

ROMANIA

Newsletter

Year 27, No. 4 (108), 4th 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

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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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Laws

Law 163, published on 27 October 2025, on amendment and supplementation of certain regulatory acts and on establishment of measures in the healthcare field;

Government decisions

Government Decision no. 1.012, published on 1 December 2025, 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;

Emergency Ordinances

Emergency Ordinance no. 72, published on 11 December 2025, establishing legal measures for implementing Romania's National Recovery and Resilience Plan (PNRR), as well as on amendment of certain regulatory acts;

Emergency Ordinance no. 84, published on 19 December 2025, on amendment and supplementation of Law 95/2006 on healthcare reform, as well as on amendment and supplementation of certain regulatory acts;

Emergency Ordinance no. 91, published on 31 December 2025, on establishment of measures in the healthcare field;

Orders

Order no. 1849 and Order no. 1636, published on 27 November 2025, 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. 1072, published on 1 October 2025, on amendment and supplementation of Annex 1;

Order no. 1325, published on 24 October 2025, on amendment and supplementation of Annex 1;

Order no. 1381, published on 3 November 2025, on amendment and supplementation of Annex 1;

Order no. 1614, published on 25 November 2025, on amendment and supplementation of Annex 1;

Order no. 1827, published on 12 December 2025, on amendment and supplementation of Annex 1;

Order no. 1903, published on 15 December 2025, on amendment and supplementation of Annex 1;

Order no. 2139, published on 23 December 2025, on amendment and supplementation of Annex 1;

Order no. 1230, published on 22 October 2025, on amendment of the Annex to Order of the Minister of Health no. 2.494/2023;

Order no. 1713, published on 9 December 2025, on amendment of the Annex to Order of the Minister of Health no. 2.494/2023.

Order no. 1351, published on 30 October 2025, on amendment and supplementation of the Annex to Order of the Minister of Health no. 368/2017;

Order no. 2056, published on 19 December 2025, on amendment and supplementation of the Annex to Order of the Minister of Health no. 368/2017;

Order no. 2339 and Order no. 2015, published on 31 December 2025, on amendment and supplementation of Order of the Minister of Health and of the President of the National Health Insurance House no. 1.857/441/2023.

Order no. 2140 and Order no. 1943, published on 31 December 2025, on amendment of Order of the Minister of Health and of the President of the National Health Insurance House no. 735/976/2018.

Order no. 1833, published on 12 December 2025, on amendment of Order of the President of the National Health Insurance House no. 516/2023.

Order no. 1944, published on 31 December 2025, on amendment of Annex 1 to Order of the President of the National Health Insurance House no. 141/2017;

Order no. 1548 and Order no. 1145, published on 9 October 2025, 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. 1753 and Order no. 1471, published on 28 November 2025, 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. 1870 and Order no. 1795, published on 10 December 2025, 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;

Medicinal product batches recalled during the 4th 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	ASCORD 80 mg film-coated tablets	film-coated tablets	80 mg	Atorvastatinum	Terapia S.A., Romania	PTF5991C	Out-of-specification outcomes	Voluntary recall	12.11.2025
2	Atofab 10 mg capsules	capsules	10 mg	Atomoxetine	Lannacher Heilmittel Ges.m.b.H., Austria	H10233	Out-of-specification outcomes	Voluntary recall	13.11.2025
3	TANDESAR 8 mg tablets	tablets	8 mg	Candesartanum cilexetil	TERAPIA SA, Romania	PTF4010A	Out-of-specification outcomes	Voluntary recall	03.12.2025
4	TANDESAR 16 mg tablets	tablets	16 mg	Candesartanum cilexetil	TERAPIA SA, Romania	PTF2351A PTF4633A PTF4634A PTF6060A	Out-of-specification outcomes	Voluntary recall	03.12.2025
5	Tandesar 32 mg tablets	tablets	32 mg	Candesartanum cilexetil	TERAPIA SA, Romania	PTF2689A	Out-of-specification outcomes	Voluntary recall	03.12.2025
6	Loperamid Laropharm 2 mg capsules	capsules	2 mg	Loperamidum	S.C. Laropharm S.R.L., Romania	M506941	Quality defect	Voluntary recall	09.12.2025
7	Loprex 2 mg capsules	capsules	2 mg	Loperamidum	S.C. Laropharm S.R.L., Romania	M506942	Quality defect	Voluntary recall	09.12.2025

Applications for marketing authorisation/marketing authorisation renewal received during the 3rd quarter of 2025

21 marketing authorisation/marketing authorisation renewal applications for medicinal products have been received during the 3rd quarter of 2025, corresponding to the following therapeutic groups:

AUTHORISATION	RENEWAL
L03 - IMMUNOSTIMULANTS	H03 - THYROID THERAPY
N06 - PSYCHOANALEPTICS	H03 - THYROID THERAPY
N06 - PSYCHOANALEPTICS	C05 - VASOPROTECTIVES
C07 - BETA BLOCKING AGENTS	R06 – ANTIHISTAMINES FOR SYSTEMIC USE
C07 - BETA BLOCKING AGENTS	H03 - THYROID THERAPY
A10 - DRUGS USED IN DIABETES	H03 - THYROID THERAPY
A10 - DRUGS USED IN DIABETES	
A10 - DRUGS USED IN DIABETES	
N05 - PSYCHOLEPTICS	
L01 – ANTINEOPLASTIC AGENTS	
M01 – ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	
J05 – ANTIVIRALS FOR SYSTEMIC USE	

Medicinal products authorised for marketing during the 3rd quarter of 2025

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	ACICLOVIRUM	VIROLEX 250 mg	POWDER FOR SOLUTION FOR INJECTION/INFUSION	250mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16223	2025
2	ACICLOVIRUM	ACICLOVIR ACCORD 25 mg/ml	CONCENTRATE FOR SOLUTION FOR INFUSION	25mg/ml	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	16134	2025
3	ACIDUM TIOCTICUM (ALFA-LIPOICUM)	ACID TIOCTIC ZENTIVA 600 mg	FILM-COATED TABLETS	600mg	ZENTIVA K.S.	THE CZECH REPUBLIC	16183	2025
4	ACIDUM TRANEXAMICUM	MEDSAMIC 500 mg	FILM-COATED TABLETS	500mg	MEDOICHEMIE LTD.	CYPRUS	16185	2025
5	AMBROXOLUM	BIOFLU TUSS 30 mg	TABLETS	30mg	BIOFARM S.A.	ROMANIA	16254	2025
6	AMOXICILLINUM	MOXILEN 500 mg	CAPSULES	500mg	MEDOICHEMIE LTD.	CYPRUS	16182	2025
7	AMPHOTERICINUM B	AMFOTERICINA B LIPOZOMALA TILLOMED 50 mg	POWDER FOR CONCENTRATE FOR DISPERSION FOR INFUSION	50mg	TILOMED MALTA LIMITED	MALTA	16216	2025
8	APIXABANUM	APIXABAN TEVA B.V. 2.5 mg	FILM-COATED TABLETS	2.5mg	TEVA B.V.	THE NETHERLANDS	16205	2025

9	APIXABANUM	APIXABAN TEVA B.V. 5 mg	FILM-COATED TABLETS	5mg	TEVA B.V.	THE NETHERLANDS	16206	2025
10	APIXABANUM	APIXABAN TEVA 2.5 mg	FILM-COATED TABLETS	2.5mg	TEVA PHARMACEUTI CALS S.R.L.	ROMANIA	16201	2025
11	APIXABANUM	APIXABAN TEVA 5 mg	FILM-COATED TABLETS	5mg	TEVA PHARMACEUTI CALS S.R.L.	ROMANIA	16202	2025
12	APIXABANUM	VOZIBERIN 2.5 mg	FILM-COATED TABLETS	2.5mg	MSN LABS EUROPE LIMITED	MALTA	16174	2025
13	APIXABANUM	VOZIBERIN 5 mg	FILM-COATED TABLETS	5mg	MSN LABS EUROPE LIMITED	MALTA	16175	2025
14	APIXABANUM	APIXABAN VIATRIS PHARMA 2.5 mg	FILM-COATED TABLETS	2.5mg	VIATRIS LIMITED	IRELAND	16229	2025
15	APIXABANUM	APIXABAN VIATRIS PHARMA 5 mg	FILM-COATED TABLETS	5mg	VIATRIS LIMITED	IRELAND	16230	2025
16	APIXABANUM	FYDOCO 2.5 mg	FILM-COATED TABLETS	2.5mg	VIATRIS LIMITED	IRELAND	16237	2025
17	APIXABANUM	FYDOCO 5 mg	FILM-COATED TABLETS	5mg	VIATRIS LIMITED	IRELAND	16238	2025
18	ATROPINUM	SULFAT DE ATROPINA ACCORD 0.1 mg/ml	SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	0.1mg/ml	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	16200	2025

19	AZACITIDINUM	AZACITIDINA STADA 25 mg/ml	POWDER FOR SUSPENSION FOR INJECTION	25mg/ml	STADA M&D SRL	ROMANIA	16226	2025
20	AZELASTINUM	ALLERGODIL 1.5 mg/ml	NASAL SPRAY, SOLUTION	1.5 mg/ml	COOPER CONSUMER HEALTH B.V.	THE NETHERLANDS	16144	2025
21	BETAHISTINUM	BETAHISTINA GEMAX PHARMA 24 mg	TABLETS	24mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	16184	2025
22	CEFIXIMUM	AXTRIFIA 100 mg/5 ml	POWDER FOR ORAL SOLUTION	100mg/5ml	SANDOZ PHARMACEUTI CALS S.R.L.	ROMANIA	16133	2025
23	CEFOTAXIMUM	CEFOTAXIMA SWYSSI 1 g	POWDER FOR SOLUTION FOR INJECTION/INFUS ION	1g	SWYSSI AG	GERMANY	16142	2025
24	COLISTINUM	COLISTIMETAT ROMPHARM 1000000 UI	POWDER FOR SOLUTION FOR INJECTION/INFUS ION	1000000IU	ROMPHARM COMPANY S.R.L.	ROMANIA	16224	2025
25	COMBINATIONS (ACIDUM ACETYLSALICYLIC UM+PARACETAMOL UM+CAFEINUM)	NEVRALGIO 250 mg/150 mg/20 mg	TABLETS	250mg/150mg/2 0mg	SINTOFARM S.A.	ROMANIA	16244	2025

26	COMBINATIONS (BENFOTIAMINUM+ PYRIDOXINUM+CY ANOCOBALAMINU M)	NEUROMULTIVIT NEURO	FILM-COATED TABLETS	40mg/90mg/0.25 mg	G.L. PHARMA GMBH	AUSTRIA	16239	2025
27	COMBINATIONS (BENZYDAMINUM+ CETYLPYRIDINII CHLORIDUM)	SEPTOLETE OMNI COLA 3 mg/1 mg	LOZENGES	3mg/1mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16186	2025
28	COMBINATIONS (FENAZONUM+LIDO CAINUM)	OTILERIN 47.2 mg/11.8 mg/ml	EAR DROPS, SOLUTION	47.2mg/11.8mg/ ml	BIOFARM S.A.	ROMANIA	16241	2025
29	COMBINATIONS (NETILMICINUM+DE XAMETHASONUM)	NETILDEX 3 mg/ml + 1 mg/ml	EYE GEL IN SINGLE DOSE CONTAINER	3mg/ml+1mg/ml	SIFI S.P.A	ITALY	16247	2025
30	COMBINATIONS (OCTENIDINUM+PH ENOXYETHANOL)	OCTICIDE 1 mg/g+20 mg/g	CUTANEOUS SPRAY, SOLUTION	1mg/g+20mg/g	ENEO PHARMACEUTI CALS S.R.O.	THE CZECH REPUBLIC	16249	2025
31	COMBINATIONS (OLMESARTANUM MEDOXOMILUM+A MLODIPINUM)	REVERANTZA 20 mg/5 mg	FILM-COATED TABLETS	20mg/5mg	SWYSSI AG	GERMANY	16203	2025

32	COMBINATIONS (OLMESARTANUM MEDOXOMILUM+A MLODIPINUM)	REVERANTZA 40 mg/5 mg	FILM-COATED TABLETS	40mg/5mg	SWYSSI AG	GERMANY	16204	2025
33	COMBINATIONS (PARACETAMOLUM +ACIDUM ASCORBICUM+CHL ORPHENAMINUM)	REMIFLU	GRANULES FOR ORAL SOLUTION IN SACHET	500mg/200mg/4 mg	ANTIBIOTICE S.A.	ROMANIA	16242	2025
34	COMBINATIONS (PARACETAMOLUM +ACIDUM ASCORBICUM+PSEU DOEPHEDRINUM+D EXTROMETHORPHA NUM)	CAFFETIN COLD PLUS	FILM-COATED TABLETS	500mg/60mg/30 mg/15mg	INN-FARM D.O.O.	SLOVENIA	16243	2025
35	COMBINATIONS (PARACETAMOLUM +DIPHENHYDRAMIN UM+PSEUDOEPHED RINUM)	OLYGRIP ZI 500/60 mg SI OLYGRIP NOAPTE 500/25 mg	TABLETS + FILM- COATED TABLETS	500/60mg+500/2 5mg	MCNEIL HEALTHCARE (IRELAND) LIMITED	IRELAND	16211	2025
36	COMBINATIONS (PARACETAMOLUM +PROPYPHENAZON UM+CAFEINUM)	COFEDOL	TABLETS		VITEMA S.A.	ROMANIA	16156	2025

37	COMBINATIONS (ROSUVASTATINUM +PERINDOPRILUM)	PIXOROSO 10 mg/4 mg	FILM-COATED TABLETS	10mg/4mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16150	2025
38	COMBINATIONS (ROSUVASTATINUM +PERINDOPRILUM)	PIXOROSO 10 mg/8 mg	FILM-COATED TABLETS	10mg/8mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16151	2025
39	COMBINATIONS (ROSUVASTATINUM +PERINDOPRILUM)	PIXOROSO 20 mg/4 mg	FILM-COATED TABLETS	20mg/4mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16152	2025
40	COMBINATIONS (ROSUVASTATINUM +PERINDOPRILUM)	PIXOROSO 20 mg/8 mg	FILM-COATED TABLETS	20mg/8mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16153	2025
41	COMBINATIONS (SACUBITRILUM+V ALSARTANUM)	SACUBITRIL/VALSART AN TEVA 24 mg/26 mg	FILM-COATED TABLETS	24mg/26mg	TEVA GMBH	GERMANY	16231	2025
42	COMBINATIONS (SACUBITRILUM+V ALSARTANUM)	SACUBITRIL/VALSART AN TEVA 49 mg/51 mg	FILM-COATED TABLETS	49mg/51mg	TEVA GMBH	GERMANY	16232	2025
43	COMBINATIONS (SACUBITRILUM+V ALSARTANUM)	SACUBITRIL/VALSART AN TEVA 97 mg/103 mg	FILM-COATED TABLETS	97mg/103mg	TEVA GMBH	GERMANY	16233	2025
44	COMBINATIONS (SITAGLIPTINUM+M ETFORMINUM)	EPROCLIV 50 mg/1000 mg	FILM-COATED TABLETS	50mg/1000mg	SANDOZ PHARMACEUTI CALS S.R.L.	ROMANIA	16250	2025

45	COMBINATIONS (SOLIFENACINUM SUCCINATE+TAMSU LOSINUM)	SOLIFENACIN/TAMSU LOSIN GEMAX PHARMA 6 mg/0.4 mg	MODIFIED- RELEASE TABLETS	6mg/0.4mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	16160	2025
46	COMBINATIONS (TELMISARTANUM+ INDIPAMIDUM)	YLPIO 80 mg/2.5 mg	TABLETS	80mg/2.5mg	PRO. MED.CS PRAHA A.S.	THE CZECH REPUBLIC	16246	2025
47	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILAT DR. REDDY'S 75 mg	CAPSULES	75mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	16196	2025
48	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILAT DR. REDDY'S 110 mg	CAPSULES	110mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	16197	2025
49	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILAT DR. REDDY'S 150 mg	CAPSULES	150mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	16198	2025
50	EDOXABANUM	ERJULIZAM 15 mg	FILM-COATED TABLETS	15mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	16207	2025
51	EDOXABANUM	ERJULIZAM 30 mg	FILM-COATED TABLETS	30mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	16208	2025

52	EDOXABANUM	ERJULIZAM 60 mg	FILM-COATED TABLETS	60mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	16209	2025
53	ELTROMBOPAG	ELTROMBOPAG DR. REDDY'S 25 mg	FILM-COATED TABLETS	25mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	16154	2025
54	ELTROMBOPAG	ELTROMBOPAG DR. REDDY'S 50 mg	FILM-COATED TABLETS	50mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	16155	2025
55	EPINEPHRINUM	ADRENALINA NORIDEM 1 mg/ml	SOLUTION FOR INJECTION	1mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	16180	2025
56	ERLOTINIBUM	ERLOTINIB KRKA 25 mg	FILM-COATED TABLETS	25mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16147	2025
57	ERLOTINIBUM	ERLOTINIB KRKA 100 mg	FILM-COATED TABLETS	100mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16148	2025
58	ERLOTINIBUM	ERLOTINIB KRKA 150 mg	FILM-COATED TABLETS	150mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16149	2025
59	FINASTERIDUM	FINJUVE PENTRU BARBATI 2.275 mg/ml	CUTANEOUS SPRAY, SOLUTION	2.275mg/ml	POLICHEM S.A.	LUXEMBOURG	16199	2025

60	FLUCONAZOLUM	FLUCONAZOL NORIDEM 2 mg/ml	SOLUTION FOR INFUSION	2mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	16161	2025
61	FOSFOMYCINUM	FOSFOMICINA ROMPHARM 3 g	GRANULES FOR ORAL SUSPENSION IN SACHET	3g	ROMPHARM COMPANY S.R.L.	ROMANIA	16145	2025
62	HOMEOPATHIC	CAMILIA	ORAL SOLUTION IN SINGLE-DOSE CONTAINER		BOIRON	FRANCE	16181	2025
63	IBUPROFENUM	PADUDEN JUNIOR 40 mg/ml	ORAL SUSPENSION	40mg/ml	TERAPIA S.A.	ROMANIA	16227	2025
64	IBUPROFENUM	IBUPROFEN KABI 400 mg	SOLUTION FOR INFUSION	400mg	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	16135	2025
65	INOSINUM	INOVIRA 500 mg	TABLETS	500mg	SANIENCE S.R.L.	ROMANIA	16146	2025
66	INOSINUM	INOVIRA 50 mg/ml	SYRUP	50mg/ml	SANIENCE S.R.L.	ROMANIA	16245	2025
67	LEVOSIMENDANUM	LEVOSIMENDAN SALA 2.5 mg/ml concentrate for solution for infusion EFG	CONCENTRATE FOR SOLUTION FOR INFUSION	2.5mg/ml	BESMAX PHARMA SOLUTIONS S.R.L.	ROMANIA	16	2025
68	LIDOCAINUM	LIDOCAINA NORIDEM 10 mg/ml	SOLUTION FOR INJECTION	10mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	16178	2025

69	LIDOCAINUM	LIDOCAINA NORIDEM 20 mg/ml (see C01BB01)	SOLUTION FOR INJECTION	20mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	16179	2025
70	LIDOCAINUM	LIDOCAINA NORIDEM 20 mg/ml (see N01BB02)	SOLUTION FOR INJECTION	20mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	16179	2025
71	MACITENTANUM	MACITENTAN TEVA 10 mg	FILM-COATED TABLETS	10mg	TEVA PHARMACEUTI CALS S.R.L.	ROMANIA	16212	2025
72	MACITENTANUM	MACITENTAN STADA 10 mg	FILM-COATED TABLETS	10mg	STADA ARZNEIMITTEL AG	GERMANY	16228	2025
73	MICAFUNGINUM	MICAFUNGIN ROMPHARM 50 mg	POWDER FOR SOLUTION FOR INFUSION	50mg	ROMPHARM COMPANY S.R.L.	ROMANIA	16162	2025
74	MICAFUNGINUM	MICAFUNGIN ROMPHARM 100 mg	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	100mg	ROMPHARM COMPANY S.R.L.	ROMANIA	16163	2025
75	MIDAZOLAMUM	MIDAZOLAM DESITIN 2.5 mg	OROMUCOSAL SOLUTION	5mg/ml	DESITIN ARZNEIMITTEL GMBH	GERMANY	16138	2025
76	MIDAZOLAMUM	MIDAZOLAM DESITIN 5 mg	OROMUCOSAL SOLUTION	5mg/ml	DESITIN ARZNEIMITTEL GMBH	GERMANY	16139	2025

77	MIDAZOLAMUM	MIDAZOLAM DESITIN 7.5 mg	OROMUCOSAL SOLUTION	5mg/ml	DESITIN ARZNEIMITTEL GMBH	GERMANY	16140	2025
78	MIDAZOLAMUM	MIDAZOLAM DESITIN 10 mg	OROMUCOSAL SOLUTION	5mg/ml	DESITIN ARZNEIMITTEL GMBH	GERMANY	16141	2025
79	NINTEDANIBUM	NINTEDANIB DR. REDDY'S 100 mg	SOFT CAPSULES	100 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	16164	2025
80	NINTEDANIBUM	NINTEDANIB DR. REDDY'S 150 mg	SOFT CAPSULES	150 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	16165	2025
81	OSELTAMIVIRUM	OSELTAMIVIR LAROPHARM 30 mg	CAPSULES	30mg	LAROPHARM S.R.L.	ROMANIA	16220	2025
82	OSELTAMIVIRUM	OSELTAMIVIR LAROPHARM 45 mg	CAPSULES	45mg	LAROPHARM S.R.L.	ROMANIA	16221	2025
83	OSELTAMIVIRUM	OSELTAMIVIR LAROPHARM 75 mg	CAPSULES	75mg	LAROPHARM S.R.L.	ROMANIA	16222	2025
84	PANTOPRAZOLUM	PANTOPRAZOL NORIDEM 40 mg	POWDER FOR SOLUTION FOR INJECTION	40mg	NORIDEM ENTERPRISES LIMITED	CYPRUS	16173	2025

85	PANTOPRAZOLUM	PANTOPRAZOL APTAPHARMA 40 mg	POWDER FOR SOLUTION FOR INJECTION	40mg	APTA MEDICA INTERNACIONA L D.O.O.	SLOVENIA	16194	2025
86	PARACETAMOLUM	DEFEBRYL 500 mg	TABLETS	500mg	BIOEEL MANUFACTURI NG S.R.L.	ROMANIA	16132	2025
87	PIPERACILLINUM + TAZOBACTAMUM	PIPERACILINA/TAZOB ACTAM APTAPHARMA 2 g/0.25 g	POWDER FOR SOLUTION FOR INFUSION	2g/0.25g	APTA MEDICA INTERNACIONA L D.O.O.	SLOVENIA	16192	2025
88	PIPERACILLINUM + TAZOBACTAMUM	PIPERACILINA/TAZOB ACTAM APTAPHARMA 4 g/0.5 g	POWDER FOR SOLUTION FOR INFUSION	4g/0.5g	APTA MEDICA INTERNACIONA L D.O.O.	SLOVENIA	16193	2025
89	HERBS	IMUPRET	DRAGEES		BIONORICA SE	GERMANY	16225	2025
90	PLANTE (EXTRACT DE MUSCATA)	PELAVOMED 20 mg/4 ml	ORAL SOLUTION	20mg/4ml	US PHARMACIA SP. Z O.O	POLAND	16240	2025
91	POSACONAZOLUM	POSACONAZOL ZENTIVA 100 mg	GASTRORESISTA NT TABLETS	100mg	ZENTIVA K.S.	THE CZECH REPUBLIC	16137	2025
92	PROGESTERONUM	PROLUTEX 25 mg	SOLUTION FOR INJECTION	25mg	IBSA FARMACEUTICI ITALY SRL	ITALY	16210	2025
93	RALTEGRAVIRUM	RALTEGRAVIR VIATRIS 600 mg	FILM-COATED TABLETS	600mg	VIATRIS LIMITED	IRELAND	16195	2025

94	RISPERIDONUM	RISPERIDONA TEVA 25 mg	POWDER AND SOLVENT FOR PROLONGED-RELEASE SUSPENSION FOR INJECTION	25mg	TEVA B.V.	THE NETHERLANDS	16170	2025
95	RISPERIDONUM	RISPERIDONA TEVA 37.5 mg	POWDER AND SOLVENT FOR PROLONGED-RELEASE SUSPENSION FOR INJECTION	37.5mg	TEVA B.V.	THE NETHERLANDS	16171	2025
96	RISPERIDONUM	RISPERIDONA TEVA 50 mg	POWDER AND SOLVENT FOR PROLONGED-RELEASE SUSPENSION FOR INJECTION	50mg	TEVA B.V.	THE NETHERLANDS	16172	2025
97	RIVAROXABANUM	RIVAROXABAN G.L. PHARMA 10 mg	FILM-COATED TABLETS	10mg	G.L. PHARMA GMBH	AUSTRIA	16217	2025
98	RIVAROXABANUM	RIVAROXABAN G.L. PHARMA 15 mg	FILM-COATED TABLETS	15mg	G.L. PHARMA GMBH	AUSTRIA	16218	2025
99	RIVAROXABANUM	RIVAROXABAN G.L. PHARMA 20 mg	FILM-COATED TABLETS	20mg	G.L. PHARMA GMBH	AUSTRIA	16219	2025
100	RIVAROXABANUM	RIVAROXABAN GRINDEKS 10 mg	FILM-COATED TABLETS	10mg	AS GRINDEKS	LATVIA	16187	2025
101	RIVAROXABANUM	RIVAROXABAN GRINDEKS 15 mg	FILM-COATED TABLETS	15mg	AS GRINDEKS	LATVIA	16188	2025

102	RIVAROXABANUM	RIVAROXABAN GRINDEKS 20 mg	FILM-COATED TABLETS	20mg	AS GRINDEKS	LATVIA	16189	2025
103	SOMATROPINUM	NORDITROPIN FLEXPPO 10 mg/1.5 ml	SOLUTION FOR INJECTION IN PRE-FILLED PEN	10mg/1.5ml	NOVO NORDISK A/S	DENMARK	16143	2025
104	SUNITINIBUM	SUNITINIB G.L. PHARMA 12.5 mg	CAPSULES	12.5mg	G.L. PHARMA GMBH	AUSTRIA	16251	2025
105	SUNITINIBUM	SUNITINIB G.L. PHARMA 25 mg	CAPSULES	25mg	G.L. PHARMA GMBH	AUSTRIA	16252	2025
106	SUNITINIBUM	SUNITINIB G.L. PHARMA 50 mg	CAPSULES	50mg	G.L. PHARMA GMBH	AUSTRIA	16253	2025
107	SUNITINIBUM	SUNITINIB ZENTIVA 12.5 mg	CAPSULES	12.5mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	16157	2025
108	SUNITINIBUM	SUNITINIB ZENTIVA 25 mg	CAPSULES	25mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	16158	2025
109	SUNITINIBUM	SUNITINIB ZENTIVA 50 mg	CAPSULES	50mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	16159	2025
110	TADALAFILUM	XENESO 5 mg	FILM-COATED TABLETS	5mg	ANTIBIOTICE S.A.	ROMANIA	16213	2025
111	TADALAFILUM	XENESO 10 mg	FILM-COATED TABLETS	10mg	ANTIBIOTICE S.A.	ROMANIA	16214	2025
112	TADALAFILUM	XENESO 20 mg	FILM-COATED TABLETS	20mg	ANTIBIOTICE S.A.	ROMANIA	16215	2025
113	TADALAFILUM	TADALAFIL GEMAX PHARMA 5 mg	FILM-COATED TABLETS	5mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	16234	2025

114	TADALAFILUM	TADALAFIL GEMAX PHARMA 10 mg	FILM-COATED TABLETS	10mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	16235	2025
115	TADALAFILUM	TADALAFIL GEMAX PHARMA 20 mg	FILM-COATED TABLETS	20mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	16236	2025
116	THIOTEPUM	THIOTEPA MSN 15 mg	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	15mg	MSN LABS EUROPE LIMITED	MALTA	16190	2025
117	THIOTEPUM	THIOTEPA MSN 100 mg	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	100mg	MSN LABS EUROPE LIMITED	MALTA	16191	2025
118	TREPROSTINILUM	TRESUVI 1 mg/ml	SOLUTION FOR INFUSION	1mg/ml	AMOMED PHARMA GMBH	AUSTRIA	16166	2025
119	TREPROSTINILUM	TRESUVI 2.5 mg/ml	SOLUTION FOR INFUSION	2.5mg/ml	AMOMED PHARMA GMBH	AUSTRIA	16167	2025
120	TREPROSTINILUM	TRESUVI 5 mg/ml	SOLUTION FOR INFUSION	5mg/ml	AMOMED PHARMA GMBH	AUSTRIA	16168	2025
121	TREPROSTINILUM	TRESUVI 10 mg/ml	SOLUTION FOR INFUSION	10mg/ml	AMOMED PHARMA GMBH	AUSTRIA	16169	2025
122	VINPOCETINUM	VINPOCETINA COVEX 10 mg	TABLETS	10mg	COVEX S.A.	SPAIN	16177	2025
123	VINPOCETINUM	VINPOCETINA COVEX 5 mg	TABLETS	5mg	COVEX S.A.	SPAIN	16176	2025

EMA centrally authorised medicinal products notified for marketing in Romania during the 3rd quarter of 2025

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	DONANEMABUM	ITOVEBI 3 mg	FILM-COATED TABLETS	3mg	ROCHE REGISTRATION GMBH	GERMANY	1942	2025
2	EMTRICITABINUM+ TENOFVIRUM ALAFENAMIDA	ITOVEBI 9 mg	FILM-COATED TABLETS	9mg	ROCHE REGISTRATION GMBH	GERMANY	1942	2025
3	EMTRICITABINUM+ TENOFVIRUM ALAFENAMIDA	OGSIVEO 50 mg	FILM-COATED TABLETS	50mg	SPRINGWORKS THERAPEUTICS IRELAND LIMITED	IRELAND	1932	2025
4	INAVOLISIBUM	OGSIVEO 100 mg	FILM-COATED TABLETS	100mg	SPRINGWORKS THERAPEUTICS IRELAND LIMITED	IRELAND	1932	2025
5	INAVOLISIBUM	OGSIVEO 150 mg	FILM-COATED TABLETS	150mg	SPRINGWORKS THERAPEUTICS IRELAND LIMITED	IRELAND	1932	2025
6	MIRDAMETINIBUM	KISUNLA 350 mg	CONCENTRATE FOR SOLUTION FOR INFUSION	350mg	ELI LILLY NEDERLAND B.V.	THE NETHERLANDS	1926	2025
7	MIRDAMETINIBUM	EZMEKLY 1 mg	CAPSULES	1mg	SPRINGWORKS THERAPEUTICS IRELAND LIMITED	IRELAND	1950	2025
8	MIRDAMETINIBUM	EZMEKLY 2 mg	CAPSULES	2mg	SPRINGWORKS THERAPEUTICS	IRELAND	1950	2025

					IRELAND LIMITED			
9	NIROGACESTATUM	EZMEKLY 1 mg	DISPERSIBLE TABLETS	1mg	SPRINGWORKS THERAPEUTICS IRELAND LIMITED	IRELAND	1950	2025
10	NIROGACESTATUM	VORANIGO 10 mg	FILM-COATED TABLETS	10mg	LES LABORATOIRES SERVIER	FRANCE	1912	2025
11	NIROGACESTATUM	VORANIGO 40 mg	FILM-COATED TABLETS	40mg	LES LABORATOIRES SERVIER	FRANCE	1912	2025
12	OLEZARSENUM	TRYNGOLZA 80mg	SOLUTION FOR INJECTION IN PRE-FILLED PEN	80mg	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	SWEDEN	1969	2025
13	VORASIDENIBUM	EMTRICITABINA/TE NOFOVIR ALAFENAMIDA VIATRIS 200 mg/10 mg	FILM-COATED TABLETS	200mg/10mg	VIATRIS LIMITED	IRELAND	1952	2025
14	VORASIDENIBUM	EMTRICITABINA/TE NOFOVIR ALAFENAMIDA VIATRIS 200 mg/25 mg	FILM-COATED TABLETS	200mg/25mg	VIATRIS LIMITED	IRELAND	1952	2025