

ROMANIA

Newsletter

Year 28, No. 1 (109), 1st quarter of 2026

*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) Full names 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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Emergency Ordinances

Emergency Ordinance no. 2, published on 2 February 2026, for amendment of Law 95/2006 on healthcare reform as well as other regulatory documents in the healthcare field;

Emergency Ordinance no. 15, published on 17 March 2026, for the regulation of measures regarding the establishment of the right to administer certain assets in the public domain of the state, as well as on amendment and supplementation of other regulatory documents;

Orders

Order no. 2280 and Order no. 2264, published on 1 January 2026, on amendment and supplementation of Annex 1;

Order no. 2039 and Order no. 2016, published on 8 January 2026, on amendment and supplementation of the Annex to Order of the Minister of Health and of the President of the National Health Insurance House no. 564/499/2021;

Order no. 34, published on 19 January 2026, on amendment and supplementation of Annex 1;

Order no. 2111 and Order no. 35, published on 19 January 2026, on amendment and supplementation of Annex 2 to Order of the Minister of Health and of the President of the National Health Insurance House no. 1.605/875/2014;

Order no. 70, published on 26 January 2026, on amendment of Annex 1 to Order of the President of the National Health Insurance House no. 141/2017;

Order no. 199, published on 2 February 2026, on amendment and supplementation of Annex 1;

Order no. 382, published on 16 February 2026, on amendment and supplementation of Annex 1;

Order no. 340 and Order no. 139, published on 11 February 2026, on amendment and supplementation of Annex 2 to Order of the Minister of Health and of the President of the National Health Insurance House no. 1.605/875/2014;

Order no. 444, published on 25 February 2026, on amendment of Annex 1 to Order of the President of the National Health Insurance House no. 141/2017;

Order no. 500. published on 1 March 2026, on amendment and supplementation of Annex 1;

Order no. 533 and Order no. 502, published on 6 March 2026, on amendment and supplementation of the Annex to Order of the Minister of Health and of the President of the National Health Insurance House no. 564/499/2021;

Order no. 589, published on 6 March 2026, on amendment and supplementation of Annex 1;

Order no. 591 and Order no. 524, published on 9 March 2026, on amendment and supplementation of Annex 2 to Order of the Minister of Health and of the President of the National Health Insurance House no. 1.605/875/2014;

Order no. 745, published on 23 March 2026, on amendment and supplementation of Annex 1;

Order no. 612, published on 31 March 2026, on amendment of Annex 1 to Order of the President of the National Health Insurance House no. 141/2017;

Medicinal product batches recalled during the 1st quarter of 2026

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/MAH/parallel import authorisation holder	Batch	Grounds for recall	Proposed action	Date of recall
1	OMNIPAQUE 350 mg I/ml solution for injection	solution for injection	350mg I/ml	Iohexolum	GE HEALTHCARE AS - NORWAY	17306297/exp. 07.2028 17308416/exp. 07.2028 17314055/exp. 08.2028 17328722/exp. 11.2028 17358222/exp. 12.2028 17376107/exp. 10.2028 17409644/exp. 11.2028 17433391/exp. 12.2028	Out-of-specification outcomes	Withdrawal upon NAMMDR request	06.04.2026
2	VISIPAQUE 320 mg I/ml solution for injection	solution for injection	320mg I/ml	Iodixanolum	GE HEALTHCARE AS - NORWAY	17275012/exp. 08.2028	Out-of-specification outcomes	Withdrawal upon NAMMDR request	06.04.2026
3	CUROSURF 120 mg, endotracheopulmonary instillation suspension	Endotracheopulmonary instillation suspension	80mg/ml	VARIOUS	CHIESI FARMACEUTICI SPA - ITALY	1212908/exp. 07.2026 1224254/exp. 03.2027	Preventive withdrawal due to increase in some parameters	Voluntary withdrawal	01.04.2026
4	Byetta 5 micrograms solution for injection in pre-filled pen	solution for injection in pre-filled pen	5 mcg/mL	Exenatidum	ASTRA ZENECA AB - SWEDEN		MA withdrawal at EU level	Voluntary withdrawal	01.01.2026

5	Byetta 10 micrograms solution for injection in pre-filled pen	solution for injection in pre-filled pen	10 mcg/mL	Exenatidum	ASTRA ZENECA AB - SWEDEN		MA withdrawal at EU level	Voluntary withdrawal	01.01.2026
6	Bydureon 2 mg prolonged-release suspension for injection in pre-filled pen	prolonged-release suspension for injection in pre-filled pen	2 mg/mL	Exenatidum	ASTRA ZENECA AB - SWEDEN		MA withdrawal at EU level	Voluntary withdrawal	01.01.2026

**Applications for marketing authorisation/marketing authorisation renewal
received during the 4th quarter of 2025**

9 marketing authorisation/marketing authorisation renewal applications for medicinal products have been received during the 4th quarter of 2025, corresponding to the following therapeutic groups:

AUTHORISATION	RENEWAL
J01 - ANTIBACTERIALS FOR SYSTEMIC USE	N02 - ANALGESICS
J01 - ANTIBACTERIALS FOR SYSTEMIC USE	N02 - ANALGESICS
D06 – ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	B03 – ANTIANEMIC PREPARATIONS
N02 - ANALGESICS	
A06 – DRUGS FOR CONSTIPATION	
A02 - DRUGS FOR ACID RELATED DISORDERS	

Medicinal products authorised for marketing during the 4th quarter of 2025

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	ACETYLCYSTEINUM	TUSS OFF MAX 600 mg	POWDER FOR ORAL SOLUTION IN SACHET	600mg	SLAVIA PHARM S.R.L.	ROMANIA	16387	2025
2	ACICLOVIRUM	VIRICIN 250 mg	POWDER FOR SOLUTION FOR INFUSION	250mg	MEDOCHEMIE LTD.	CYPRUS	16314	2025
3	ACIDUM ACETYLSALICYLICUM	ASAPRIN CARDIO 75 mg	GASTRORESISTANT TABLETS	75mg	AC HELCOR PHARMA S.R.L.	ROMANIA	16321	2025
4	ACIDUM URSODEOXYCHOLICUM	URSOLITH 250 mg	CAPSULES	250mg	VITEMA S.A.	ROMANIA	16354	2025
5	ACIDUM ZOLEDRONICUM	ACID ZOLEDRONIC ROMPHARM 4 mg/5 ml	CONCENTRATE FOR SOLUTION FOR INFUSION	4mg/5ml	ROMPHARM COMPANY S.R.L.	ROMANIA	16315	2025
6	AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOXICILINA/A CID CLAVULANIC APTAPHARMA 1000 mg/200 mg	POWDER FOR SOLUTION FOR INJECTION/INFUSION	1000mg/200mg	APTA MEDICA INTERNACIONA L D.O.O.	SLOVENIA	16369	2025
7	APIXABANUM	APIXABAN GRINDEKS 2.5 mg	FILM-COATED TABLETS	2.5mg	AS GRINDEKS	LATVIA	16333	2025
8	APIXABANUM	APIXABAN GRINDEKS 5 mg	FILM-COATED TABLETS	5mg	AS GRINDEKS	LATVIA	16334	2025
9	ATORVASTATINUM	ATORVASTATIN A EIPICO 10 mg	FILM-COATED TABLETS	10mg	E.I.P.I.CO MED S.R.L.	ROMANIA	16313	2025

10	AZACITIDINUM	AZACITIDINA MSN 25 mg/ml	POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	25mg/ml	MSN LABS EUROPE LIMITED	MALTA	16328	2025
11	AZTREONAMUM	AZACTAM 2 g	POWDER FOR SOLUTION FOR INJECTION OR INFUSION	2g	BRISTOL- MYERS SQUIBB ROMANIA SRL	ROMANIA	17	2025
12	BIBROCATHOLUM	POSIFORLID 20 mg/g	EYE OINTMENT	20mg/g	AMD NOBEL PHARMACEUTIC AL SRL	ROMANIA	16277	2025
13	BILASTINUM	BILASTINA GEMAX PHARMA 20 mg	TABLETS	20mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	16278	2025
14	BISACODYLUM	BISACODIL LAROPHARM 5 mg	GASTRORESISTANT TABLETS	5mg	LAROPHARM S.R.L.	ROMANIA	16309	2025
15	BRIVARACETAMUM	BRIVARACETAM ACCORD 10 mg	FILM-COATED TABLETS	10mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	16271	2025
16	BRIVARACETAMUM	BRIVARACETAM ACCORD 25 mg	FILM-COATED TABLETS	25mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	16272	2025
17	BRIVARACETAMUM	BRIVARACETAM ACCORD 50 mg	FILM-COATED TABLETS	50mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	16273	2025
18	BRIVARACETAMUM	BRIVARACETAM ACCORD 75 mg	FILM-COATED TABLETS	75mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	16274	2025

19	BRIVARACETAMUM	BRIVARACETAM ACCORD 100 mg	FILM-COATED TABLETS	100mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	16275	2025
20	BRIVARACETAMUM	ABAVALEX 10 mg	FILM-COATED TABLETS	10mg	G.L. PHARMA GMBH	AUSTRIA	16373	2025
21	BRIVARACETAMUM	ABAVALEX 25 mg	FILM-COATED TABLETS	25mg	G.L. PHARMA GMBH	AUSTRIA	16374	2025
22	BRIVARACETAMUM	ABAVALEX 50 mg	FILM-COATED TABLETS	50mg	G.L. PHARMA GMBH	AUSTRIA	16375	2025
23	BRIVARACETAMUM	ABAVALEX 75 mg	FILM-COATED TABLETS	75mg	G.L. PHARMA GMBH	AUSTRIA	16376	2025
24	BRIVARACETAMUM	ABAVALEX 100 mg	FILM-COATED TABLETS	100mg	G.L. PHARMA GMBH	AUSTRIA	16377	2025
25	BRIVARACETAMUM	BRIVARACETAM DESITIN 10 mg	FILM-COATED TABLETS	10mg	DESITIN ARZNEIMITTEL GMBH	GERMANY	16381	2025
26	BRIVARACETAMUM	BRIVARACETAM DESITIN 25 mg	FILM-COATED TABLETS	25mg	DESITIN ARZNEIMITTEL GMBH	GERMANY	16382	2025
27	BRIVARACETAMUM	BRIVARACETAM DESITIN 50 mg	FILM-COATED TABLETS	50mg	DESITIN ARZNEIMITTEL GMBH	GERMANY	16383	2025
28	BRIVARACETAMUM	BRIVARACETAM DESITIN 75 mg	FILM-COATED TABLETS	75mg	DESITIN ARZNEIMITTEL GMBH	GERMANY	16384	2025
29	BRIVARACETAMUM	BRIVARACETAM DESITIN 100 mg	FILM-COATED TABLETS	100mg	DESITIN ARZNEIMITTEL GMBH	GERMANY	16385	2025

30	CEFUROXIMUM	CEFUROXIMA SWISSI 1.5 g	POWDER FOR SOLUTION FOR INJECTION	1.5g	SWYSSI AG	GERMANY	16279	2025
31	COMBINATIONS	PEDISMOF PRE	EMULSION FOR INFUSION		FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	16298	2025
32	COMBINATIONS	PEDISMOF NEO	EMULSION FOR INFUSION		FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	16299	2025
33	COMBINATIONS	PEDISMOF JUNIOR	EMULSION FOR INFUSION		FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	16300	2025
34	COMBINATIONS (ACIDUM FUSIDICUM+BETAMETHASONUM)	IMAXEMA 20 mg/g+1 mg/g	CREAM	20mg/g+1mg/g	LABORATOIRES BAILLEUL S.A.	LUXEMBOURG	16371	2025
35	COMBINATIONS (AZELASTINUM+FLUTICASONUM)	FLAZONEXAR 137 micrograms/50 micrograms/dose	NASAL SPRAY, SUSPENSION	137micrograms/ 50micrograms/ dose	SIGILLATA LIMITED	IRELAND	16297	2025
36	COMBINATIONS (BENZYDAMINUM+CETYLPIRIDINII CHLORIDUM)	SEPTOLETE OMNI LAMAIE SI GHIMBIR 3 mg/1 mg	LOZENGES	3mg/1mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16312	2025
37	COMBINATIONS (BIMATOPROSTUM+TIMOLOLUM)	DUELYM 0.1 mg/g+1 mg/g	EYE GEL IN SINGLE- DOSE CONTAINER	0.1mg/g+1mg/g	LABORATOIRES THEA	FRANCE	16372	2025

38	COMBINATIONS (DAPAGLIFLOZINUM+METFORMINUM)	MEXDAGRY 5 mg/850 mg	FILM-COATED TABLETS	5mg/850mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16360	2025
39	COMBINATIONS (DAPAGLIFLOZINUM+METFORMINUM)	MEXDAGRY 5 mg/1000 mg	FILM-COATED TABLETS	5mg/1000mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16361	2025
40	COMBINATIONS (DEXAMETHASONUM+LEVOFLOXACIN UM)	DUCRESSA 1 mg/ml+5 mg/ml	EYE DROPS, SOLUTION	1mg/ml+5mg/m l	SANTEN OY	FINLANDA	16292	2025
41	COMBINATIONS (DOXYLAMINUM+PYRIDOXINUM)	NUPERAL 10 mg/10 mg	MODIFIED-RELEASE CAPSULES	10mg/10mg	ITALFARMACO S.P.A.	ITALY	16368	2025
42	COMBINATIONS (GESTODENUM+ETINILESTRADIOLUM)	KARISSA ZILNIC 75 micrograms/20 micrograms	DRAGEES	75micrograms/2 0micrograms	GEDEON RICHTER ROMANIA S.A.	ROMANIA	16355	2025
43	COMBINATIONS (IBUPROFENUM+PSEUDOEPHEDRINUM)	TEDOLFEN 200 mg/30 mg (see R01BA52)	FILM-COATED TABLETS	200mg/30mg	TEVA PHARMACEUTIC ALS S.R.L.	ROMANIA	16338	2025
44	COMBINATIONS (IBUPROFENUM+PSEUDOEPHEDRINUM)	TEDOLFEN 200 mg/30 mg (see R05X)	FILM-COATED TABLETS	200mg/30mg	TEVA PHARMACEUTIC ALS S.R.L.	ROMANIA	16338	2025
45	COMBINATIONS (LIDOCAINUM+CHLORHEXIDINUM)	CATHEJELL 17.31 mg+0.5 mg/g	GEL	17.31mg+0.5m g/g	PHARMAZEUTIS CHE FABRIK MONTAVIT GES.M.B.H.	AUSTRIA	16295	2025
46	COMBINATIONS (LIPIDS)	ZIREMILON 200 mg/ml	EMULSION FOR INFUSION	200mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	16291	2025

47	COMBINATIONS (ROSUVASTATINUM+EZETIMIBUM)	TWICOR 5 mg/10 mg	FILM-COATED TABLETS	5mg/10mg	VIATRIS HEALTHCARE LIMITED	IRELAND	16324	2025
48	COMBINATIONS (ROSUVASTATINUM+EZETIMIBUM)	TWICOR 40 mg/10 mg	FILM-COATED TABLETS	40mg/10mg	VIATRIS HEALTHCARE LIMITED	IRELAND	16325	2025
49	COMBINATIONS (ROSUVASTATINUM+EZETIMIBUM)	ZEVASTOR DUO 10 mg/10 mg	TABLETS	10mg/10mg	ANTIBIOTICE S.A.	ROMANIA	16357	2025
50	COMBINATIONS (ROSUVASTATINUM+EZETIMIBUM)	ZEVASTOR DUO 20 mg/10 mg	TABLETS	20mg/10mg	ANTIBIOTICE S.A.	ROMANIA	16358	2025
51	COMBINATIONS (ROSUVASTATINUM+EZETIMIBUM)	ZEVASTOR DUO 40 mg/10 mg	TABLETS	40mg/10mg	ANTIBIOTICE S.A.	ROMANIA	16359	2025
52	COMBINATIONS (SACUBITRILUM+VALSARTANUM)	SACUBITRIL/VA LSARTAN GEDEON RICHTER 24 mg/26 mg	FILM-COATED TABLETS	24mg/26mg	GEDEON RICHTER PLC.	HUNGARY	16265	2025
53	COMBINATIONS (SACUBITRILUM+VALSARTANUM)	SACUBITRIL/VA LSARTAN GEDEON RICHTER 49 mg/51 mg	FILM-COATED TABLETS	49mg/51mg	GEDEON RICHTER PLC.	HUNGARY	16266	2025
54	COMBINATIONS (SACUBITRILUM+VALSARTANUM)	SACUBITRIL/VA LSARTAN GEDEON RICHTER 97 mg/103 mg	FILM-COATED TABLETS	97mg/103mg	GEDEON RICHTER PLC.	HUNGARY	16267	2025
55	COMBINATIONS (SACUBITRILUM+VALSARTANUM)	VALKUBIT 24 mg/26 mg	FILM-COATED TABLETS	24mg/26mg	KRKA D.D, NOVO MESTO	SLOVENIA	16317	2025

56	COMBINATIONS (SACUBITRILUM+VALSARTANUM)	VALKUBIT 49 mg/51 mg	FILM-COATED TABLETS	49mg/51mg	KRKA D.D, NOVO MESTO	SLOVENIA	16318	2025
57	COMBINATIONS (SACUBITRILUM+VALSARTANUM)	VALKUBIT 97 mg/103 mg	FILM-COATED TABLETS	97mg/103mg	KRKA D.D, NOVO MESTO	SLOVENIA	16319	2025
58	COMBINATIONS (SITAGLIPTINUM+METFORMINUM)	SITAGLIPTINA/M ETFORMIN ATB 50 mg/1000 mg	FILM-COATED TABLETS	50mg/1000mg	ANTIBIOTICE S.A.	ROMANIA	16320	2025
59	COMBINATIONS (TRAMADOLUM+PARACETAMOLUM)	TRAMADOL/PAR ACETAMOL GEMAX PHARMA 37.5 mg/325 mg	FILM-COATED TABLETS	37.5mg/325mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	16280	2025
60	COMBINATIONS (VILDAGLIPTINUM+METFORMINUM)	AGARTHA DUO 50 mg/850 mg	FILM-COATED TABLETS	50mg/850mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	16269	2025
61	COMBINATIONS (VILDAGLIPTINUM+METFORMINUM)	AGARTHA DUO 50 mg/1000 mg	FILM-COATED TABLETS	50mg/1000mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	16270	2025
62	COMBINATIONS (XYLOMETAZOLINUM+DEXPANTENOLU M)	BIXTONIM XYLO DUO 0.5 mg/ml + 50 mg/ml	NASAL SPRAY, SOLUTION	0.5mg/ml+50 mg/ml	BIOFARM S.A.	ROMANIA	16388	2025
63	COMBINATIONS (XYLOMETAZOLINUM+DEXPANTENOLU M)	BIXTONIM XYLO DUO 1 mg/ml + 50 mg/ml	NASAL SPRAY, SOLUTION	1mg/ml+50 mg/ml	BIOFARM S.A.	ROMANIA	16389	2025
64	DAPAGLIFLOZINUM	FIGOZAP 5 mg	FILM-COATED TABLETS	5mg	TERAPIA S.A.	ROMANIA	16364	2025
65	DAPAGLIFLOZINUM	FIGOZAP 10 mg	FILM-COATED TABLETS	10mg	TERAPIA S.A.	ROMANIA	16365	2025

66	DES Loratadinum	DES Loratadin A STADA 5 mg	Film-coated Tablets		STADA Arzneimittel AG	GERMANY	16284	2025
67	DEXketoprofenum	DEKENOR 25 mg	Film-coated Tablets	25mg	KRKA, D.D., Novo Mesto	SLOVENIA	16302	2025
68	Drospirinonum	SLINDA 4 mg	Film-coated Tablets	4mg	EXELTIS Healthcare, S.L.	SPAIN	16316	2025
69	ESomeprazolum	ESomeprazol Rompharm 40 mg	Powder for solution for injection/infusion	40mg	ROMPHARM Company S.R.L.	ROMANIA	16276	2025
70	Finasteridum	Finasterida Sanexcel 5 mg	Film-coated Tablets	5mg	J.J.Bishop Health A.S.	THE CZECH REPUBLIC	16307	2025
71	Fingolimodum	Fingolimod MSN 0.5 mg	Capsules	0.5mg	MSN LABS EUROPE LIMITED	MALTA	16327	2025
72	Fingolimodum	Fingolimod Zentiva 0.5 mg	Capsules	0.5mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	16370	2025
73	Flurbiprofenum	OROFAR Intensiv 8.75 mg	Lozenges	8.75mg	STADA M&D SRL	ROMANIA	16310	2025
74	Flurbiprofenum	VOCAFLAM Portocale Fara Zahar 8.75 mg	Lozenges	8.75mg	MAPAEX Consumer Healthcare (Ireland) Private Limited	IRELAND	16326	2025
75	GEfitinibum	PHROMPO 250 mg	Film-coated Tablets	250mg	ALKALOID-INT D.O.O.	SLOVENIA	16366	2025

76	GERMANIUM (68GE) CHLORIDUM/GALLIUM (68GA) CHLORIDUM	GALLI AD 0.74 – 1.85 GBq	RADIONUCLIDE GENERATOR	0.74-1.85GBq	IRE-ELIT	BELGIUM	16255	2025
77	GRANISETRONUM	GRANISETRON STADA 1 mg	FILM-COATED TABLETS	1mg	STADA ARZNEIMITTEL AG	GERMANY	16322	2025
78	GRANISETRONUM	GRANISETRON STADA 2 mg	FILM-COATED TABLETS	2mg	STADA ARZNEIMITTEL AG	GERMANY	16323	2025
79	IBUPROFENUM	IBUPROFEN ZENTIVA 400 mg	FILM-COATED TABLETS	400mg	ZENTIVA K.S.	THE CZECH REPUBLIC	16294	2025
80	IBUPROFENUM	INFLANOR 400 mg	FILM-COATED TABLETS	400mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	16293	2025
81	IBUPROFENUM	IBUPROFEN STRIDES 200 mg	FILM-COATED TABLETS	200mg	STRIDES NORDIC APS	DENMARK	16303	2025
82	IBUPROFENUM	IBUPROFEN TERAPIA 400 mg	FILM-COATED TABLETS	400mg	TERAPIA S.A.	ROMANIA	16304	2025
83	IBUPROFENUM	IBUPROFEN STRIDES 600 mg	FILM-COATED TABLETS	600mg	STRIDES NORDIC APS	DENMARK	16305	2025
84	IMIPENEMUM+CILASTATINUM	IMIPENEM/CILAS TATIN NORIDEM 500 mg/500 mg	POWDER FOR SOLUTION FOR INFUSION	500mg/500mg	NORIDEM ENTERPRISES LIMITED	CYPRUS	16281	2025
85	IMIPENEMUM+CILASTATINUM	VELLIRONT 500 mg/500 mg	POWDER FOR SOLUTION FOR INFUSION	500mg/500mg	MEDOCHEMIE LIMITED	CYPRUS	16367	2025

86	IVACAFTORUM	IVACAFTOR SUN 150 mg	FILM-COATED TABLETS	150mg	SUN PHARMACEUTIC AL INDUSTRIES EUROPE B.V.	THE NETHERLANDS	16341	2025
87	KETOPROFENUM	KETOMAG 25 mg/g	GEL	25mg/g	MAGISTRA C&C S.R.L.	ROMANIA	16356	2025
88	LENVATINIBUM	LENTULIL 4 mg	CAPSULES	4mg	EGIS PARMACEUTICA LS PLC	HUNGARY	16335	2025
89	LENVATINIBUM	LENTULIL 10 mg	CAPSULES	10mg	EGIS PARMACEUTICA LS PLC	HUNGARY	16336	2025
90	LEVOFLOXACINUM	LEVOFLOXACIN NORIDEM 5 mg/ml	SOLUTION FOR INFUSION	5mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	16286	2025
91	LINEZOLIDUM	LINEZOLID DEMO 2 mg/ml	SOLUTION FOR INFUSION	2mg/ml	DEMO S.A. PHARMACEUTIC AL INDUSTRY	GREECE	16353	2025
92	LIRAGLUTIDUM	LIRAGLUTID CIPLA 6 mg/ml	SOLUTION FOR INJECTION IN PRE- FILLED PEN	6mg/ml	CIPLA EUROPE NV	BELGIUM	16340	2025
93	METAMIZOLUM NATRIUM	ALGOCALMIN 500 mg/ml	ORAL DROPS, SOLUTION	500mg/ml	ZENTIVA, K.S.	THE CZECH REPUBLIC	16301	2025
94	METFORMINUM	BROTMIN 500 mg	FILM-COATED TABLETS	500mg	MEDOCEMIE LTD.	CYPRUS	16350	2025
95	METFORMINUM	BROTMIN 850 mg	FILM-COATED TABLETS	850mg	MEDOCEMIE LTD.	CYPRUS	16351	2025

96	METFORMINUM	BROTMIN 1000 mg	FILM-COATED TABLETS	1000mg	MEDOCHEMIE LTD.	CYPRUS	16352	2025
97	ONDANSETRONUM	ONDANSETRON NORIDEM 2 mg/ml	SOLUTION FOR INJECTION	2mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	16363	2025
98	PACLITAXELUM	PACLITAXEL ALBUMINA DR. REDDY 5 mg/ml	POWDER FOR DISPERSION FOR INFUSION	5mg/ml	DR. REDDY'S LABORATORIES ROMANIA S.R.L	ROMANIA	16339	2025
99	PALIPERIDONUM	MOPETIA 50 mg	PROLONGED-RELEASE SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	50mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	16329	2025
100	PALIPERIDONUM	MOPETIA 75 mg	PROLONGED-RELEASE SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	75mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	16330	2025
101	PALIPERIDONUM	MOPETIA 100 mg	PROLONGED-RELEASE SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	100mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	16331	2025
102	PALIPERIDONUM	MOPETIA 150 mg	PROLONGED-RELEASE SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	150mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	16332	2025
103	PARACETAMOLUM	PARACETAMOL NORIDEM 10 mg/ml	SOLUTION FOR INFUSION	10mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	16342	2025

104	PARICALCITOLUM	PARICALCITOL HEATON 1 microgram	SOFT CAPSULES	1microgram	HEATON K.S.	THE CZECH REPUBLIC	16285	2025
105	PEMETREXEDUM	PEMETREXED EVER PHARMA 25 mg/ml	CONCENTRATE FOR SOLUTION FOR INFUSION	25mg/ml	EVER VALINJECT GMBH	AUSTRIA	16287	2025
106	PIPERACILLINUM + TAZOBACTAMUM	PIPERACILLIN/T AZOBACTAM NORIDEM 2 g/0.25 g	POWDER FOR SOLUTION FOR INFUSION	2g/0.25g	NORIDEM ENTERPRISES LIMITED	CYPRUS	16282	2025
107	PIPERACILLINUM + TAZOBACTAMUM	PIPERACILLIN/T AZOBACTAM NORIDEM 4 g/0.5 g	POWDER FOR SOLUTION FOR INFUSION	4g/0.5g	NORIDEM ENTERPRISES LIMITED	CYPRUS	16283	2025
108	PRASUGREL	ELISKARDIA 10 mg	FILM-COATED TABLETS	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16308	2025
109	PREDNISOLONUM	ULTRACORTENO L 5 mg/g	UNG. OFT.	5mg/g	AGEPHA PHARMA S.R.O.	SLOVAKIA	16268	2025
110	RIVAROXABANUM	RIVAROXABAN INDOCO 2.5 mg	FILM-COATED TABLETS	2.5mg	INDOCO REMEDIES CZECH S.R.O	THE CZECH REPUBLIC	16256	2025
111	RIVAROXABANUM	RIVAROXABAN INDOCO 10 mg	FILM-COATED TABLETS	10mg	INDOCO REMEDIES CZECH S.R.O	THE CZECH REPUBLIC	16257	2025
112	RIVAROXABANUM	RIVAROXABAN INDOCO 15 mg	FILM-COATED TABLETS	15mg	INDOCO REMEDIES CZECH S.R.O	THE CZECH REPUBLIC	16258	2025
113	RIVAROXABANUM	RIVAROXABAN INDOCO 20 mg	FILM-COATED TABLETS	20mg	INDOCO REMEDIES CZECH S.R.O	THE CZECH REPUBLIC	16259	2025

114	RIVAROXABANUM	RIVAROXABAN INDOCO 15 mg+20 mg (INITIAL TREATMENT)	FILM-COATED TABLETS	15mg+20mg	INDOCO REMEDIES CZECH S.R.O	THE CZECH REPUBLIC	16260	2025
115	RIVAROXABANUM	RIVAROXABAN TEVA 2.5 mg	FILM-COATED TABLETS	2.5mg	TEVA GMBH	GERMANY	16261	2025
116	RIVAROXABANUM	RIVAROXABAN TEVA 10 mg	FILM-COATED TABLETS	10mg	TEVA GMBH	GERMANY	16262	2025
117	RIVAROXABANUM	RIVAROXABAN TEVA 15 mg	FILM-COATED TABLETS	15mg	TEVA GMBH	GERMANY	16263	2025
118	RIVAROXABANUM	RIVAROXABAN TEVA 20 mg	FILM-COATED TABLETS	20mg	TEVA GMBH	GERMANY	16264	2025
119	RIVAROXABANUM	RIVAROXABAN PHARMAZAC 2,5 mg	FILM-COATED TABLETS	2,5mg	PHARMAZAC S.A.	GREECE	16346	2025
120	RIVAROXABANUM	RIVAROXABAN PHARMAZAC 10 mg	FILM-COATED TABLETS	10mg	PHARMAZAC S.A.	GREECE	16347	2025
121	RIVAROXABANUM	RIVAROXABAN PHARMAZAC 15 mg	FILM-COATED TABLETS	15mg	PHARMAZAC S.A.	GREECE	16348	2025
122	RIVAROXABANUM	RIVAROXABAN PHARMAZAC 20 mg	FILM-COATED TABLETS	20mg	PHARMAZAC S.A.	GREECE	16349	2025
123	ROPINIROLUM	ROPINIROL SANEXCEL 2 mg	PROLONGED- RELEASE TABLETS	2mg	J.J. BISHOP HEALTH A.S.	THE CZECH REPUBLIC	16343	2025
124	ROPINIROLUM	ROPINIROL SANEXCEL 4 mg	PROLONGED- RELEASE TABLETS	4mg	J.J. BISHOP HEALTH A.S.	THE CZECH REPUBLIC	16344	2025
125	ROPINIROLUM	ROPINIROL SANEXCEL 8 mg	PROLONGED- RELEASE TABLETS	8mg	J.J. BISHOP HEALTH A.S.	THE CZECH REPUBLIC	16345	2025

126	SUGAMMADEXUM	SUGAMMADEX ROMPHARM 100 mg/ml	SOLUTION FOR INJECTION	100mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	16288	2025
127	SUGAMMADEXUM	SUGAMMADEX SANDOZ 100 mg/ml	SOLUTION FOR INJECTION	100mg/ml	SANDOZ PHARMACEUTIC ALS S.R.L.	ROMANIA	16362	2025
128	SULFAMETHOXAZOLUM + TRIMETHOPRIMUM	DUBLUSEPTOL 120 mg	TABLETS	100mg+20mg	APC INSTYTUT SP. Z O.O.	POLAND	16296	2025
129	TERBINAFINUM	EXOTERFYN 78.22 mg/ml	MEDICATED NAIL POLISH	78.22mg/ml	SANDOZ PHARMACEUTIC ALS S.R.L.	ROMANIA	16306	2025
130	THIAMINUM	VITAMINA B1 KABI 50 mg/ml	SOLUTION FOR INJECTION/INFUSION	50mg/ml	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	16386	2025
131	TICAGRELOR	IGZELYM 60 mg	FILM-COATED TABLETS	60mg	VIATRIS LIMITED	IRELAND	16289	2025
132	TICAGRELOR	IGZELYM 90 mg	FILM-COATED TABLETS	90mg	VIATRIS LIMITED	IRELAND	16290	2025
133	VANCOMYCINUM	VANCOMICINA ROMPHARM 1000 mg	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	1000mg	ROMPHARM COMPANY S.R.L.	ROMANIA	16311	2025
134	VINORELBINUM	VINORELBINA LABORMED 20 mg	SOFT CAPSULES	20mg	LABORMED PHARMA S.A.	ROMANIA	16378	2025
135	VINORELBINUM	VINORELBINA LABORMED 30 mg	SOFT CAPSULES	30mg	LABORMED PHARMA S.A.	ROMANIA	16379	2025
136	VINORELBINUM	VINORELBINA LABORMED 80 mg	SOFT CAPSULES	80mg	LABORMED PHARMA S.A.	ROMANIA	16380	2025
137	VORICONAZOLUM	VORICONAZOL SANEXCEL 200 mg	POWDER FOR SOLUTION FOR INFUSION	200mg	J.J. BISHOP HEALTH A.S.	THE CZECH REPUBLIC	16337	2025

EMA centrally authorised medicinal products notified for marketing in Romania during the 4th quarter of 2025

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	CLASCOTERONUM	WINLEVI 10 mg/g	CREAM	10mg/g	CASSIOPEA S.P.A.	ITALY	1927	2025
2	DENOSUMABUM	KEFDENSIS 60 mg	SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	60mg/ml	STADA ARZNEIMITTEL AG	GERMANY	1980	2025
3	DENOSUMABUM	ZVOGRA 120 mg	SOLUTION FOR INJECTION	70mg/ml	STADA ARZNEIMITTEL AG	GERMANY	1981	2025
4	RANIBIZUMABUM	RANLUSPEC	SOLUTION FOR INJECTION	10mg/ml	LUPIN EUROPE GMBH	GERMANY	2012	2025
5	RANIBIZUMABUM	RANLUSPEC	SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	10mg/ml	LUPIN EUROPE GMBH	GERMANY	2012	2025
6	RILZABRUTINIBUM	WAYRILZ 400 mg	FILM-COATED TABLETS	400mg	SANOFI B.V.	THE NETHERLANDS	1974	2025
7	USTEKINUMABUM	USYMRO 45 mg	SOLUTION FOR INJECTION	45mg/0.5ml	GEDEON RICHTER PLC.	HUNGARY	1058	2025

8	USTEKINUMABUM	USYMRO 45 mg	SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	45mg/0.5ml	GEDEON RICHTER PLC.	HUNGARY	1058	2025
9	USTEKINUMABUM	USYMRO 90 mg/ml	SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	90mg/ml	GEDEON RICHTER PLC.	HUNGARY	1058	2025
10	USTEKINUMABUM	USYMRO 130 mg	CONCENTRATE FOR SOLUTION FOR INFUSION	130mg	GEDEON RICHTER PLC.	HUNGARY	1058	2025