

ROMANIA

Newsletter

Year 28, No. 2 (110), 2nd 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) 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

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h) Public documents and NAMMDR managed/generated documents

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Laws

Law 159, published on 22 April 2026, on amendment and supplementation of Law 95/2006 on healthcare reform;

Law 61, published on 3 May 2026, on amendment and supplementation of Law 95/2006 on healthcare reform.

Government decisions

Government Decision no. 121, published on 1 April 2026, on amendment and supplementation of the Annex to Government Decision no. 720/2008 on approval of the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs

Orders

Order no. 901, published on 2 April 2026, on amendment and supplementation of Annex 1;

Order no. 993, published on 16 April 2026, on amendment and supplementation of Annex 1;

Order no. 940 and Order no. 698, published on 7 April 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. 999 and Order no. 726, published on 14 April 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. 820 and Order no. 40, published on 12 May 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. 1076 and Order no. 789, published on 30 April 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. 1156, published on 4 May 2026, on amendment and supplementation of Annex 1;

Order no. 1089, published on 7 May 2026, on amendment and supplementation of the Annex to Order of the Minister of Health no. 1.584/2023.

Order no. 193, published on 25 May 2026, on amendment and supplementation of Annex 1;

Order no. 196, published on 25 May 2026, on supplementation of the Annex to Order of the Minister of Health no. 607/2019.

Order no. 873, published on 26 May 2026, on amendment of Annex 1 to Order of the President of the National Health Insurance House no. 141/2017;

Order no. 239, published on 1 June 2026, on amendment and supplementation of Annex 1;

Order no. 363, published on 12 June 2026, on amendment and supplementation of Annex 1;

Order no. 960 and Order no. 362, published on 12 June 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. 373, published on 16 June 2026, on amendment and supplementation of Annex 1.

Order no. 1005, published on 26 June 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 2nd 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	Gripoff, granules for oral solution in sachets	Granules for oral solution	500mg/200mg / 4mg	Paracetamolum+ Acidum ascorbicum+ Chlorphenaminum	S.C. Slavia Pharm S.R.L., Romania	230943/ exp. 06.2025	Out-of-specification outcomes	Withdrawal upon NAMMDR request	07.04.2025
2	Onglyza 5 mg, film-coated tablets	Film-coated tablets	5 mg	Saxagliptinum	AstraZeneca AB, Sweden		Expiry of the validity of the maximum price in the National Catalogue of the Prices of Medicinal Products Authorised for Marketing in Romania (also known as the CANAMED).	Voluntary withdrawal	28.05.2025

Applications for marketing authorisation/marketing authorisation renewal received during the 1st quarter of 2026

5 marketing authorisation applications for medicinal products have been received during the 1st quarter of 2026, corresponding to the following therapeutic groups:

AUTHORISATION
B01 - ANTITHROMBOTIC AGENTS
M02 - TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN
N03 - ANTIEPILEPTICS
V03 - ALL OTHER THERAPEUTIC PRODUCTS
J02 – ANTIMYCOTICS FOR SYSTEMIC USE

No marketing authorisation renewal applications for medicinal products have been received during the 1st quarter of 2026.

Medicinal products authorised for marketing during the 1st quarter of 2026

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	ABIRATERONUM	ABIRATERONA PHARMAZAC 250 mg	TABLETS	250mg	PHARMAZAC S.A.	GREECE	16451	2026
2	ABIRATERONUM	ABIRATERONA PHARMAZAC 500 mg	FILM-COATED TABLETS	500mg	PHARMAZAC S.A.	GREECE	16452	2026
3	ABIRATERONUM	ABIRATERONA LANNACHER 250 mg	TABLETS	250mg	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	16441	2026
4	ABIRATERONUM	ABIRATERONA LANNACHER 500 mg	FILM-COATED TABLETS	500mg	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	16442	2026
5	ABIRATERONUM	ABIRATERONA ZENTIVA 250 mg	TABLETS	250mg	ZENTIVA K.S.	THE CZECH REPUBLIC	16396	2026
6	ABIRATERONUM	ABIRATERONA ZENTIVA 500 mg	FILM-COATED TABLETS	500mg	ZENTIVA K.S.	THE CZECH REPUBLIC	16397	2026

7	ABIRATERONUM	BIXODALAN 250 mg	FILM-COATED TABLETS	250mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16460	2026
8	ABIRATERONUM	BIXODALAN 500 mg	FILM-COATED TABLETS	500mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16461	2026
9	ABIRATERONUM	BIXODALAN 1000 mg	FILM-COATED TABLETS	1000mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16410	2026
10	ABIRATERONUM	TATICA 500 mg	FILM-COATED TABLETS	500mg	EGIS PHARMACEUTICA LS PLC	HUNGARY	16427	2026
11	ABIRATERONUM	ABIRATERONA DR. REDDY'S 500 mg	FILM-COATED TABLETS	500mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	16536	2026

12	ACIDUM ACETYLSALICYLICUM	ASPENTER ACUT 300 mg	POWDER AND SOLVENT FOR ORAL SOLUTION	300mg	TERAPIA S.A.	ROMANIA	16514	2026
13	ACIDUM ASCORBICUM	VITAMIN C - RICHTER 500 mg	FILM-COATED TABLETS	500mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	16415	2026
14	ACIDUM TRANEXAMICUM	NIMRA 1000 mg	COATED GRANULES IN SACHET	1000mg	CEMAG CARE	FRANCE	16422	2026
15	ALLOPURINOLUM	ALOPURINOL STADA 100 mg	TABLETS	100mg	STADA ARZNEIMITTEL AG	GERMANY	16523	2026
16	ALLOPURINOLUM	ALOPURINOL STADA 200 mg	TABLETS	200mg	STADA ARZNEIMITTEL AG	GERMANY	16524	2026
17	ALLOPURINOLUM	ALOPURINOL STADA 300 mg	TABLETS	300mg	STADA ARZNEIMITTEL AG	GERMANY	16525	2026
18	ALPROSTADILUM	NEUPEDIX 500 micrograms	CONCENTRATE FOR SOLUTION FOR INFUSION	500micrograms	ORESUND PHARMA APS	DENMARK	16395	2026

19	AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOKSIKLAV 600 mg/42.9 mg/5 ml	POWDER FOR ORAL SUSPENSION	600mg/42.9mg/ 5ml	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16490	2026
20	BOTULINUM ANTITOXIN	BOTULINUM ANTITOXIN ABE	SOLUTION FOR INJECTION	500 IU+500 IU+100 IU/ml	CN UNIFARM S.A.	ROMANIA	19	2026
21	APIXABANUM	ABATIXENT 2.5 mg	FILM-COATED TABLETS	2.5mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16519	2026
22	APIXABANUM	ABATIXENT 5 mg	FILM-COATED TABLETS	5mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16520	2026
23	APIXABANUM	LYXARO 2.5 mg	FILM-COATED TABLETS	2.5mg	ANTIBIOTICE S.A.	ROMANIA	16432	2026
24	APIXABANUM	LYXARO 5 mg	FILM-COATED TABLETS	5mg	ANTIBIOTICE S.A.	ROMANIA	16433	2026
25	APIXABANUM	APIXABAN TOWA PHARMACEUTICAL EUROPE 2.5 mg	FILM-COATED TABLETS	2.5mg	TOWA PHARMACEUTICA L EUROPE, S.L.	SPAIN	16437	2026

26	APIXABANUM	APIXABAN TOWA PHARMACEUTICAL EUROPE 5 mg	FILM-COATED TABLETS	5mg	TOWA PHARMACEUTICA L EUROPE, S.L.	SPAIN	16438	2026
27	APIXABANUM	APIXABAN BIOEEL 2.5 mg	FILM-COATED TABLETS	2.5mg	BIOEEL MANUFACTURIN G S.R.L.	ROMANIA	16449	2026
28	APIXABANUM	APIXABAN BIOEEL 5 mg	FILM-COATED TABLETS	5mg	BIOEEL MANUFACTURIN G S.R.L.	ROMANIA	16450	2026
29	APIXABANUM	APIXABAN SLAVIA 2.5 mg	FILM-COATED TABLETS	2.5mg	SLAVIA PHARM S.R.L.	ROMANIA	16491	2026
30	APIXABANUM	APIXABAN SLAVIA 5 mg	FILM-COATED TABLETS	5mg	SLAVIA PHARM S.R.L.	ROMANIA	16492	2026
31	APIXABANUM	BANXIOI 2.5 mg	FILM-COATED TABLETS	2.5mg	VIATRIS LIMITED	IRELAND	16541	2026
32	APIXABANUM	BANXIOI 5 mg	FILM-COATED TABLETS	5mg	VIATRIS LIMITED	IRELAND	16542	2026

33	ARIPIPAZOLUM	ARIPIPAZOL STADA 300 mg	PROLONGED- RELEASE POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	300mg	STADA ARZNEIMITTEL AG	GERMANY	16462	2026
34	ARIPIPAZOLUM	ARIPIPAZOL STADA 400 mg	PROLONGED- RELEASE POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	400mg	STADA ARZNEIMITTEL AG	GERMANY	16463	2026
35	ARSENICUM TRIOXIDUM	TRIOXID DE ARSEN TILLOMED 2 mg/ml	CONCENTRATE FOR SOLUTION FOR INFUSION	2mg/ml	TILLOMED MALTA LIMITED	MALTA	16394	2026
36	AZACITIDINUM	VIDACULEM 25 mg/ml	POWDER FOR SUSPENSION FOR INJECTION	25mg/ml	BIOEEL MANUFACTURIN G SRL	ROMANIA	16513	2026
37	BOSENTANUM	BOSENTAN ACCORD 125 mg	FILM-COATED TABLETS	125mg	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	16484	2026
38	BRIVARACETAMUM	CLIZAY 25 mg	FILM-COATED TABLETS	25mg	MSN LABS EUROPE LIMITED	MALTA	16507	2026

39	BRIVARACETAMUM	CLIZAY 50 mg	FILM-COATED TABLETS	50mg	MSN LABS EUROPE LIMITED	MALTA	16508	2026
40	BRIVARACETAMUM	CLIZAY 100 mg	FILM-COATED TABLETS	100mg	MSN LABS EUROPE LIMITED	MALTA	16509	2026
41	BUTAMIRATUM	STOPTUSSIN 1.5 mg/ml	SYRUP	1.5mg/ml	TEVA B.V.	THE NETHERLANDS	16403	2026
42	CABAZITAXELUM	ELEBER 60 mg	CONCENTRATE AND SOLVENT FOR SOLUTION FOR INFUSION	60 mg	ZENTIVA K.S.	THE CZECH REPUBLIC	16398	2026
43	CEFTRIAXONUM	CEFTRIAXONA APTAPHARMA 1 g	POWDER FOR SOLUTION FOR INJECTION/ INFUSION	1g	APTA MEDICA INTERNACIONAL D.O.O.	SLOVENIA	16510	2026
44	CEFTRIAXONUM	CEFTRIAXONA APTAPHARMA 2 g	POWDER FOR SOLUTION FOR INJECTION/ INFUSION	2g	APTA MEDICA INTERNACIONAL D.O.O.	SLOVENIA	16511	2026
45	CINACALCETUM	CINACALCET DEVATIS 30 mg	FILM-COATED TABLETS	30mg	CN UNIFARM S.A.	ROMANIA	18	2026
46	CINACALCETUM	CINACALCET STADA 90 mg	FILM-COATED TABLETS	90mg	STADA M&D S.R.L.	ROMANIA	22	2026
47	CINACALCETUM	CINACALCET EG 60 mg	FILM-COATED TABLETS	60mg	STADA M&D S.R.L.	ROMANIA	21	2026

48	CISATRACURIUM	CISATRACURIUM NORIDEM 2 mg/ml	SOLUTION FOR INJECTION/ INFUSION	2mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	16522	2026
49	CLINDAMYCINUM	CLINDAMICINA HAMELN 150 mg/ml	SOLUTION FOR INJECTION/ INFUSION	150mg/ml	HAMELN PHARMA GMBH	GERMANY	16402	2026
50	COMBINATIONS (DUTASTERIDUM+ TAMSULOSINUM)	TWINPROS 0.5 mg/0.4 mg	CAPSULES	0,5mg/0,4mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16478	2026
51	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	EZETIMIB/ATORVAS TATINA ALTHERA LABORATORIES 10 mg/10 mg	FILM-COATED TABLETS	10mg/10mg	ALTHERA LABORATORIES LIMITED	IRELAND	16470	2026
52	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	EZETIMIB/ATORVAS TATINA ALTHERA LABORATORIES 10 mg/20 mg	FILM-COATED TABLETS	10mg/20mg	ALTHERA LABORATORIES LIMITED	IRELAND	16471	2026

53	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	EZETIMIB/ATORVAS TATINA ALTHERA LABORATORIES 10 mg/40 mg	FILM-COATED TABLETS	10mg/40mg	ALTHERA LABORATORIES LIMITED	IRELAND	16472	2026
54	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	EZETIMIB/ATORVAS TATINA ALTHERA LABORATORIES 10 mg/80 mg	FILM-COATED TABLETS	10mg/80mg	ALTHERA LABORATORIES LIMITED	IRELAND	16473	2026
55	COMBINATIONS (PARACETAMOLUM+ CAFEINUM)	FERVEX DURERE SI FEBRA EXTRA 500 mg/65 mg	TABLETS	500mg/65mg	UPSA SAS	FRANCE	16428	2026
56	COMBINATIONS (PARACETAMOLUM+ IBUPROFENUM)	ADVIL DUO 500 mg/200 mg	FILM-COATED TABLETS	200mg/500mg	HALEON ROMANIA S.R.L.	ROMANIA	16535	2026
57	COMBINATIONS (PARACETAMOLUM+ IBUPROFENUM)	COMBOGESIC 500 mg/150 mg	POWDER FOR ORAL SOLUTION IN SACHET	500mg/150mg	MEDOCHEMIE LTD.	CYPRUS	16392	2026
58	COMBINATIONS (PARACETAMOLUM+ IBUPROFENUM)	COMBOGESIC 1000 mg/300 mg	POWDER FOR ORAL SOLUTION IN SACHET	1000mg/300mg	MEDOCHEMIE LTD.	CYPRUS	16393	2026

59	COMBINATIONS (PARACETAMOLUM+ PROPYPHENAZONUM+ CAFEINUM	SINDOLOR	TABLETS	250mg/150mg/ 50mg	FITERMAN PHARMA S.R.L.	ROMANIA	16458	2026
60	COMBINATIONS (PITAVASTATINUM+ EZETIMIBUM)	CO-PITIPIX 2 mg/10 mg	TABLETS	2mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16429	2026
61	COMBINATIONS (PITAVASTATINUM+ EZETIMIBUM)	CO-PITIPIX 4 mg/10 mg	TABLETS	4mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16430	2026
62	COMBINATIONS (RAMIPRILUM+ INDAPAMIDUM)	RAMIKOMB 5 mg/1.5 mg	MODIFIED- RELEASE CAPSULES	5mg/1.5mg	EGIS PHARMACEUTICA LS PLC	HUNGARY	16474	2026
63	COMBINATIONS (RAMIPRILUM+ INDAPAMIDUM)	RAMIKOMB 10 mg/1.5 mg	MODIFIED- RELEASE CAPSULES	10mg/1.5mg	EGIS PHARMACEUTICA LS PLC	HUNGARY	16475	2026
64	COMBINATIONS (SACUBITRILUM+ VALSARTANUM)	ALBALIVA 24 mg/26 mg	FILM-COATED TABLETS	24mg/26mg	EGIS PHARMACEUTICA LS PLC.	HUNGARY	16423	2026

65	COMBINATIONS (SACUBITRILUM+ VALSARTANUM)	ALBALIVA 49 mg/ 51 mg	FILM-COATED TABLETS	49mg/51mg	EGIS PHARMACEUTICA LS PLC.	HUNGARY	16424	2026
66	COMBINATIONS (SACUBITRILUM+ VALSARTANUM)	ALBALIVA 97 mg/ 103 mg	FILM-COATED TABLETS	97mg/103mg	EGIS PHARMACEUTICA LS PLC.	HUNGARY	16425	2026
67	COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	MAYMETSI 50 mg/ 850 mg	FILM-COATED TABLETS	50mg/850mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16495	2026
68	COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	MAYMETSI 50 mg/1000 mg	FILM-COATED TABLETS	50mg/1000mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16496	2026
69	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILAT SANEXCEL 75 mg	CAPSULES	75mg	J.J. BISHOP HEALTH A.S.	THE CZECH REPUBLIC	16502	2026
70	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILAT SANEXCEL 110 mg	CAPSULES	110mg	J.J. BISHOP HEALTH A.S.	THE CZECH REPUBLIC	16503	2026
71	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILAT SANEXCEL 150 mg	CAPSULES	150mg	J.J. BISHOP HEALTH A.S.	THE CZECH REPUBLIC	16504	2026

72	DAPAGLIFLOZINUM	DAPAGLIFLOZIN DR. REDDY'S 5 mg	FILM-COATED TABLETS	5mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	16505	2026
73	DAPAGLIFLOZINUM	DAPAGLIFLOZIN DR. REDDY'S 10 mg	FILM-COATED TABLETS	10mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	16506	2026
74	DAPAGLIFLOZINUM	DAPLEMSSEN 5 mg	FILM-COATED TABLETS	5mg	MSN LABS EUROPE LIMITED	MALTA	16531	2026
75	DAPAGLIFLOZINUM	DAPLEMSSEN 10 mg	FILM-COATED TABLETS	10mg	MSN LABS EUROPE LIMITED	MALTA	16532	2026
76	DEFERASIROXUM	ZEOKS 180 mg	FILM-COATED TABLETS	180mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	16529	2026
77	DEFERASIROXUM	ZEOKS 360 mg	FILM-COATED TABLETS	360mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	16530	2026
78	DEXAMETHASONUM	DEXAMETAZONA FOSFAT HAMELN 4 mg/ml	SOLUTION FOR INJECTION	4mg/ml	HAMELN PHARMA GMBH	GERMANY	16420	2026

79	DIGOXINUM	DIGOXIN ENEO 0.05 mg/ml	ORAL SOLUTION	0.05mg/ml	ENEO PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	16426	2026
80	MISCELLANEA	WATER FOR INJECTIONS/ NORIDEM	SOLVENT FOR PARENTERAL PREPARATION		NORIDEM ENTERPRISES LIMITED	CYPRUS	16413	2026
81	ENZALUTAMIDUM	ENZALUTAMIDA SANDOZ PHARMACEUTICALS 160 mg	FILM-COATED TABLETS	160mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	16479	2026
82	ENZALUTAMIDUM	ENZALUTAMIDA TEVA 40 mg	FILM-COATED TABLETS	40mg	TEVA GMBH	GERMANY	16533	2026
83	ENZALUTAMIDUM	ENZALUTAMIDA TEVA 80 mg	FILM-COATED TABLETS	80mg	TEVA GMBH	GERMANY	16534	2026
84	ETOFENAMATUM	ETOFENAMAT GREENCANGO 100 mg/g	GEL	100mg/g	GREENCANGO KFT.	HUNGARY	16391	2026
85	EVEROLIMUS	SYRLENO 2.5 mg	TABLETS	2.5mg	ALKALOID - INT D.O.O.	SLOVENIA	16516	2026
86	EVEROLIMUS	SYRLENO 5 mg	TABLETS	5mg	ALKALOID - INT D.O.O.	SLOVENIA	16517	2026

87	EVEROLIMUS	SYRLENO 10 mg	TABLETS	10mg	ALKALOID - INT D.O.O.	SLOVENIA	16518	2026
88	STANDARDIZED PREPARATIONS DERIVED FROM HOUSE DUST MITES	ACTAIR 100 IR	SUBLINGUAL TABLETS	100IR	STALLERGENES	FRANCE	16526	2026
89	STANDARDIZED PREPARATIONS DERIVED FROM HOUSE DUST MITES	ACTAIR 100 IR AND 300 IR	SUBLINGUAL TABLETS	100IR&300IR	STALLERGENES	FRANCE	16527	2026
90	STANDARDIZED PREPARATIONS DERIVED FROM HOUSE DUST MITES	ACTAIR 300 IR	SUBLINGUAL TABLETS	300IR	STALLERGENES	FRANCE	16528	2026
91	FENTANYLUM	TABFYL 100 micrograms	SUBLINGUAL TABLETS	100micrograms	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16404	2026
92	FENTANYLUM	TABFYL 200 micrograms	SUBLINGUAL TABLETS	200micrograms	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16405	2026

93	FENTANYLUM	TABFYL 300 micrograms	SUBLINGUAL TABLETS	300micrograms	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16406	2026
94	FENTANYLUM	TABFYL 400 micrograms	SUBLINGUAL TABLETS	400micrograms	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16407	2026
95	FENTANYLUM	TABFYL 600 micrograms	SUBLINGUAL TABLETS	600micrograms	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16408	2026
96	FENTANYLUM	TABFYL 800 micrograms	SUBLINGUAL TABLETS	800micrograms	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16409	2026
97	FLURBIPROFENUM	RELINEX 8.75 mg	LOZENGES	8.75mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	16489	2026
98	FUROSEMIDUM	FUROSEMID GEMAX PHARMA 40 mg	TABLETS	40mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	16499	2026
99	HOMEOPATHIC PRODUCTS	STORINYL	SYRUP		BOIRON	FRANCE	16434	2026
100	HOMEOPATHIC PRODUCTS	SLEEP CALM	SYRUP		BOIRON	FRANCE	16547	2026
101	IBUPROFENUM	IBUCALMIN 200 mg	FILM-COATED TABLETS	200mg	LAROPHARM S.R.L.	ROMANIA	16436	2026

102	ICODEXTRINUM	NOTECOR	PERITONEAL DIALYSIS SOLUTION		NORIDEM ENTERPRISES LIMITED	CYPRUS	16485	2026
103	INOSINUM	ISOPRINOSINE EWOPHARMA 1 g	GRANULES FOR ORAL SOLUTION IN SACHET	1g	EWOPHARMA INTERNATIONAL, S.R.O.	SLOVAKIA	16414	2026
104	KALII CHLORIDUM	CLORURA DE POTASIU NORIDEM 150 mg/ml	CONCENTRATE FOR SOLUTION FOR INFUSION	150mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	16501	2026
105	LANREOTIDUM	MYTOLAC 60 mg	SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	60mg	AMDIPHARM LIMITED	IRELAND	16486	2026
106	LANREOTIDUM	MYTOLAC 90 mg	SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	90mg	AMDIPHARM LIMITED	IRELAND	16487	2026
107	LANREOTIDUM	MYTOLAC 120 mg	SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	120mg	AMDIPHARM LIMITED	IRELAND	16488	2026
108	LEVOMEPRMAZINUM	LEVOMEPRMAZIN ASPIRE 25 mg	TABLETS	25mg	ASPIRE PHARMA (MALTA) LIMITED	MALTA	16543	2026

109	LEVOMEPROMAZINUM	LEVOMEPROMAZIN ASPIRE 100 mg	TABLETS	100mg	ASPIRE PHARMA (MALTA) LIMITED	MALTA	16544	2026
110	LIRAGLUTIDUM	EJULIR 6 mg/ml	SOLUTION FOR INJECTION IN PRE-FILLED PEN	6mg/ml	VIATRIS LIMITED	IRELAND	16469	2026
111	MACITENTANUM	MACITENTAN VIATRIS 10 mg	FILM-COATED TABLETS	10mg	VIATRIS LIMITED	IRELAND	16512	2026
112	MEMANTINUM	MEMANTINA GRINDEKS 10 mg	FILM-COATED TABLETS	10mg	AS GRINDEKS	LATVIA	16464	2026
113	MENOTROPINUM	MENOPUR 600 IU	SOLUTION FOR INJECTION IN PRE-FILLED PEN	600 IU	FERRING GMBH	GERMANY	16439	2026
114	MENOTROPINUM	MENOPUR 1200 IU	SOLUTION FOR INJECTION IN PRE-FILLED PEN	1200 IU	FERRING GMBH	GERMANY	16440	2026
115	MERCAPTOPURINUM	MERCAPTOPURINA ACCORD 50 mg	TABLETS	50mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	16400	2026

116	MEROPENEMUM	MEROPENEM NORIDEM 500 mg	POWDER FOR SOLUTION FOR INJECTION/INF USION	500mg	NORIDEM ENTERPRISES LIMITED	CYPRUS	16411	2026
117	MEROPENEMUM	MEROPENEM NORIDEM 1 g	POWDER FOR SOLUTION FOR INJECTION/INF USION	1g	NORIDEM ENTERPRISES LIMITED	CYPRUS	16412	2026
118	METHYLFENIDATUM	METHYLPHENIDATE HYDROCHLORIDE G.L. PHARMA 18 mg	PROLONGED- RELEASE TABLETS	18mg	G.L. PHARMA GMBH	AUSTRIA	16465	2026
119	METHYLFENIDATUM	METHYLPHENIDATE HYDROCHLORIDE G.L. PHARMA 27 mg	PROLONGED- RELEASE TABLETS	27mg	G.L. PHARMA GMBH	AUSTRIA	16466	2026
120	METHYLFENIDATUM	METHYLPHENIDATE HYDROCHLORIDE G.L. PHARMA 36 mg	PROLONGED- RELEASE TABLETS	36mg	G.L. PHARMA GMBH	AUSTRIA	16467	2026
121	METHYLFENIDATUM	METHYLPHENIDATE HYDROCHLORIDE G.L. PHARMA 54 mg	PROLONGED- RELEASE TABLETS	54mg	G.L. PHARMA GMBH	AUSTRIA	16468	2026
122	METOPROLOLUM	METOPROLOL GEMAX PHARMA 50 mg	FILM-COATED TABLETS	50mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	16481	2026
123	METOPROLOLUM	METOPROLOL GEMAX PHARMA 100 mg	FILM-COATED TABLETS	100mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	16482	2026

124	MIDAZOLAMUM	MIDAZOLAM HAMELN 1 mg/ml	SOLUTION FOR INJECTION/ INFUSION	1mg/ml	HAMELN PHARMA GMBH	GERMANY	16538	2026
125	MIDAZOLAMUM	MIDAZOLAM HAMELN 2 mg/ml	SOLUTION FOR INJECTION/ INFUSION	2mg/ml	HAMELN PHARMA GMBH	GERMANY	16539	2026
126	MIDAZOLAMUM	MIDAZOLAM HAMELN 5 mg/ml	SOLUTION FOR INJECTION/ INFUSION	5mg/ml	HAMELN PHARMA GMBH	GERMANY	16540	2026
127	NATRII CHLORIDUM	SODIUM CHLORIDE NORIDEM 9 mg/ml	SOLUTION FOR INJECTION	9mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	16483	2026
128	NORADRENALINUM	NORADRENALINA AMDIPHARM 1 mg/ml	CONCENTRATE FOR SOLUTION FOR INFUSION	1mg/ml	AMDIPHARM LIMITED	IRELAND	16521	2026
129	NORADRENALINUM	MYKRONOR 10 micrograms/ml	SOLUTION FOR INJECTION/ INFUSION	10micrograms/ ml	LABORATOIRE AGUETTANT	FRANCE	16497	2026
130	OXALIPLATINUM	OXALIPLATINA AQVIDA 5 mg/ml	CONCENTRATE FOR SOLUTION FOR INFUSION	5mg/ml	AQVIDA GMBH	GERMANY	16545	2026
131	PARACETAMOLUM	PANADOL JUNIOR 48 mg/ml	ORAL SUSPENSION	48mg/ml	HALEON ROMANIA S.R.L.	ROMANIA	16546	2026
132	PARECOXIBUM	PARECOXIB NORIDEM 40 mg	POWDER FOR SOLUTION FOR INJECTION	40mg	NORIDEM ENTERPRISES LIMITED	CYPRUS	16515	2026

133	PAZOPANIBUM	PAZOPANIB FRONTIER 200 mg	FILM-COATED TABLETS	200mg	FRONTIER BIOPHARMA SP. Z.O.O.	POLAND	16456	2026
134	PAZOPANIBUM	PAZOPANIB FRONTIER 400 mg	FILM-COATED TABLETS	400mg	FRONTIER BIOPHARMA SP. Z.O.O.	POLAND	16457	2026
135	PEMETREXEDUM	PEMETREXED PHARMA D&S 100 mg	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	100mg	PHARMACEUTICA L DEVELOPMENT AND SERVICES S.R.L.	ITALY	16476	2026
136	PEMETREXEDUM	PEMETREXED PHARMA D&S 500 mg	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	500mg	PHARMACEUTICA L DEVELOPMENT AND SERVICES S.R.L.	ITALY	16477	2026
137	PLANTS (ARCTOSTAPHYLOS UVA-URSI)	CYSTINOL 265 mg	DRAGEES	265mg	SCHAPER&BRÜM MER GMBH & CO. KG	GERMANY	16435	2026
138	PLANTS (CIMICIFUGA EXTRACT)	KLIMADYNON 2.8 mg	FILM-COATED TABLETS	2.8mg	BIONORICA SE	GERMANY	16431	2026
139	PLANTS (EXTRACT USCAT DIN RADACINA DE REVENT)	FEMILOGES 4 mg	GASTRORESIST ANT TABLETS	4mg	DR. LOGES + CO. GMBH	GERMANY	16537	2026
140	PLANTS (MALLOW+TILIA+ PLANTEN)	BRONCHOSTOP TRIO FOR COUGH AND COLD	ORAL SOLUTION		KWIZDA PHARMA GMBH	AUSTRIA	16419	2026

141	NITROUS OXIDE + OXYGEN	SERYNOX 50% / 50%	COMPRESSED MEDICINAL GAS	50%/50%	MESSER ROMANIA GAZ S.R.L.	ROMANIA	16480	2026
142	ROPIVACAINUM	ROPIVACAINA INFOMED 2 mg/ml	SOLUTION FOR INFUSION	2mg/ml	INFOMED FLUIDS S.R.L.	ROMANIA	16421	2026
143	ROSUVASTATINUM	TERSAL 5 mg	CAPSULES	5mg	SUN PHARMACEUTICA L INDUSTRIES EUROPE B.V.	THE NETHERLANDS	16443	2026
144	ROSUVASTATINUM	TERSAL 10 mg	CAPSULES	10mg	SUN PHARMACEUTICA L INDUSTRIES EUROPE B.V.	THE NETHERLANDS	16444	2026
145	ROSUVASTATINUM	TERSAL 20 mg	CAPSULES	20mg	SUN PHARMACEUTICA L INDUSTRIES EUROPE B.V.	THE NETHERLANDS	16445	2026
146	ROSUVASTATINUM	TERSAL 40 mg	CAPSULES	40mg	SUN PHARMACEUTICA L INDUSTRIES EUROPE B.V.	THE NETHERLANDS	16446	2026
147	SER ANTIVIPERINIC (TRIVALENT)	VIPERFAV	SOLUTION FOR DILUTION FOR INFUSION		C.N. UNIFARM S.A.	ROMANIA	20	2026

148	SILDENAFILUM	SILDENAFIL ADAMED 50 mg	FILM-COATED TABLETS	50mg	ADAMED PHARMA S.A.	POLAND	16399	2026
149	SITAGLIPTINUM	ADIMUPLAN 100 mg	FILM-COATED TABLETS	100mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16459	2026
150	SITAGLIPTINUM	JUZINA 100 mg	FILM-COATED TABLETS	100mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	16418	2026
151	SORAFENIBUM	SORAFENIB STADA 400 mg	FILM-COATED TABLETS	400mg	STADA M&D S.R.L.	ROMANIA	16401	2026
152	SUNITINIBUM	SUNITINIB SANEXCEL 12.5 mg	CAPSULES	12.5mg	J.J. BISHOP HEALTH A.S.	THE CZECH REPUBLIC	16453	2026
153	SUNITINIBUM	SUNITINIB SANEXCEL 25 mg	CAPSULES	25mg	J.J. BISHOP HEALTH A.S.	THE CZECH REPUBLIC	16454	2026
154	SUNITINIBUM	SUNITINIB SANEXCEL 50 mg	CAPSULES	50mg	J.J. BISHOP HEALTH A.S.	THE CZECH REPUBLIC	16455	2026
155	TEICOPLANINUM	TEICOPLANINA DEMO 200 mg	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INF USION OR ORAL SOLUTION	200mg	DEMO S.A. PHARMACEUTICA L INDUSTRY	GREECE	16447	2026

156	TEICOPLANINUM	TEICOPLANINA DEMO 400 mg	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INF USION OR ORAL SOLUTION	400mg	DEMO S.A. PHARMACEUTICA L INDUSTRY	GREECE	16448	2026
157	TERIFLUNOMIDUM	TERIFLUNOMIDA TEVA 14 mg	FILM-COATED TABLETS	14mg	TEVA B.V.	THE NETHERLANDS	16390	2026
158	TICAGRELOR	ATIXARSO 60 mg	FILM-COATED TABLETS	60mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16416	2026
159	TICAGRELOR	ATIXARSO 90 mg	FILM-COATED TABLETS	90mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16417	2026
160	URAPIDILUM	URAPIDIL KALCEKS 25 mg	SOLUTION FOR INJECTION/ INFUSION	25mg	AS KALCEKS	LATVIA	16493	2026
161	URAPIDILUM	URAPIDIL KALCEKS 50 mg	SOLUTION FOR INJECTION/ INFUSION	50mg	AS KALCEKS	LATVIA	16494	2026
162	VORICONAZOLUM	VEDIDA 200 mg	POWDER FOR SOLUTION FOR INFUSION	200mg	MEDOCHEMIE LTD.	CYPRUS	16500	2026
163	VORICONAZOLUM	VORICONAZOL NORIDEM 200 mg	POWDER FOR SOLUTION FOR INFUSION	200mg	NORIDEM ENTERPRISES LIMITED	CYPRUS	16498	2026

EMA centrally authorised medicinal products notified for marketing in Romania during the 1st quarter of 2026

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	GOLIMUMABUM	GOTENFIA 50 mg	SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE		STADA ARZNEIMITTEL AG	GERMANY	2009	2026