg	prolonged-release tablets	500mg	BERLIN-CHEMIE AG	GERMANY	15065	2023	01
74	METFORMINUM	SIOFOR 750 mg	prolonged-release tablets	750mg	BERLIN-CHEMIE AG	GERMANY	15066	2023	01

75	METFORMINUM	SIOFOR 1000 mg	prolonged-release tablets	1000mg	BERLIN-CHEMIE AG	GERMANY	15067	2023	01
76	METFORMINUM	METFORMIN MEDREG 500 mg	film-coated tablets	500mg	MEDREG S.R.O.	THE CZECH REPUBLIC	15147	2023	01
77	METFORMINUM	METFORMIN MEDREG 850 mg	film-coated tablets	850mg	MEDREG S.R.O.	THE CZECH REPUBLIC	15148	2023	01
78	METFORMINUM	METFORMIN MEDREG 1000 mg	film-coated tablets	1000mg	MEDREG S.R.O.	THE CZECH REPUBLIC	15149	2023	01
79	METYRAPONUM	METOPIRONE 250 mg	soft capsules	250mg	HRA PHARMA RARE DISEASES	FRANCE	15076	2023	01
80	NEBIVOLOLUM	NOLET 5 mg	tablets	5mg	ANTIBIOTICE S.A.	ROMANIA	15068	2023	01
81	OMEPRAZOLUM	OMEPRAZOL NORIDEM 40 mg	powder for solution for infusion	40mg	NORIDEM ENTERPRISES LIMITED	CYPRUS	15103	2023	01
82	OXIGENUM	OXIGEN LINDE 100%	cryogenic medicinal gas	100%	LINDE GAS A.S.	THE CZECH REPUBLIC	15073	2023	01
83	PANTOPRAZOLUM	PANTOPRAZOL KALCEKS 40 mg	powder for solution for injection	40mg	AS KALCEKS	LATVIA	15052	2023	01

84	PROTAMINI SULFAS	SULFAT DE PROTAMINA LEO PHARMA 1400 UI ANTI-HEPARINA/ml	solution for injection/infusion	10mg/ml	LEO PHARMA A/S	DENMARK	6	2023	01
85	RISPERIDONUM	RISPERIDONA GRINDEKS 0.5 mg	film-coated tablets	0.5mg	AS GRINDEKS	LATVIA	15131	2023	01
86	RISPERIDONUM	RISPERIDONA GRINDEKS 1 mg	film-coated tablets	1mg	AS GRINDEKS	LATVIA	15132	2023	01
87	RISPERIDONUM	RISPERIDONA GRINDEKS 2 mg	film-coated tablets	2mg	AS GRINDEKS	LATVIA	15133	2023	01
88	RISPERIDONUM	RISPERIDONA GRINDEKS 3 mg	film-coated tablets	3mg	AS GRINDEKS	LATVIA	15134	2023	01
89	RISPERIDONUM	RISPERIDONA GRINDEKS 4 mg	film-coated tablets	4mg	AS GRINDEKS	LATVIA	15135	2023	01
90	RISPERIDONUM	RISPERIDONA GRINDEKS 6 mg	film-coated tablets	6mg	AS GRINDEKS	LATVIA	15136	2023	01
91	RIVAROXABANUM	RIVAROXABAN MEDREG 2.5 mg	film-coated tablets	2.5mg	MEDREG S.R.O.	THE CZECH REPUBLIC	15057	2023	01
92	RIVAROXABANUM	RIVAROXABAN MEDREG 10 mg	film-coated tablets	10mg	MEDREG S.R.O.	THE CZECH REPUBLIC	15058	2023	01

93	RIVAROXABANUM	RIVAROXABAN MEDREG 15 mg	film-coated tablets	15mg	MEDREG S.R.O.	THE CZECH REPUBLIC	15059	2023	01
94	RIVAROXABANUM	RIVAROXABAN MEDREG 20 mg	film-coated tablets	20mg	MEDREG S.R.O.	THE CZECH REPUBLIC	15060	2023	01
95	ROCURONIUM BROMIDE	ROCURONIUM AGUETTANT 10 mg/ml	solution for injection in pre- filled syringe	10mg/ml	LABORATOIRE AGUETTANT	FRANCE	15112	2023	01
96	SALMETEROLUM+ FLUTICASONUM	SALMEX 50 micrograms/ 500 micrograms/dose	inhalation powder, single dose	50micrograms/ 500micrograms	GLENMARK PHARMACEUTIC ALS S.R.O.	THE CZECH REPUBLIC	15077	2023	01
97	SELENIUM (75SE) ACID TAUROSELCOLIC	SeHCAT 370 kBq	capsules	370kBq	GE HEALTHCARE BUCHLER GMBH & CO. KG	GERMANY	15075	2023	01
98	SIMVASTATINUM	VASILIP 20 mg	film-coated tablets	20mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15048	2023	01
99	SIMVASTATINUM	VASILIP 10 mg	film-coated tablets	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15047	2023	01
100	SITAGLIPTINUM	SUPROVIA 50 mg	film-coated tablets	50mg	MERCK ROMANIA SRL	ROMANIA	15145	2023	01

101	SITAGLIPTINUM	SUPROVIA 100 mg	film-coated tablets	100mg	MERCK ROMANIA SRL	ROMANIA	15146	2023	01
102	SUGAMMADEXUM	SUGAMMADEX PHARMAZAC 100 mg/ml	solution for injection	100mg/ml	PHARMAZAC S.A.	GREECE	15064	2023	01
103	TERIFLUNOMIDUM	TERIFLUNOMIDA DR. REDDY'S 14 mg	film-coated tablets	14mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	15072	2023	01
104	TESTOSTERONUM	TESTAVAN 20 mg/g	transdermal gel	20mg/g	THE SIMPLE PHARMA COMPANY LIMITED	IRELAND	15152	2023	01
105	TRABECTEDINUM	TRABECTEDIN EVER PHARMA 0.25 mg	powder for concentrate for solution for infusion	0.25mg	EVER VALINJECT GMBH	AUSTRIA	15054	2023	01
106	TRABECTEDINUM	TRABECTEDIN EVER PHARMA 1 mg	powder for concentrate for solution for infusion	1mg	EVER VALINJECT GMBH	AUSTRIA	15055	2023	01

EMA centrally authorised medicinal products notified for marketing in Romania during the 3rd quarter of 2023

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.		
1	EPCORITAMABUM	TEPKINLY 4 mg/0.8 ml	concentrate for solution for injection	5mg/ml	ABBVIE DEUTSCHLAND GMBH & CO. KG	GERMANY	1759	2023	01
2	EPCORITAMABUM	TEPKINLY 48 mg	solution for injection	60mg/ml	ABBVIE DEUTSCHLAND GMBH & CO. KG	GERMANY	1759	2023	01
3	GLOFITAMABUM	COLUMVI 2.5 mg	concentrate for solution for infusion	1mg/ml	ROCHE REGISTRATION GMBH	GERMANY	1742	2023	01
4	GLOFITAMABUM	COLUMVI 10 mg	concentrate for solution for infusion	1mg/ml	ROCHE REGISTRATION GMBH	GERMANY	1742	2023	01
5	TALQUETAMABUM	TALVEY 2 mg/ml	solution for injection	2mg/ml	JANSSEN CILAG INTERNATIONAL NV	BELGIUM	1748	2023	01
6	TALQUETAMABUM	TALVEY 40 mg/ml	solution for injection	40mg/ml	JANSSEN CILAG INTERNATIONAL NV	BELGIUM	1748	2023	01
7	VACCINE AGAINST THE RESPIRATORY SYNCYTIAL VIRUS	ABRYSVO	powder and solvent for solution for injection		PFIZER EUROPE MA EEIG	BELGIUM	1752	2023	01