

ROMANIA
Newsletter

Year 27, No. 1 (105), 1st quarter of 2025

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

a) 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. 2318/2021 on approval of the organisational structure 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. 3994 of 2024 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:

Order of the Minister of Health no. 3994 of 2024 on approval of the organisational structure of the National Agency for Medicines and Medical Devices of Romania

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 balance sheet

Budget and funding source

Balance sheet

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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Orders

Order of the Minister of Health no. 650/2025 on approval of the procedural rules for enforcement of the provisions of Article 5 (5) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC of the Council on medical devices and in vitro diagnostic medical devices and used only within health institutions

Order of the Minister of Health no. 6120/2024 on approval of the Methodological Rules for the elaboration of the Romanian List of critical medicinal products

Medicinal product batches recalled during the 1st quarter of 2025

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/ MAH/parallel import authorisation holder	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		Out-of-specification outcomes	Voluntary withdrawal upon NAMMDR request	16.01.2024
2	ALPRAZOLAM LPH 0.25 mg tablets	tablets	0.25 mg	Alprazolamum	Labormed Pharma S.A., Romania	3L00274A/exp.31.01.2025 3L00460A/exp.28.02.2025 3L00461A/exp.28.02.2025 3L00641A/exp.30.04.2025 3L00725A/exp.31.05.2025 3L00945A/exp.31.07.2025 3L01082A/exp.31.08.2025 3L01083A/exp.31.08.2025 3L01170A/exp.31.08.2025 3L01171A/exp.31.08.2025 3L01436A/exp.31.10.2025 3L01490A/exp.30.11.2025 3L01491A/exp.30.11.2025 3L01492A/exp.30.11.2025 3L01493A/exp.30.11.2025 4L00273A/exp.31.01.2026 4L00274A/exp.31.01.2026	Out-of-specification outcomes	Voluntary withdrawal	17.02.2025
3	ACC 600 mg effervescent tablets	effervescent tablets	600 mg	Acetylcysteinum	Genco Pharmaceuticals S.R.L., Romania	MR5413/exp. 30.06.2026	Out-of-specification outcomes	Voluntary withdrawal	25.03.2025

Applications for marketing authorisation/marketing authorisation renewal received during the 4th quarter of 2024

29 marketing authorisation/marketing authorisation renewal applications for medicinal products have been received during the 4th quarter of 2024, corresponding to the following therapeutic groups:

AUTHORISATION	RENEWAL
V03 – ALL OTHER THERAPEUTIC PRODUCTS	A03 - DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS
A04 – ANTIEMETICS AND ANTINAUSEANTS	N05 - PSYCHOLEPTICS
B01 – ANTITHROMBOTIC AGENTS	N02 - ANALGESICS
B01 – ANTITHROMBOTIC AGENTS	R05 - COUGH AND COLD PREPARATIONS
B01 – ANTITHROMBOTIC AGENTS	R06 - ANTIHISTAMINES FOR SYSTEMIC USE
B01 – ANTITHROMBOTIC AGENTS	N02 - ANALGESICS
R01 – NASAL PREPARATIONS	M01 - ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
N02 - ANALGESICS	R01 – NASAL PREPARATIONS
N02 - ANALGESICS	A03 - DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS
R01 – NASAL PREPARATIONS	R06 - ANTIHISTAMINES FOR SYSTEMIC USE
R01 – NASAL PREPARATIONS	N02 - ANALGESICS
A10 - DRUGS USED IN DIABETES	A06 – DRUGS FOR CONSTIPATION
A10 - DRUGS USED IN DIABETES	B01 – ANTITHROMBOTIC AGENTS
H02 - CORTICOSTEROIDS FOR SYSTEMIC USE	A02 – DRUGS FOR ACID RELATED DISORDERS
	A02 – DRUGS FOR ACID RELATED DISORDERS

Medicinal products authorised for marketing during the 4th quarter of 2024

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	ACICLOVIRUM	XOROX 30 mg/g	eye ointment	30mg/g	AGEPHA PHARMA S.R.O.	SLOVAKIA	15761	2024
2	ACIDUM ACETYLSALICYLICUM	ACECARDIN 75 mg	gastroresistant tablets	75mg	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	15725	2024
3	ACIDUM ASCORBICUM	VITAMINA C BÉRES 100 mg/ml	oral drops, solution	100mg/ml	BERES PHARMACEUTICALS LTD.	HUNGARY	15664	2024
4	ANTITHROMBINUM III HUMANUM	ATENATIV 50 IU/ml	powder and solvent for solution for infusion	50UI/ml	OCTAPHARMA (IP) SPRL	BELGIUM	15636	2024
5	APIXABANUM	XAPA 2.5 mg	film-coated tablets	2.5 mg	EGIS PHARMACEUTICALS PLC	HUNGARY	15683	2024
6	APIXABANUM	XAPA 5 mg	film-coated tablets	5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	15684	2024
7	BENFOTIAMINUM	BENFOTIAMINA G.L. PHARMA 50 mg	film-coated tablets	50mg	G.L. PHARMA GMBH	AUSTRIA	15629	2024
8	BENFOTIAMINUM	TIABELLA 300 mg	film-coated tablets	300mg	G.L. PHARMA GMBH	AUSTRIA	15630	2024

9	BIOTINUM	BELBITAL 10 mg	tablets	10mg	NATUR PRODUKT ZDROVIT SP. Z O.O.	POLAND	15626	2024
10	BORTEZOMIBUM	BORTEZOMIB SANDOZ 2.5 mg	powder for solution for injection	2.5 mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15666	2024
11	BOSUTINIBUM	BOSUTINIB TEVA 100 mg	film-coated tablets	100mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	15734	2024
12	BOSUTINIBUM	BOSUTINIB TEVA 400 mg	film-coated tablets	400mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	15735	2024
13	BOSUTINIBUM	BOSUTINIB TEVA 500 mg	film-coated tablets	500mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	15736	2024
14	BUPIVACAINUM	BUPIVACAINA SPINAL HEAVY PANPHARMA 5 mg/ml	solution for injection	5mg/ml	PANPHARMA	FRANCE	15720	2024
15	CALCITRIOLUM	DECOSTRIOL 0.25 micrograms	soft capsules	0.25 micrograms	MIBE GMBH ARZNEIMITTEL	GERMANY	13	2024
16	CALCITRIOLUM	DECOSTRIOL 0.50 micrograms	soft capsules	0.50 micrograms	MIBE GMBH ARZNEIMITTEL	GERMANY	14	2024
17	CEFTAZIDIMUM	CEFTAZIDIMA SWYSSI 1 g	powder for solution for injection/infusion	1g	SWYSSI AG	GERMANY	15755	2024
18	CETIRIZINUM	ALLEMAX 10 mg	film-coated tablets	10mg	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	15762	2024

19	COLECALCIFEROLUM	VITAMIN D3 KRKA 30000 IU	tablets	30000UI	KRKA, D.D., NOVO MESTO	SLOVENIA	15705	2024
20	COLISTINUM	COLISTIMETAT DE SODIU ACCORD 1000000 IU	powder for solution for injection/infusion	1000000UI	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	15667	2024
21	COMBINATIONS	PANANGIN FORTE 316 mg/280 mg	film-coated tablets	316mg/280mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	15660	2024
22	COMBINATIONS	ASPIGOLA MIERE SI LAMAIE FARA ZAHAR	lozenges		BAYER S.R.L.	ROMANIA	15648	2024
23	COMBINATIONS	ASPIGOLA MENTA	oromucosal spray, solution		BAYER S.R.L.	ROMANIA	15649	2024
24	COMBINATIONS	PLASMALYTE	solution for infusion		BAXTER HEALTHCARE S.R.L.	ROMANIA	12	2024
25	COMBINATIONS (ACIDUM ACETYLSALICYLICUM+ PARACETAMOLUM+ CAFEINUM)	FASCOMIT	tablets	200mg/200mg/ 25mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	15729	2024
26	COMBINATIONS (BECLOMETASONUM+ FORMOTEROLUM)	VIVAIRE 200 micrograms/ 6 micrograms/dose	pressurised solution for inhalation	200 micrograms/ 6micrograms/ dose	ZENTIVA, K.S.	THE CZECH REPUBLIC	15704	2024
27	COMBINATIONS (BIMATOPROSTUM+ TIMOLOLUM)	ECBIRIO 0.3 mg/ 5 mg/ml	eye drops, solution	0.3mg/5mg/ml	SIFI S.P.A.	ITALY	15698	2024

28	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	ZETOVAR 10 mg/10 mg	tablets	10mg/10mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15632	2024
29	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	ZETOVAR 10 mg/20 mg	tablets	10mg/20mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15633	2024
30	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	ZETOVAR 10 mg/40 mg	tablets	10mg/40mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15634	2024
31	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	ZETOVAR 10 mg/80 mg	tablets	10mg/80mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15635	2024
32	COMBINATIONS (IBUPROFENUM+ PARACETAMOLUM)	COMBIFEXIN 200 mg/500 mg	film-coated tablets	200mg/500mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15752	2024
33	COMBINATIONS (LEVODOPUM+ CARBIDOPUM)	ALEDOV 100 mg/25 mg	tablets	100mg/25mg	MEDOCHEMIE LTD.	CYPRUS	15627	2024
34	COMBINATIONS (LEVODOPUM+ CARBIDOPUM)	ALEDOV 250 mg/25 mg	tablets	250mg/25mg	MEDOCHEMIE LTD.	CYPRUS	15628	2024
35	COMBINATIONS (OCTENIDINUM+ PHENOXYETHANOL)	OCTIZY 1 mg/g+10 mg/g	gel	1mg/g+10mg/g	EGIS PHARMACEUTICALS PLC.	HUNGARY	15754	2024

36	COMBINATIONS (PARACETAMOLUM+ PROPYPHENAZONUM+ CAFEINUM)	PARACETAMOL/ PROPIFENAZONA/ CAFEINA LAROPHARM 250 mg/150 mg/50 mg	tablets	250mg/150mg/ 50mg	LAROPHARM S.R.L.	ROMANIA	15730	2024
37	COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM+ AMLODIPINUM)	PERINDOPRIL ARGININA/ INDAPAMIDA/ AMLODIPINA TEVA 5 mg/1.25 mg/5 mg	film-coated tablets	5mg/1.25mg/ 5mg	TEVA B.V.	THE NETHERLANDS	15721	2024
38	COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM+ AMLODIPINUM)	PERINDOPRIL ARGININA/ INDAPAMIDA/ AMLODIPINA TEVA 5 mg/1.25 mg/10 mg	film-coated tablets	5mg/1.25mg/ 10mg	TEVA B.V.	THE NETHERLANDS	15722	2024
39	COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM+ AMLODIPINUM)	PERINDOPRIL ARGININA/ INDAPAMIDA/ AMLODIPINA TEVA 10 mg/2.5 mg/5 mg	film-coated tablets	10mg/2.5 mg/ 5mg	TEVA B.V.	THE NETHERLANDS	15723	2024
40	COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM+ AMLODIPINUM)	PERINDOPRIL ARGININA/ INDAPAMIDA/ AMLODIPINA TEVA 10 mg/2.5 mg/10 mg	film-coated tablets	10mg/2.5 mg/ 10mg	TEVA B.V.	THE NETHERLANDS	15724	2024
41	COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	CO-ROSWERA 5 mg/10 mg	film-coated tablets	5mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15744	2024

42	COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	CO-ROSWERA 10 mg/10 mg	film-coated tablets	10mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15745	2024
43	COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	CO-ROSWERA 15 mg/10 mg	film-coated tablets	15mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15746	2024
44	COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	CO-ROSWERA 20 mg/10 mg	film-coated tablets	20mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15747	2024
45	COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	CO-ROSWERA 40 mg/10 mg	film-coated tablets	40mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15748	2024
46	COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	JAMESI NOVUM 50 mg/1000 mg	film-coated tablets	50mg/1000mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15665	2024
47	DAPAGLIFLOZINUM	DAGETIA 5 mg	film-coated tablets	5mg	PHARMAPATH S.A.	GREECE	15706	2024
48	DAPAGLIFLOZINUM	DAGETIA 10 mg	film-coated tablets	10mg	PHARMAPATH S.A.	GREECE	15707	2024
49	DASATINIBUM	DASATINIB MSN 20 mg	film-coated tablets	20mg	MSN LABS EUROPE LIMITED	MALTA	15711	2024
50	DASATINIBUM	DASATINIB MSN 50 mg	film-coated tablets	50mg	MSN LABS EUROPE LIMITED	MALTA	15712	2024
51	DASATINIBUM	DASATINIB MSN 70 mg	film-coated tablets	70mg	MSN LABS EUROPE LIMITED	MALTA	15713	2024
52	DASATINIBUM	DASATINIB MSN 80 mg	film-coated tablets	80mg	MSN LABS EUROPE LIMITED	MALTA	15714	2024

53	DASATINIBUM	DASATINIB MSN 100 mg	film-coated tablets	100mg	MSN LABS EUROPE LIMITED	MALTA	15715	2024
54	DASATINIBUM	DASATINIB MSN 140 mg	film-coated tablets	140mg	MSN LABS EUROPE LIMITED	MALTA	15716	2024
55	DEFERASIROXUM	DEFERASIROX STADA 90 mg	film-coated tablets	90mg	STADA M&D S.R.L.	ROMANIA	15717	2024
56	DEFERASIROXUM	DEFERASIROX STADA 180 mg	film-coated tablets	180mg	STADA M&D S.R.L.	ROMANIA	15718	2024
57	DEFERASIROXUM	DEFERASIROX STADA 360 mg	film-coated tablets	360mg	STADA M&D S.R.L.	ROMANIA	15719	2024
58	DIENOGESTUM	ZAFRILLA 2 mg	tablets	2mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	15733	2024
59	DIMETHYL FUMARATE	DIMETIL FUMARAT SANDOZ 120 mg	gastroresistant capsules	120mg	SANDOZ PHARMACEUTICALS GMBH	ROMANIA	15662	2024
60	DIMETHYL FUMARATE	DIMETIL FUMARAT SANDOZ 240 mg	gastroresistant capsules	240mg	SANDOZ PHARMACEUTICALS GMBH	ROMANIA	15663	2024
61	DIMETINDENUM	FLENTY 1 mg/g	gel	1mg/g	ALKALOID-INT D.O.O.	SLOVENIA	15702	2024
62	DIOSMINUM	HIVIS 1000 mg	film-coated tablets	1000mg	TERAPIA S.A.	ROMANIA	15763	2024

63	DIVERSE	APA PENTRU PREPARATE INJECTABILE CSL BEHRING	solvent for parenteral preparation		CSL BEHRING GMBH	GERMANY	15685	2024
64	EDOXABANUM	DELIANDA 15 mg	film-coated tablets	15mg	KRKA D.D., NOVO MESTO	SLOVENIA	15749	2024
65	EDOXABANUM	DELIANDA 30 mg	film-coated tablets	30mg	KRKA D.D., NOVO MESTO	SLOVENIA	15750	2024
66	EDOXABANUM	DELIANDA 60 mg	film-coated tablets	60mg	KRKA D.D., NOVO MESTO	SLOVENIA	15751	2024
67	ENZALUTAMIDUM	TAGANT 40 mg	film-coated tablets	40mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	15645	2024
68	ENZALUTAMIDUM	TAGANT 80 mg	film-coated tablets	80mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	15646	2024
69	ENZALUTAMIDUM	ENZALUTAMIDA SANDOZ PHARMACEUTICALS 40 mg	film-coated tablets	40mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15670	2024
70	ENZALUTAMIDUM	ENZALUTAMIDA SANDOZ PHARMACEUTICALS 80 mg	film-coated tablets	80mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15671	2024

71	ENZALUTAMIDUM	ENZALUTAMIDA STADA 40 mg	film-coated tablets	40mg	STADA M&D S.R.L.	ROMANIA	15691	2024
72	ENZALUTAMIDUM	ENZALUTAMIDA STADA 80 mg	film-coated tablets	80mg	STADA M&D S.R.L.	ROMANIA	15692	2024
73	EVEROLIMUS	SYRLENO 2.5 mg	tablets	2.5 mg	ALKALOID - INT D.O.O.	SLOVENIA	15679	2024
74	EVEROLIMUS	SYRLENO 5 mg	tablets	5mg	ALKALOID - INT D.O.O.	SLOVENIA	15680	2024
75	EVEROLIMUS	SYRLENO 10 mg	tablets	10mg	ALKALOID - INT D.O.O.	SLOVENIA	15681	2024
76	FLURBIPROFENUM	STREPSILS INTENSIV PORTOCAL FARA ZAHAR 8.75 mg	lozenges	8.75mg	RECKITT BENCKISER (ROMANIA) S.R.L.	ROMANIA	15640	2024
77	FLURBIPROFENUM	SEPTAZULEN PORTOCAL 8.75 mg	lozenges	8.75mg	PHARMA NET SOLUTIONS SRL	ROMANIA	15701	2024
78	FULVESTRANTUM	FULVESTRANT SUN 250 mg	solution for injection in pre- filled syringe	250mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	THE NETHERLANDS	15703	2024
79	HYDROXYETHYL- AMIDON	VOLULYTE 6%	solution for infusion	6%	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	15623	2024
80	IBUPROFENUM	IBUPROFEN DR. MAX 400 mg	soft capsules	400mg	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	15756	2024

81	IBUPROFENUM	IBUCALMIN 400 mg	film-coated tablets	400mg	LAROPHARM S.R.L.	ROMANIA	15639	2024
82	IBUPROFENUM	IBUCALMIN COPII 100 mg/5 ml	oral suspension	100mg/5ml	LAROPHARM S.R.L.	ROMANIA	15669	2024
83	IRINOTECANUM	IRINOTECAN SUN 1.5 mg/ml	solution for infusion	1.5 mg/ml	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	THE NETHERLANDS	15728	2024
84	KETOROLACUM TROMETHAMIN	KETOROLAC TROMETAMOL ROMPHARM 5 mg/ml	eye drops, solution	5mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	15668	2024
85	LEVETIRACETAMUM	LEVETIRACETAM TERAPIA 750 mg	film-coated tablets	750mg	TERAPIA S.A.	ROMANIA	15727	2024
86	LEVOFLOXACINUM	FOVELID 500 mg	film-coated tablets	500mg	ALKALOID-INT D.O.O.	SLOVENIA	15760	2024
87	LIDOCAINUM	LIVOHEP 10 mg/ml	solution for injection	10mg/ml	AS GRINDEKS	LATVIA	15699	2024
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89	LINAGLIPTINUM	JELIGO 5 mg	film-coated tablets	5mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	15753	2024
90	LIRAGLUTIDUM	DIAVIC 6 mg/ml	solution for injection in pre- filled pen	6mg/ml	TERAPIA S.A.	ROMANIA	15659	2024

91	METFORMINUM	METFORMIN ACCORD 500 mg	prolonged-release tablets	500mg	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	15738	2024
92	METHOTREXATUM	METOTREXAT VITEMA 2.5 mg	tablets	2.5 mg	VITEMA S.A.	ROMANIA	15731	2024
93	MIRABEGRONUM	IRETIG 50 mg	prolonged-release tablets	50mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15686	2024
94	NEBIVOLOLUM	NEBIVOLOL GEMAX PHARMA 5 mg	tablets	5mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	15673	2024
95	NILOTINIBUM	NILOTINIB STADA 50 mg	capsules	50mg	STADA ARZNEIMITTEL AG	GERMANY	15757	2024
96	NILOTINIBUM	NILOTINIB STADA 150 mg	capsules	150mg	STADA ARZNEIMITTEL AG	GERMANY	15758	2024
97	NILOTINIBUM	NILOTINIB STADA 200 mg	capsules	200mg	STADA ARZNEIMITTEL AG	GERMANY	15759	2024
98	NITROFURANTOINUM	FUROLIN 50 mg	capsules	50mg	IASIS PHARMACEUTICALS HELLAS S.A.	GREECE	15624	2024
99	NITROFURANTOINUM	FUROLIN 100 mg	capsules	100mg	IASIS PHARMACEUTICALS HELLAS S.A.	GREECE	15625	2024
100	OSELTAMIVIRUM	SEGOSANA 30 mg	capsules	30mg	ZENTIVA K.S.	THE CZECH REPUBLIC	15739	2024
101	OSELTAMIVIRUM	SEGOSANA 75 mg	capsules	75mg	ZENTIVA K.S.	THE CZECH REPUBLIC	15740	2024

102	PHENYLEPHRINUM	FENILEFRINA AGUETTANT 100 micrograms/ml	solution for injection/infusion	100 micrograms/ml	LABORATOIRE AGUETTANT	FRANCE	15658	2024
103	PITAVASTATINUM	PITIPIX 1 mg	film-coated tablets	1mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15741	2024
104	PITAVASTATINUM	PITIPIX 2 mg	film-coated tablets	2mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15742	2024
105	PITAVASTATINUM	PITIPIX 4 mg	film-coated tablets	4mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15743	2024
106	PLANTE	ILON	ointment		CESRA ARZNEIMITTEL GMBH & CO. KG	GERMANY	15622	2024
107	PLANTE	IBEROGAST BALANCE	oral drops, solution		BAYER S.R.L.	ROMANIA	15647	2024
108	PLANTE	HERBION LICHEN DE ISLANDA	lozenges		KRKA, D.D., NOVO MESTO	SLOVENIA	15682	2024
109	PLANTE (EXTRACT DE MUSCATA)	PELAVOMED 20 mg/4 ml	oral solution	20mg/4ml	US PHARMACIA SP. ZO.O	POLAND	15631	2024
110	POMALIDOMIDUM	POMALIDOMIDA SANDOZ 1 mg	capsules	1mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15641	2024
111	POMALIDOMIDUM	POMALIDOMIDA SANDOZ 2 mg	capsules	2mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15642	2024

112	POMALIDOMIDUM	POMALIDOMIDA SANDOZ 3 mg	capsules	3mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15643	2024
113	POMALIDOMIDUM	POMALIDOMIDA SANDOZ 4 mg	capsules	4mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15644	2024
114	POMALIDOMIDUM	POMALIDOMIDA DR. REDDY'S 1 mg	capsules	1mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	15650	2024
115	POMALIDOMIDUM	POMALIDOMIDA DR. REDDY'S 2 mg	capsules	2mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	15651	2024
116	POMALIDOMIDUM	POMALIDOMIDA DR. REDDY'S 3 mg	capsules	3mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	15652	2024
117	POMALIDOMIDUM	POMALIDOMIDA DR. REDDY'S 4 mg	capsules	4mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	15653	2024
118	POSACONAZOLUM	POSACONAZOL VIATRIS 100 mg	gastroresistant tablets	100mg	VIATRIS LIMITED	IRELAND	15764	2024
119	POSACONAZOLUM	POSACONAZOL MSN 100 mg	gastroresistant tablets	100mg	MSN LABS EUROPE LIMITED	MALTA	15737	2024
120	PRUCALOPRIDUM	COLSELAX 1 mg	film-coated tablets	1mg	TERAPIA S.A.	ROMANIA	15637	2024

121	PRUCALOPRIDUM	COLSELAX 2 mg	film-coated tablets	2mg	TERAPIA S.A.	ROMANIA	15638	2024
122	RIVAROXABANUM	XANIRVA 2.5 mg	film-coated tablets	2.5 mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15675	2024
123	RIVAROXABANUM	XANIRVA 10 mg	film-coated tablets	10mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15676	2024
124	RIVAROXABANUM	XANIRVA 15 mg	film-coated tablets	15mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15677	2024
125	RIVAROXABANUM	XANIRVA 20 mg	film-coated tablets	20mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15678	2024
126	ROSUVASTATINUM	ROSUVASTATINA MSN LABORATORIES 5 mg	film-coated tablets	5mg	MSN LABS EUROPE LIMITED	MALTA	15654	2024
127	ROSUVASTATINUM	ROSUVASTATINA MSN LABORATORIES 10 mg	film-coated tablets	10mg	MSN LABS EUROPE LIMITED	THE CZECH REPUBLIC	15655	2024
128	ROSUVASTATINUM	ROSUVASTATINA MSN LABORATORIES 20 mg	film-coated tablets	20mg	MSN LABS EUROPE LIMITED	MALTA	15656	2024
129	ROSUVASTATINUM	ROSUVASTATINA MSN LABORATORIES 40 mg	film-coated tablets	40mg	MSN LABS EUROPE LIMITED	MALTA	15657	2024
130	SIMETHICONUM	NONFLATIN 80 mg	soft capsules	80mg	BIOFARM S.A.	ROMANIA	15661	2024

131	SITAGLIPTINUM	MAYSIGLU 25 mg	film-coated tablets	25mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15708	2024
132	SITAGLIPTINUM	MAYSIGLU 50 mg	film-coated tablets	50mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15709	2024
133	SITAGLIPTINUM	MAYSIGLU 100 mg	film-coated tablets	100mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15710	2024
134	SITAGLIPTINUM	METLINKA 50 mg/850 mg	film-coated tablets	50mg/850mg	SWYSSI AG	GERMANY	15696	2024
135	SITAGLIPTINUM	METLINKA 50 mg/1000 mg	film-coated tablets	50mg/1000mg	SWYSSI AG	GERMANY	15697	2024
136	STIRIPENTOLUM	STIRIPENTOL BILLEV 250 mg	powder for oral suspension	250mg	BILLEV PHARMA APS	DENMARK	15689	2024
137	STIRIPENTOLUM	STIRIPENTOL BILLEV 500 mg	powder for oral suspension	500mg	BILLEV PHARMA APS	DENMARK	15690	2024
138	STIRIPENTOLUM	STIRIPENTOL BILLEV 250 mg	capsules	250mg	BILLEV PHARMA APS	DENMARK	15687	2024
139	STIRIPENTOLUM	STIRIPENTOL BILLEV 500 mg	capsules	500mg	BILLEV PHARMA APS	DENMARK	15688	2024
140	TAMSULOSINUM	TAMSULOSIN LICONSA 0.4 mg	modified-release capsules	0.4mg	LABORATORIOS LICONSA S.A.	SPAIN	15672	2024

141	TERIFLUNOMIDUM	TERIFLUNOMIDA DESITIN 14 mg	film-coated tablets	14mg	DESITIN ARZNEIMITTEL GMBH	GERMANY	15726	2024
142	VACCIN GRIPAL INACTIVAT	EFLUELDA TETRA	suspension for injection in pre- filled syringe		SANOFI WINTHROP INDUSTRIE	FRANCE	15674	2024
143	VILDAGLIPTINUM	AGARTHA 50 mg	tablets	50mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	15732	2024
144	ZOPICLONUM	ZOPICLONA BALTIJOS BITE 3.75 mg	film-coated tablets	3.75mg	UAB "BALTIJOS BITE"	LITHUANIA	15693	2024
145	ZOPICLONUM	ZOPICLONA BALTIJOS BITE 5 mg	film-coated tablets	5mg	UAB "BALTIJOS BITE"	LITHUANIA	15694	2024
146	ZOPICLONUM	ZOPICLONA BALTIJOS BITE 7.5 mg	film-coated tablets	7.5 mg	UAB "BALTIJOS BITE"	LITHUANIA	15695	2024

EMA centrally authorised medicinal products notified for marketing in Romania during the 4th quarter of 2024

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	AFLIBERCEPTUM	AFQLIR 40 mg/ml	solution for injection in pre-filled syringe	40mg/ml	SANDOZ GMBH	AUSTRIA	1867	2024
2	AFLIBERCEPTUM	AFQLIR 40 mg/ml	solution for injection	40mg/ml	SANDOZ GMBH	AUSTRIA	1867	2024
3	MIRVETUXIMABUM SORAVTANSINUM	ELAHERE 5 mg/ml	concentrate for solution for infusion	5mg/ml	ABBVIE DEUTSCHLAND GMBH & CO. KG	GERMANY	1866	2024
4	USTEKINUMABUM	IMULDOSA 130 mg	concentrate for solution for infusion	130mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1872	2024
5	USTEKINUMABUM	IMULDOSA 45 mg	solution for injection in pre-filled syringe	45mg/0.5ml	ACCORD HEALTHCARE S.L.U.	SPAIN	1872	2024
6	USTEKINUMABUM	IMULDOSA 90 mg	solution for injection in pre-filled syringe	90mg/ml	ACCORD HEALTHCARE S.L.U.	SPAIN	1872	2024