

ROMANIA

Newsletter

Year 27, No. 3 (107), 3rd 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:

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

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

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

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

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

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

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

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

d) The institution's contact data

e) Audiences

Business hours

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g) The institution's programmes and strategies

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Laws

Law 141, published on 28 July 2025, on some fiscal-budgetary measures;

Ordinance no. 12, published on 16 August 2025, on amendment and supplementation of Law 95/2006 on healthcare reform and amendment of certain healthcare regulatory acts;

Orders

Order no. 1044 and Order no. 467, published on 6 August 2025, on amendment and supplementation of the Annex to Order of the Minister of Health and of the National Health Insurance House President no. 564/499/2021;

Order no. 1371 and Order no. 728, published on 25 August 2025, on amendment and supplementation of the Annex to Order of the Minister of Health and of the National Health Insurance House President no. 564/499/2021;

Order no. 1512 and Order no. 958, published on 29 September 2025, on amendment and supplementation of the Annex to Order of the Minister of Health and of the National Health Insurance House President no. 564/499/2021;

Order no. 2104 and Order no. 2157, published on 1 July 2025, on amendment and supplementation of Annex 1;

Order no. 201, published on 10 July 2025, on amendment and supplementation of Annex 1;

Order no. 323, published on 14 July 2025, on amendment and supplementation of Annex 1;

Order no. 2103 and Order no. 470, published on 1 August 2025, on amendment and supplementation of Annex 1;

Order no. 733, published on 20 August 2025, on amendment and supplementation of Annex 1;

Order no. 842 and Order no. 794, published on 1 September 2025, on amendment and supplementation of Annex 1;

Order no. 926, published on 11 September 2025, on amendment and supplementation of Annex 1;

Order no. 2105, published on 1 July 2025, on amendment of the Annex to Order of the Minister of Health no. 2.494/2023;

Order no. 2085 and Order no. 471, published on 1 August 2025, on amendment of the Annex to Order of the Minister of Health no. 2.494/2023;

Order no. 1047 and Order no. 525, published on 1 August 2025, on amendment and supplementation of Order of the Minister of Health and of the National Health Insurance House President no. 1.857/441/2023;

Order no. 1370 and Order no. 824, published on 28 August 2025, on amendment and supplementation of Order of the Minister of Health and of the National Health Insurance House President no. 1.857/441/2023;

Order no. 776, published on 27 August 2025, on supplementation of the Annex to Order of the Minister of Health no. 607/2019.

Order no. 895, published on 24 July 2025, on amendment of Annex 1 to Order of the National Health Insurance House President no. 141/2017;

Order no. 1359, published on 28 August 2025, on amendment of Annex 1 to Order of the National Health Insurance House President no. 141/2017;

Order no. 1431, published on 25 September 2025, on amendment of Annex 1 to Order of the National Health Insurance House President no. 141/2017;

Order no. 855 and Order no. 170, published on 9 July 2025, on amendment and supplementation of Annex 2 to Order of the Minister of Health and of the National Health Insurance House President no. 1.605/875/2014;

Order no. 1043 and Order no. 524, published on 4 August 2025, on amendment and supplementation of Annex 2 to Order of the Minister of Health and of the National Health Insurance House President no. 1.605/875/2014;

Order no. 1395 and Order no. 885, published on 5 September 2025, on amendment and supplementation of Annex 2 to Order of the Minister of Health and of the National Health Insurance House President no. 1.605/875/2014;

Medicinal product batches recalled during the 3rd 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	KIMMTRAK 100 micrograms/0.5 ml concentrate for solution for infusion	concentrate for solution for infusion	100 micrograms/0.5 ml	Tebentafuspum	Immunocore Ireland Limited, Ireland	3D009AA31 3D009AA04	Out-of-specification outcomes	Voluntary withdrawal	15.07.2025
2	MYDOCALM 150 mg film-coated tablets	film-coated tablets	150 mg	Tolperisonum	Gedeon Richter Romania S.A.	T49471 T49476	Withdrawal from the market, due to impurities	Voluntary withdrawal	19.08.2025

Applications for marketing authorisation/marketing authorisation renewal received during the 2nd quarter of 2025

35 marketing authorisation/marketing authorisation renewal applications for medicinal products have been received during the 2nd quarter of 2025, corresponding to the following therapeutic groups:

AUTHORISATION	RENEWAL
C03 - DIURETICS	R05 - COUGH AND COLD PREPARATIONS
A02 - DRUGS FOR ACID RELATED DISORDERS	R05 - COUGH AND COLD PREPARATIONS
G04 - UROLOGICALS	P01 - ANTIPROTOZOALS
C10 - LIPID MODIFYING AGENTS	P01 - ANTIPROTOZOALS
C10 - LIPID MODIFYING AGENTS	N02 - ANALGESICS
C10 - LIPID MODIFYING AGENTS	B01 - ANTITHROMBOTIC AGENTS
C10 - LIPID MODIFYING AGENTS	A11 - VITAMINS
C03 - DIURETICS	A11 - VITAMINS
R05 - COUGH AND COLD PREPARATIONS	N05 - PSYCHOLEPTICS
L04 - IMMUNOSUPPRESSANTS	
A10 – DRUGS USED IN DIABETES	
N06 - PSYCHOANALEPTICS	
C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	
C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	
C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	
R02 - THROAT PREPARATIONS	
R02 - THROAT PREPARATIONS	
B01 - ANTITHROMBOTIC AGENTS	
B01 - ANTITHROMBOTIC AGENTS	
C08 - CALCIUM CHANNEL BLOCKERS	
C08 - CALCIUM CHANNEL BLOCKERS	
C07 - BETA BLOCKING AGENTS	
C07 - BETA BLOCKING AGENTS	
C07 - BETA BLOCKING AGENTS	
L01 – ANTINEOPLASTIC AGENTS	
R05 - COUGH AND COLD PREPARATIONS	

Medicinal products authorised for marketing during the 2nd quarter of 2025

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	ABACAVIRUM+LAMIVUDINUM	ABACAVIR/LAMIVUDINA TERAPIA 600 mg/300 mg	FILM-COATED TABLETS	600mg/300 mg	TERAPIA S.A.	ROMANIA	16052	2025
2	ABACAVIRUM+LAMIVUDINUM	ABACAVIR/LAMIVUDINA VIATRIS 600 mg/300 mg	FILM-COATED TABLETS	600mg/300 mg	VIATRIS LIMITED	IRELAND	16084	2025
3	AMPHOTERICINUM B	AMBISOME LIPOSOMAL AMPHOTERICIN B 50 mg	POWDER FOR CONCENTRATE FOR DISPERSION FOR INFUSION	50mg	GILEAD SCIENCES IRELAND UC	IRELAND	15	2025
4	APIXABANUM	EMBAVI 2.5 mg	FILM-COATED TABLETS	2.5mg	EGIS PARMACEUTICAL S PLC	HUNGARY	15983	2025
5	APIXABANUM	EMBAVI 5 mg	FILM-COATED TABLETS	5mg	EGIS PARMACEUTICAL S PLC	HUNGARY	15984	2025
6	APIXABANUM	APIXABAN ADALVO 2.5 mg	FILM-COATED TABLETS	2.5mg	ADALVO LIMITED	MALTA	16030	2025
7	APIXABANUM	APIXABAN ADALVO 5 mg	FILM-COATED TABLETS	5mg	ADALVO LIMITED	MALTA	16031	2025
8	APIXABANUM	APIXABAN INDOCO 2.5 mg	FILM-COATED TABLETS	2.5mg	INDOCO REMEDIES CZECH S.R.O	THE CZECH REPUBLIC	16044	2025

9	APIXABANUM	APIXABAN INDOCO 5 mg	FILM-COATED TABLETS	5mg	INDOCO REMEDIES CZECH S.R.O	THE CZECH REPUBLIC	16045	2025
10	APOMORFINUM	APO-GO 5 mg/ml	SOLUTION FOR INFUSION IN CARTUS	5mg/ml	STADA ARZNEIMITTEL AG	GERMANY	15997	2025
11	ATROPINUM	SULFAT DE ATROPINA NORIDEM 1 mg/ml	SOLUTION FOR INJECTION	1mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	16101	2025
12	AZACITIDINUM	AZACITIDINA SANDOZ 25 mg/ml	POWDER FOR SUSP. INJ.	25mg/ml	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	16016	2025
13	AZELASTINUM	AZELASTINA MISOM 0.5 mg/ml	EYE DROPS, SOLUTION	0.5mg/ml	BROWN & BURK IR LIMITED	IRELAND	16039	2025
14	BEMIPARINUM	ZIBOR 25 000 IU anti-Xa /ml	SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	25000UI anti-XA/ml	GINELADIUS, S.L.	SPAIN	15966	2025
15	BENZYDAMINUM	ZOTRINA LAMAIE 3 mg	LOZENGES	3mg	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	16049	2025
16	BENZYDAMINUM	ZOTRINA MIERE SI PORTOCALA 3 mg	LOZENGES	3mg	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	16083	2025
17	BETAHISTINUM	DICLORHIDRAT DE BETAHISTINA TERAPIA 8 mg	TABLETS	8 mg	TERAPIA SA	ROMANIA	16061	2025
18	BETAHISTINUM	DICLORHIDRAT DE BETAHISTINA TERAPIA 16 mg	TABLETS	16 mg	TERAPIA SA	ROMANIA	16062	2025
19	BETAHISTINUM	DICLORHIDRAT DE BETAHISTINA TERAPIA 24 mg	TABLETS	24 mg	TERAPIA SA	ROMANIA	16063	2025

20	BRIMONIDINUM	BRIMONAL 2 mg/ml	EYE DROPS, SOLUTION	2mg/ml	UNIMED PHARMA SPOL. S.R.O.	THE SLOVAK REPUBLIC	15960	2025
21	BRIVARACETAMUM	BRELUNCOL 10 mg	FILM-COATED TABLETS	10mg	EGIS PARMACEUTICAL S PLC	HUNGARY	16021	2025
22	BRIVARACETAMUM	BRELUNCOL 25 mg	FILM-COATED TABLETS	25mg	EGIS PARMACEUTICAL S PLC	HUNGARY	16022	2025
23	BRIVARACETAMUM	BRELUNCOL 50 mg	FILM-COATED TABLETS	50mg	EGIS PARMACEUTICAL S PLC	HUNGARY	16023	2025
24	BRIVARACETAMUM	BRELUNCOL 75 mg	FILM-COATED TABLETS	75mg	EGIS PARMACEUTICAL S PLC	HUNGARY	16024	2025
25	BRIVARACETAMUM	BRELUNCOL 100 mg	FILM-COATED TABLETS	100mg	EGIS PARMACEUTICAL S PLC	HUNGARY	16025	2025
26	BRIVARACETAMUM	BRIVARACETAM TEVA 10 mg	FILM-COATED TABLETS	10mg	TEVA B.V.	THE NETHERLANDS	16078	2025
27	BRIVARACETAMUM	BRIVARACETAM TEVA 25 mg	FILM-COATED TABLETS	25mg	TEVA B.V.	THE NETHERLANDS	16079	2025
28	BRIVARACETAMUM	BRIVARACETAM TEVA 50 mg	FILM-COATED TABLETS	50mg	TEVA B.V.	THE NETHERLANDS	16080	2025
29	BRIVARACETAMUM	BRIVARACETAM TEVA 75 mg	FILM-COATED TABLETS	75mg	TEVA B.V.	THE NETHERLANDS	16081	2025
30	BRIVARACETAMUM	BRIVARACETAM TEVA 100 mg	FILM-COATED TABLETS	100mg	TEVA B.V.	THE NETHERLANDS	16082	2025

31	CABAZITAXELUM	CABAZITAXEL EVER PHARMA 10 mg/ml	CONCENTRATE FOR SOLUTION FOR INFUSION	10mg/ml	EVER VALINJECT GMBH	AUSTRIA	15967	2025
32	CALCII CHLORIDUM	ICALZISS 340 mmol/l	SOLUTION FOR INFUSION	340mmol/l	VANTIVE BELGIUM SRL	BELGIUM	15975	2025
33	CASPOFUNGINUM	CASPOFUNGINA DEMO 50 mg	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	50mg	DEMO S.A. PHARMACEUTICA L INDUSTRY	GREECE	15956	2025
34	CASPOFUNGINUM	CASPOFUNGINA DEMO 70 mg	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	70mg	DEMO S.A. PHARMACEUTICA L INDUSTRY	GREECE	15957	2025
35	CEFAZOLINUM	ZOLINEF FORTE 2 g	POWDER FOR SOLUTION FOR INJECTION/INFU SION	2g	MEDOCHEMIE ROMANIA S.R.L.	ROMANIA	16038	2025
36	CEFIXIMUM	AXTRIFIA 200 mg	FILM-COATED TABLETS	200mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16123	2025
37	CEFIXIMUM	AXTRIFIA 400 mg	FILM-COATED TABLETS	400mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16124	2025
38	CEFTAZIDIMUM	ALFAGEM 1 g	POWDER FOR SOLUTION FOR INJECTION/INFU SION	1g	MEDOCHEMIE LTD.	CYPRUS	16092	2025
39	CEFTAZIDIMUM	ALFAGEM 2 g	POWDER FOR SOLUTION FOR INJECTION/INFU SION	2g	MEDOCHEMIE LTD.	CYPRUS	16093	2025

40	COMBINATIONS	CALCIU-SANDOZ FORTE 500 mg	EFFERVESCENT TABLETS	500mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	16106	2025
41	COMBINATIONS	VOXSILL MIERE SI LAMAIE 0.6 mg/1.2 mg	LOZENGES	0.6mg/1.2mg	MAPAEX CONSUMER HEALTHCARE (IRELAND) PRIVATE LIMITED	IRELAND	15941	2025
42	COMBINATIONS	VOXSILL CAPSUNI FARA ZAHAR 0.6 mg/1.2 mg	LOZENGES	0.6mg/1.2mg	MAPAEX CONSUMER HEALTHCARE (IRELAND) PRIVATE LIMITED	IRELAND	15942	2025
43	COMBINATIONS	VOXSILL LAMAIE FARA ZAHAR 0.6 mg/1.2 mg	LOZENGES	0.6mg/1.2mg	MAPAEX CONSUMER HEALTHCARE (IRELAND) PRIVATE LIMITED	IRELAND	15943	2025
44	COMBINATIONS	INOVOX FARA ZAHAR 0.6 mg/1.2 mg	LOZENGES	0.6mg/1.2mg	US PHARMACIA SP. Z.O.O.	POLAND	15955	2025
45	COMBINATIONS (ACIDUM ACETYLSALICYLICUM+ ACIDUM ASCORBICUM)	MAXIPIRIN C 400 mg/240 mg	EFFERVESCENT TABLETS	400mg/240 mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	15948	2025

46	COMBINATIONS (ACIDUM ACETYLSALICYLICUM+ PARACETAMOLUM+ CODEINUM)	ASPACO	TABLETS	300mg/250 mg/12mg	BIOEEL MANUFACTURING S.R.L.	ROMANIA	16046	2025
47	COMBINATIONS (BENFOTIAMINUM+ PYRIDOXINUM)	NEURODUOVIT 100mg/100mg	FILM-COATED TABLETS	100mg/100 mg	G.L. PHARMA GMBH	AUSTRIA	16008	2025
48	COMBINATIONS (BUDESONIDUM+ FORMOTEROLUM)	SYMBICORT 80 micrograms/2.25 micrograms/inhalation	PRESSURISED INHALATION SUSPENSION	80micrograms /2.25 micrograms	ASTRAZENECA AB	SWEDEN	15945	2025
49	COMBINATIONS (CALCII CARBONAS+ COLECALCIFEROLUM)	CALCIVID 600 mg/800 IU	FILM-COATED TABLETS	600mg/800 IU	BERES PHARMACEUTICA LS LTD.	HUNGARY	15944	2025
50	COMBINATIONS (CANDESARTANUM CILEXETIL+AMLODIPIN UM)	KANDOSSET 16 mg/10 mg	TABLETS	16mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16047	2025
51	COMBINATIONS (DOXAZOSINUM+ FINASTSERIDUM)	DOXAZOSIN/FINASTERIDA MIP 4 mg/5mg	FILM-COATED TABLETS	4mg/5mg	MIP PHARMA GMBH	GERMANY	16003	2025
52	COMBINATIONS (IBUPROFENUM+ PARACETAMOLUM)	PADUDEN DUO 200 mg/500 mg	FILM-COATED TABLETS	200mg/500 mg	TERAPIA S.A.	ROMANIA	15968	2025
53	COMBINATIONS (PARACETAMOLUM+ IBUPROFENUM)	ELOMEN 1000 mg/300 mg	SOLUTION FOR INFUSION	1000mg/300m g	MEDOCHEMIE LTD.	CYPRUS	15947	2025
54	COMBINATIONS (PARACETAMOLUM+ IBUPROFENUM)	CAFFETIN DUO 500 mg/200 mg	FILM-COATED TABLETS	500mg/200 mg	ALKALOID-INT D.O.O.	SLOVENIA	16015	2025

55	COMBINATIONS (PARACETAMOLUM+ PHENYLEPHRINUM)	COLDACT HOT DRINK 600 mg/12.2 mg	POWDER FOR ORAL SOLUTION IN SACHET	600mg/12.2 mg	TERAPIA S.A.	ROMANIA	15998	2025
56	COMBINATIONS (SITAGLIPTINUM+ DAPAGLIFLOZINUM)	DAGRADUO 100 mg/10 mg	FILM-COATED TABLETS	100mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16116	2025
57	COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	SITAGLIPTIN/METFORMIN GENERINOBEL 50 mg/850 mg	FILM-COATED TABLETS	50mg/850mg	GENERINOBEL GMBH	GERMANY	16057	2025
58	COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	SITAGLIPTIN/METFORMIN GENERINOBEL 50 mg/1000 mg	FILM-COATED TABLETS	50mg/1000 mg	GENERINOBEL GMBH	GERMANY	16058	2025
59	COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	SITAGLIPTIN/METFORMIN GEMAX PHARMA 50 mg/1000 mg	FILM-COATED TABLETS	50mg/1000 mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	16105	2025
60	COMBINATIONS (TELMISARTANUM+ INDAPAMIDUM)	TOLMIDUO 40 mg/1.5 mg	MODIFIED- RELEASE TABLETS	40mg/1.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16028	2025
61	COMBINATIONS (TELMISARTANUM+ INDAPAMIDUM)	TOLMIDUO 80 mg/1.5 mg	MODIFIED- RELEASE TABLETS	80mg/1.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16029	2025
62	COMBINATIONS (TRAMADOLUM+ DEXKETOPROFENUM)	DELXORA 75 mg/25 mg	TABLETS	75mg/25mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16051	2025
63	COMBINATIONS (VILDAGLIPTINUM+ METFORMINUM)	DIPTIVIL DUO 50 mg/850 mg	FILM-COATED TABLETS	50mg/850mg	MSN LABS EUROPE LIMITED	MALTA	16059	2025

64	COMBINATIONS (VILDAGLIPTINUM+ METFORMINUM)	DIPTIVIL DUO 50 mg/1000 mg	FILM-COATED TABLETS	50mg/1000 mg	MSN LABS EUROPE LIMITED	MALTA	16060	2025
65	DAPTOMYCINUM	DAPTOMICINA MIP 350 mg	POWDER FOR SOLUTION FOR INJECTION/INFU SION	350mg	MIP PHARMA GMBH	GERMANY	16035	2025
66	DAPTOMYCINUM	DAPTOMICINA MIP 500 mg	POWDER FOR SOLUTION FOR INJECTION/INFU SION	500mg	MIP PHARMA GMBH	GERMANY	16036	2025
67	DEXAMETHASONUM	DEXAMETAZONA FOSFAT GALENKA 4 mg/ml	SOLUTION FOR INJECTION/INFU SION	4mg/ml	GALENKA INTERNATIONAL KFT.	HUNGARY	15972	2025
68	DICLOFENACUM	DICLAC ACTILONG 23.2 mg/g	GEL	23.2mg/g	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16048	2025
69	DICLOFENACUM	RAPLON 23.2 mg/g	GEL	23.2mg/g	MEDOCHEMIE LTD.	CYPRUS	16122	2025
70	DIMETHYL FUMARATE	ZEIMEM 120 mg	GASTRORESIST ANT CAPSULES	120mg	TERAPIA S.A.	ROMANIA	16001	2025
71	DIMETHYL FUMARATE	ZEIMEM 240 mg	GASTRORESIST ANT CAPSULES	240mg	TERAPIA S.A.	ROMANIA	16002	2025
72	DOXORUBICINUM	DOXLOX 2 mg/ml	CONCENTRATE FOR DISPERSION FOR INFUSION	2 mg/ml	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	16094	2025
73	EDOXABANUM	SETIAPO 15 mg	FILM-COATED TABLETS	15mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15963	2025

74	EDOXABANUM	SETIAPO 30 mg	FILM-COATED TABLETS	30mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15964	2025
75	EDOXABANUM	SETIAPO 60 mg	FILM-COATED TABLETS	60mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15965	2025
76	EDOXABANUM	EDOXABAN STADA 15 mg	FILM-COATED TABLETS	15mg	STADA ARZNEIMITTEL AG	GERMANY	15989	2025
77	EDOXABANUM	EDOXABAN STADA 30 mg	FILM-COATED TABLETS	30mg	STADA ARZNEIMITTEL AG	GERMANY	15990	2025
78	EDOXABANUM	EDOXABAN STADA 60 mg	FILM-COATED TABLETS	60mg	STADA ARZNEIMITTEL AG	GERMANY	15991	2025
79	EDOXABANUM	EDOXABAN TEVA 15 mg	FILM-COATED TABLETS	15mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	16040	2025
80	EDOXABANUM	EDOXABAN TEVA 30 mg	FILM-COATED TABLETS	30mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	16041	2025
81	EDOXABANUM	EDOXABAN TEVA 60 mg	FILM-COATED TABLETS	60mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	16042	2025
82	EDOXABANUM	EDOXABAN ACCORD 15 mg	FILM-COATED TABLETS	15mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	16117	2025

83	EDOXABANUM	EDOXABAN ACCORD 30 mg	FILM-COATED TABLETS	30mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	16118	2025
84	EDOXABANUM	EDOXABAN ACCORD 60 mg	FILM-COATED TABLETS	60mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	16119	2025
85	EDOXABANUM	EDOFLUSIO 15 mg	FILM-COATED TABLETS	15mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16128	2025
86	EDOXABANUM	EDOFLUSIO 30 mg	FILM-COATED TABLETS	30mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16129	2025
87	EDOXABANUM	EDOFLUSIO 60 mg	FILM-COATED TABLETS	60mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16130	2025
88	EFAVIRENZUM+ EMTRICITABINUM+ TENOFOVIRUM DISOPROXIL	EFAVIRENZ/EMTRICITABINA /TENOFOVIR DISOPROXIL ZENTIVA K.S. 600 mg/200 mg/245 mg	FILM-COATED TABLETS	600mg/200 mg/245mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	16102	2025
89	ELTROMBOPAG	ELTROMBOPAG TEVA 25 mg	FILM-COATED TABLETS	25mg	TEVA PHARMACEUTICA LS S.R.L.	ROMANIA	15950	2025
90	ELTROMBOPAG	ELTROMBOPAG TEVA 50 mg	FILM-COATED TABLETS	50mg	TEVA PHARMACEUTICA LS S.R.L.	ROMANIA	15951	2025
91	ELTROMBOPAG	ELTROMBOPAG TEVA 75 mg	FILM-COATED TABLETS	75mg	TEVA PHARMACEUTICA LS S.R.L.	ROMANIA	15952	2025

92	ELTROMBOPAG	ELTROMBOPAG STADA 25 mg	FILM-COATED TABLETS	25mg	STADA ARZNEIMITTEL AG	GERMANY	15976	2025
93	ELTROMBOPAG	ELTROMBOPAG STADA 50 mg	FILM-COATED TABLETS	50mg	STADA ARZNEIMITTEL AG	GERMANY	15977	2025
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96	ELTROMBOPAG	ELTROMBOPAG SANDOZ 25 mg	FILM-COATED TABLETS	25mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	16010	2025
97	ELTROMBOPAG	ELTROMBOPAG SANDOZ 50 mg	FILM-COATED TABLETS	50mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	16011	2025
98	ELTROMBOPAG	ELTROMBOPAG SANDOZ 75 mg	FILM-COATED TABLETS	75mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	16012	2025
99	ELTROMBOPAG	ELTROMBOPAG MSN 25 mg	FILM-COATED TABLETS	25mg	MSN LABS EUROPE LIMITED	MALTA	16053	2025
100	ELTROMBOPAG	ELTROMBOPAG MSN 50 mg	FILM-COATED TABLETS	50mg	MSN LABS EUROPE LIMITED	MALTA	16054	2025

101	ELTROMBOPAG	ELTROMBOPAG MSN 75 mg	FILM-COATED TABLETS	75mg	MSN LABS EUROPE LIMITED	MALTA	16055	2025
102	EMTRICITABINUM+ TENOFIVIRUM DISOPROXIL	EMTRICITABINA/TENOFOVIR DISOPROXIL TILLOMED 200 mg/245 mg	FILM-COATED TABLETS	200mg/245 mg	TILLOMED PHARMA GMBH	GERMANY	15987	2025
103	ENZALUTAMIDUM	ENZALUTAMIDA RHEI 40 mg	FOST CAPSULES	40mg	RHEI LIFE D.O.O.	SLOVENIA	16043	2025
104	FULVESTRANTUM	IMARSA 250 mg	SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	250mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	16050	2025
105	FUROSEMIDUM	FUROSEMID TERAPIA 40 mg	TABLETS	40mg	TERAPIA S.A.	ROMANIA	16108	2025
106	GABAPENTINUM	GABAPENTINA TEVA 100 mg	CAPSULES	100mg	TEVA B.V.	THE NETHERLANDS	15969	2025
107	GABAPENTINUM	GABAPENTINA TEVA 300 mg	CAPSULES	300mg	TEVA B.V.	THE NETHERLANDS	15970	2025
108	GABAPENTINUM	GABAPENTINA TEVA 400 mg	CAPSULES	400mg	TEVA B.V.	THE NETHERLANDS	15971	2025
109	GENTAMICINUM	GENTAMICINA NORIDEM 20 mg/ml	SOLUTION FOR INJECTION/INFU SION	20mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	16095	2025
110	GENTAMICINUM	GENTAMICINA NORIDEM 40 mg/ml	SOLUTION FOR INJECTION/INFU SION	40mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	16096	2025
111	GENTAMICINUM	GENTAMICINA NORIDEM 80 mg/ml	SOLUTION FOR INJECTION/INFU SION	80mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	16097	2025
112	GINKGO BILOBA	GINKGO BILOBA SLAVIA 80 mg	CAPSULES	80mg	SLAVIA PHARM S.R.L.	ROMANIA	16075	2025

113	GINKGO BILOBA	GINKGO BILOBA SLAVIA 120 mg	CAPSULES	120mg	SLAVIA PHARM S.R.L.	ROMANIA	16076	2025
114	IBUPROFENUM	INFLANOR COMPLEX 400 mg	MODIFIED-RELEASE TABLETS	400mg	ZENIVA, K.S.	THE CZECH REPUBLIC	16037	2025
115	KETOTIFENUM	KETAZED 0.25 mg/ml	EYE DROPS, SOLUTION	0.25mg/ml	HORUS PHARMA	FRANCE	16126	2025
116	LEVOFLOXACINUM	FOVELID 500 mg	FILM-COATED TABLETS	500mg	ALKALOID-INT D.O.O.	SLOVENIA	16027	2025
117	LEVONORGESTRELUM	EMERGANA 1.5 mg	TABLETS	1.5mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	16091	2025
118	LINAGLIPTINUM	LINAGLIPTIN MEDOCHEMIE 5 mg	FILM-COATED TABLETS	5mg	MEDOCHEMIE LTD.	CYPRUS	16077	2025
119	LIRAGLUTIDUM	ZEGLUXEN 6 mg/ml	SOLUTION FOR INJECTION IN PRE-FILLED PEN	6mg/ml	ZENIVA, K.S.	THE CZECH REPUBLIC	15979	2025
120	MELDONIUM	MILDRONATE 500 mg/5 ml	SOLUTION FOR INJECTION	500mg/5ml	AS GRINDEKS	LATVIA	16085	2025
121	MEPIVACAINUM	MEPIVACAINA NORMOGEN 30 mg/ml	SOLUTION FOR INJECTION	30mg/ml	LABORATORIOS NORMON, S.A.	SPAIN	15974	2025
122	METAMIZOLUM NATRIUM	METAMIZOL SODIC SOPHARMA 500 mg/ml	SOLUTION FOR INJECTION	500mg/ml	SOPHARMA AD	BULGARIA	16026	2025
123	METAMIZOLUM NATRIUM	METAMIZOL SLAVIA 500 mg	TABLETS	500mg	SLAVIA PHARM S.R.L.	ROMANIA	16107	2025

124	MINOXIDILUM	MINOXIDIL MEDINFAR 20 mg/ml	CUTANEOUS SOLUTION	20mg/ml	LABORATÓRIO MEDINFAR-PRODUTOS FARMACEUTICOS, S.A.	PORTUGAL	16086	2025
125	MINOXIDILUM	MINOXIDIL MEDINFAR 50 mg/ml	CUTANEOUS SOLUTION	50mg/ml	LABORATÓRIO MEDINFAR-PRODUTOS FARMACEUTICOS, S.A.	PORTUGAL	16087	2025
126	OLOPATADINUM	OLOPATADINA UNIMED PHARMA 1 mg/ml	EYE DROPS, SOLUTION	1mg/ml	UNIMED PHARMA SPOL. S R.O.	THE SLOVAK REPUBLIC	15953	2025
127	OLOPATADINUM	OLOPATADINA MISOM 1 mg/ml	EYE DROPS, SOLUTION	1mg/ml	BROWN & BURK IR LIMITED	IRELAND	16125	2025
128	OSELTAMIVIRUM	SINFLU 30 mg	CAPSULES	30mg	ANTIBIOTICE SA	ROMANIA	16089	2025
129	OSELTAMIVIRUM	SINFLU 75 mg	CAPSULES	75mg	ANTIBIOTICE SA	ROMANIA	16090	2025
130	PALIPERIDONUM	PALIPERIDONA TEVA 50 mg	PROLONGED-RELEASE SUSPENSION FOR INJECTION	50mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	15992	2025
131	PALIPERIDONUM	PALIPERIDONA TEVA 75 mg	PROLONGED-RELEASE SUSPENSION FOR INJECTION	75mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	15993	2025

132	PALIPERIDONUM	PALIPERIDONA TEVA 100 mg	PROLONGED- RELEASE SUSPENSION FOR INJECTION	100mg	TEVA PHARMACEUTICA LS S.R.L.	ROMANIA	15994	2025
133	PALIPERIDONUM	PALIPERIDONA TEVA 150 mg	PROLONGED- RELEASE SUSPENSION FOR INJECTION	150mg	TEVA PHARMACEUTICA LS S.R.L.	ROMANIA	15995	2025
134	PARACETAMOLUM	PARACETAMOL RAPID TEVA 500 mg	FILM-COATED TABLETS	500mg	TEVA PHARMACEUTICA LS S.R.L.	ROMANIA	16115	2025
135	PARACETAMOLUM	FERVEX DURERE SI FEBRA INSTANT 250 mg	GRANULES IN SACHET	250mg	UPSA SAS	FRANCE	16018	2025
136	PARACETAMOLUM	FERVEX DURERE SI FEBRA INSTANT 500 mg	GRANULES IN SACHET	500mg	UPSA SAS	FRANCE	16019	2025
137	PARACETAMOLUM	FERVEX DURERE SI FEBRA INSTANT FORTE 1000 mg	GRANULES IN SACHET	1000mg	UPSA SAS	FRANCE	16020	2025
138	PARICALCITOLUM	REXTOL 5 micrograms/ml	SOLUTION FOR INJECTION	5micrograms/ ml	HEATON K.S.	THE CZECH REPUBLIC	15954	2025
139	PAZOPANIBUM	PAZOPANIB DR. REDDY'S 200 mg	FILM-COATED TABLETS	200mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	15981	2025
140	PAZOPANIBUM	PAZOPANIB DR. REDDY'S 400 mg	FILM-COATED TABLETS	400mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	15982	2025
141	PEMETREXEDUM	PEMETREXED SANDOZ 25 mg/ml	CONCENTRATE FOR SOLUTION FOR INFUSION	25mg/ml	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16088	2025

142	PIROXICAMUM	FLAMEXIN 20 mg	TABLETS	20mg	CHIESI FARMACEUTICI SPA	ITALY	15961	2025
143	PLANTE	DENTOSEPT 0.91 g/ml	CONCENTRATE FOR OROMUCOSAL SOLUTION	0.91g/ml	PHYTOPHARM KLEKA S.A.	POLAND	16034	2025
144	PLANTE (VITEX AGNUS CASTUS)	FEMIPLANTE	CAPSULES		SCHAPER&BRÜM MER GMBH & CO. KG	GERMANY	15962	2025
145	POMALIDOMIDUM	POMALIDOMIDA STADA 1 mg	CAPSULES	1mg	STADA ARZNEIMITTEL AG	GERMANY	16064	2025
146	POMALIDOMIDUM	POMALIDOMIDA STADA 2 mg	CAPSULES	2mg	STADA ARZNEIMITTEL AG	GERMANY	16065	2025
147	POMALIDOMIDUM	POMALIDOMIDA STADA 3 mg	CAPSULES	3mg	STADA ARZNEIMITTEL AG	GERMANY	16066	2025
148	POMALIDOMIDUM	POMALIDOMIDA STADA 4 mg	CAPSULES	4mg	STADA ARZNEIMITTEL AG	GERMANY	16067	2025
149	RALTEGRAVIRUM	RALTEGRAVIR ZENTIVA 600 mg	FILM-COATED TABLETS	600mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	16131	2025
150	RIVAROXABANUM	XANIRVA 10 mg	CAPSULES	10mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	16098	2025
151	RIVAROXABANUM	XANIRVA 15 mg	CAPSULES	15mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	16099	2025

152	RIVAROXABANUM	XANIRVA 20 mg	CAPSULES	20mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	16100	2025
153	RIVAROXABANUM	DIWLEIZ 2.5 mg	FILM-COATED TABLETS	2.5mg	MSN LABS EUROPE LIMITED	MALTA	16068	2025
154	RIVAROXABANUM	DIWLEIZ 10 mg	FILM-COATED TABLETS	10mg	MSN LABS EUROPE LIMITED	MALTA	16069	2025
155	RIVAROXABANUM	DIWLEIZ 15 mg	FILM-COATED TABLETS	15mg	MSN LABS EUROPE LIMITED	MALTA	16070	2025
156	RIVAROXABANUM	DIWLEIZ 20 mg	FILM-COATED TABLETS	20mg	MSN LABS EUROPE LIMITED	MALTA	16071	2025
157	SILDENAFILUM	SILDENAFIL STADA 25 mg	CHEWABLE TABLETS	25mg	STADA M&D S.R.L.	ROMANIA	16112	2025
158	SILDENAFILUM	SILDENAFIL STADA 50 mg	CHEWABLE TABLETS	50mg	STADA M&D S.R.L.	ROMANIA	16113	2025
159	SILDENAFILUM	SILDENAFIL SANEXCEL 100 mg	FILM-COATED TABLETS	100mg	J.J.BISHOP HEALTH A.S.	THE CZECH REPUBLIC	16114	2025
160	SITAGLIPTINUM	SITAGLIPTIN GEMAX PHARMA 100 mg	FILM-COATED TABLETS	100mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	16017	2025
161	SITAGLIPTINUM	SITAGLIPTINA ATB 100 mg	FILM-COATED TABLETS	100mg	ANTIBIOTICE S.A.	ROMANIA	16033	2025
162	SITAGLIPTINUM	SITAGLIPTIN GENERINOBEL 25 mg	FILM-COATED TABLETS	25mg	GENERINOBEL GMBH	GERMANY	16072	2025
163	SITAGLIPTINUM	SITAGLIPTIN GENERINOBEL 50 mg	FILM-COATED TABLETS	50mg	GENERINOBEL GMBH	GERMANY	16073	2025

164	SITAGLIPTINUM	SITAGLIPTIN GENERINOBEL 100 mg	FILM-COATED TABLETS	100mg	GENERINOBEL GMBH	GERMANY	16074	2025
165	SORAFENIBUM	SORAFENIB SANDOZ 200 mg	FILM-COATED TABLETS	200mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	16111	2025
166	SORAFENIBUM	SORAFENIB STADA 200 mg	FILM-COATED TABLETS	200mg	STADA M&D S.R.L.	ROMANIA	15986	2025
167	SORAFENIBUM	SORAFENIB ZENTIVA 200mg	FILM-COATED TABLETS	200mg	ZENTIVA K.S.	THE CZECH REPUBLIC	16056	2025
168	SORAFENIBUM	SORAFENIB DR. REDDY'S 200 mg	FILM-COATED TABLETS	200mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	15946	2025
169	SUGAMMADEXUM	SUGAMMADEX ACCORD 100 mg/ml	SOLUTION FOR INJECTION	100mg/ml	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15980	2025
170	SULFAMETHOXAZOLUM + TRIMETHOPRIMUM	DUBLUSEPTOL 480 mg	TABLETS	400mg+80 mg	APC INSTYTUT SP. Z O.O.	POLAND	16120	2025
171	SUMATRIPTANUM	SUMATRIPTAN SUN 3 mg/0.5 ml	SOLUTION FOR INJECTION IN PRE-FILLED PEN	3mg/0.5ml	SUN PHARMACEUTICA L INDUSTRIES EUROPE B.V.	THE NETHERLANDS	15949	2025
172	TEICOPLANINUM	TEICOPLANINA ROMPHARM 200 mg	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFU SION OR ORAL SOLUTION	200mg	ROMPHARM COMPANY S.R.L.	ROMANIA	16103	2025

173	TEICOPLANINUM	TEICOPLANINA ROMPHARM 400 mg	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFU SION OR ORAL SOLUTION	400mg	ROMPHARM COMPANY S.R.L.	ROMANIA	16104	2025
174	TERIFLUNOMIDUM	TERIFLUNOMIDA TERAPIA 14 mg	FILM-COATED TABLETS	14mg	TERAPIA S.A.	ROMANIA	15985	2025
175	TESTOSTERONUM	ANDROJECT 1000 mg/4ml	SOLUTION FOR INJECTION	1000mg/4ml	BESINS HEALTHCARE SA	BELGIUM	16032	2025
176	TICAGRELOR	TICAGRELOR TERAPIA 60 mg	FILM-COATED TABLETS	60mg	TERAPIA S.A.	ROMANIA	16013	2025
177	TICAGRELOR	TICAGRELOR TERAPIA 90 mg	FILM-COATED TABLETS	90mg	TERAPIA S.A.	ROMANIA	16014	2025
178	TIOTROPIUM	TIOTROPIU VIATRIS 18 micrograms	POWDER FOR INHALATION IN CAPSULE	18micrograms	VIATRIS LIMITED	IRELAND	16127	2025
179	TRAZODONUM	TRITTICO EP 150 mg	PROLONGED- RELEASE TABLETS	150mg	ACR ANGELINI FRANCESCO S.P.A.	ITALY	15958	2025
180	TRAZODONUM	TRITTICO EP 300 mg	PROLONGED- RELEASE TABLETS	300mg	ACR ANGELINI FRANCESCO S.P.A.	ITALY	15959	2025
181	TRIPTORELINUM	DIPHERELINE 22.5 mg	POWDER AND SOLVENT FOR PROLONGED- RELEASE SUSPENSION FOR INJECTION	22.5mg	IPSEN PHARMA	FRANCE	16121	2025
182	VANCOMYCINUM	CEDEPOS 125 mg	CAPSULES	125mg	HEATON K.S.	THE CZECH REPUBLIC	15988	2025

183	VILDAGLIPTINUM	MELKART 50 mg	TABLETS	50mg	G.L. PHARMA GMBH	AUSTRIA	16110	2025
184	VILDAGLIPTINUM	DIPTIVIL 50 mg	TABLETS	50mg	MSN LABS EUROPE LIMITED	MALTA	16109	2025
185	VORTIOXETINUM	VARESTA 5 mg	FILM-COATED TABLETS	5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16004	2025
186	VORTIOXETINUM	VARESTA 10 mg	FILM-COATED TABLETS	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16005	2025
187	VORTIOXETINUM	VARESTA 15 mg	FILM-COATED TABLETS	15mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16006	2025
188	VORTIOXETINUM	VARESTA 20 mg	FILM-COATED TABLETS	20mg	KRKA, D.D., NOVO MESTO	SLOVENIA	16007	2025
189	ZONISAMIDUM	ZONISAMIDA DESITIN 20 mg/ml	ORAL SUSPENSION	20mg/ml	DESTITIN ARZNEIMITTEL GMBH	GERMANY	15973	2025

EMA centrally authorised medicinal products notified for marketing in Romania during the 2nd quarter of 2025

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	AFLIBERCEPTUM	PAVBLU 40 mg/ml	SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	40mg/ml	AMGEN TECHNOLOGY (IRELAND) UC	IRELAND	1909	2025

2	AFLIBERCEPTUM	PAVBLU 40 mg/ml	SOLUTION FOR INJECTION	40mg/ml	AMGEN TECHNOLOGY (IRELAND) UC	IRELAND	1909	2025
3	BEREMAGENUM GEPERPAVECUM	VYJUVEK 5×10 ^{9} plaque forming units /ml	SUSPENSION AND GEL FOR GEL	5×10 ^{9} UFP/ml	KRYSTAL BIOTECH NETHERLANDS, B.V.	THE NETHERLANDS	1918	2025
4	DENOSUMABUM	YAXWER 120 mg	SOLUTION FOR INJECTION	70mg/ml	GEDEON RICHTER PLC.	HUNGARY	1934	2025
5	DENOSUMABUM	OSVYRTI 60 mg	SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	60mg/ml	ACCORD HEALTHCARE S.L.U.	SPAIN	1922	2025
6	DENOSUMABUM	JUBEREQ 120 mg	SOLUTION FOR INJECTION	70mg/ml	ACCORD HEALTHCARE S.L.U.	SPAIN	1921	2025
7	DENOSUMABUM	JUNOD 60 mg	SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	60mg/ml	GEDEON RICHTER PLC.	HUNGARY	1933	2025
8	DENOSUMABUM	ZADENVI 60 mg	SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	60 mg/ml	ZENTIVA K.S.	THE CZECH REPUBLIC	1937	2025
9	DENOSUMABUM	ENWYLMA 120 mg	SOLUTION FOR INJECTION	70mg/ml	ZENTIVA K.S.	THE CZECH REPUBLIC	1944	2025
10	DENOSUMABUM	DENBRAYCE 120 mg	SOLUTION FOR INJECTION	70mg/ml	MABXIENCE RESEARCH SL	SPAIN	1936	2025
11	SEPIAPTERINUM	SEPHIENCE 250 mg	ORAL POWDER IN SACHET	250mg	PTC THERAPEUTICS INTERNATIONAL LIMITED	IRELAND	1939	2025

12	SEPIAPTERINUM	SEPHIENCE 1000 mg	ORAL POWDER IN SACHET	1000mg	PTC THERAPEUTICS INTERNATIONAL LIMITED	IRELAND	1939	2025
13	TRABECTEDINUM	TRABECTEDIN ACCORD 0.25 mg	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	0.25mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1902	2025
14	TRABECTEDINUM	TRABECTEDIN ACCORD 1 mg	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	1mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1902	2025