

ROMANIA

Informative bulletin

Year 25, No. 2 (98), 2nd quarter of 2023

*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 the following:

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

a) The 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;

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

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 the 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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Government Decisions

Government Decision no. 1336/2022 on approval of the framework regulation on the organisation and career development of contractual staff in the budgetary sector paid from public funds, as further amended and supplemented, as attached

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, republished, as further amended and supplemented

Orders of the Minister of Health

Order of the Ministry of Health no. 1772/2023 on approval of the conditions regarding the temporary authorisation of the distribution of an unauthorised medicinal product, purchased by the Ministry of Health from the Global Drug Facility (GDF) with financing from the Global Fund, in order to use it in national public health programs

Order of the Minister of Health no. 1346/2023 on amendment and supplementation of Order of the Minister of Health no. 368/2017 on approval of the Rules regarding the method of calculation and the procedure for approval of the maximum prices of medicinal products for human use, as further amended and supplemented

Order of the Minister of Health no. 1540/2021 on approval of the Rules for implementation of provisions of Article 883 of Law 95/2006 on healthcare reform regarding the authorisation for marketing of some medicinal products needed on grounds of public health, as further amended and supplemented, as attached

Order of the Ministry of Health no. 368/2017 on approval of the Rules regarding the method of calculation and the procedure for approval of the maximum prices of medicinal products for human use, as further amended and supplemented

Order of the Minister of Health no. 861/2014 for approval of criteria and methodology for assessment of health technologies, of documentation to be submitted by applicants, methodological means used in the assessment for inclusion, extension of indications, non-inclusion into or exclusion from 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 programmes, as well as the means for appeal thereof, as further amended and supplemented

Order of the Minister of Health no. 85/2013 on approval of the Norms for implementation of provisions of Article 703 (1) and (2) of Law No. 95/2006 on healthcare reform concerning medicinal products for special needs, as further amended and supplemented

Medicinal product batches recalled during the 2nd quarter of 2023

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/MAH	Batch	Grounds for recall	Proposed action	D r
1	Pentoxifilină SR Zentiva 600 mg comprimate cu eliberare prelungită	Prolonged-release tablets	600 mg	pentoxifylline	ZENTIVA a.s., the Slovak Republic	3611221/exp.11.2024, 3621221/exp11.2024, 3630221/exp.01.2024, 3631221/exp.11.2024, 3680322/exp. 02.2025, 3690322/02.2025, 3730721/exp.06.2024, 3740721/exp.06.2024, 3750721/exp. 06.2024, 3760721/exp. 06.2024, 3810721/exp.06.2024, 3830721/exp.06.2024, 3840721/exp.06.2024, 3850721/exp.06.2024, 3921120/exp.10.2023.	Voluntary recall from the market (manufacturing incapacity)	Recall from the market	20.
2	Saridon 250 mg/ 150 mg/ 50 mg comprimate	tablets	250 mg/ 150 mg/ 50 mg	Propyphenazone/paracetamol/caffeine	BAYER S.R.L. Romania	N3K511/expiry date 10.2027	Voluntary recall from the market following the identification of a deviation at the manufacturer	Voluntary recall from the market	08.
3	Komboglyze 2.5mg/100mg	film-coated tablets	2.5mg/100mg	Saxagliptinum + Metforminum	Astrazeneca AB, Sweden		Voluntary recall from the market following the expiry of the shelf-life:	Voluntary recall from the market	11.

								maximum price in the CaNaMed for the 60 film- coated tablets packaging size	
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**Applications for marketing authorisation/marketing authorisation renewal
received during the 1st quarter of 2023**

In the 1st quarter of 2023, 4 marketing authorisation renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

A03 - DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS
A03 - DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS
R07 - OTHER RESPIRATORY SYSTEM PRODUCTS
XR – HOMEOPATHIC MEDICINAL PRODUCT

Medicinal products authorised for marketing during the 1st quarter of 2023

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.		
1	ABACAVIRUM+ LAMIVUDINUM	ABACAVIR/LAMIVUDINA MYLAN 600 mg/300 mg	film-coated tablets	600mg/ 300mg	MYLAN PHARMACEUTICALS LIMITED	IRELAND	1485 2	2023	01
2	ACENOCUMAROLUM	TROMBOSTOP 2 mg	tablets	2mg	TERAPIA S.A.	ROMANIA	1488 6	2023	01
3	ACETYLCYSTEINUM	ACETILCISTEINA ROMPHARM 600 mg	effervescent tablets	600mg	ROMPHARM COMPANY S.R.L.	ROMANIA	1490 5	2023	01
4	ACICLOVIRUM	ACICLOVIR NORIDEM 250 mg	powder for solution for infusion	250mg	NORIDEM ENTERPRISES LIMITED	CYPRUS	1488 7	2023	01
5	ACICLOVIRUM	ACICLOVIR NORIDEM 500 mg	powder for solution for infusion	500mg	NORIDEM ENTERPRISES LIMITED	CYPRUS	1488 8	2023	01
6	ACIDUM ALENDRONICUM+ COLECALCIFEROLUM	ACID ALENDRONIC/ COLECALCIFEROL ZENTIVA 70 mg/2800 UI	tablets	70mg/ 2800IU	ZENTIVA, K.S.	THE CZECH REPUBLIC	1496 5	2023	01
7	ACIDUM ALENDRONICUM+ COLECALCIFEROLUM	ACID ALENDRONIC/ COLECALCIFEROL ZENTIVA 70 mg/5600 UI	tablets	70mg/ 5600IU	ZENTIVA, K.S.	THE CZECH REPUBLIC	1496 6	2023	01

8	ATOMOXETINUM	ATOFAB 10 mg	capsules	10mg	LANNACHER HEILMITTEL GES.M.B.H	AUSTRIA	1484 5	2023	01
9	ATOMOXETINUM	ATOFAB 18 mg	capsules	18mg	LANNACHER HEILMITTEL GES.M.B.H	AUSTRIA	1484 6	2023	01
10	ATOMOXETINUM	ATOFAB 25 mg	capsules	25mg	LANNACHER HEILMITTEL GES.M.B.H	AUSTRIA	1484 7	2023	01
11	ATOMOXETINUM	ATOFAB 40 mg	capsules	40mg	LANNACHER HEILMITTEL GES.M.B.H	AUSTRIA	1484 8	2023	01
12	ATOMOXETINUM	ATOFAB 60 mg	capsules	60mg	LANNACHER HEILMITTEL GES.M.B.H	AUSTRIA	1484 9	2023	01
13	AXITINIBUM	AXITINIB STADA 1 mg	film-coated tablets	1mg	STADA M&D SRL	ROMANIA	1496 2	2023	01
14	AXITINIBUM	AXITINIB STADA 5 mg	film-coated tablets	5mg	STADA M&D SRL	ROMANIA	1496 3	2023	01
15	BILASTINUM	BORENAR 20 mg	orodispersible tablets	20mg	MENARINI INTERNATION AL OPERATIONS LUXEMBOUR G S.A.	LUXEMBOUR G	1495 8	2023	01
16	BLEOMYCINUM SULFAS	BLEOMICINA ACCORD 15000IU	powder for solution for injection/infusion	15000IU	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	1488 4	2023	01

17	BORTEZOMIBUM	BORTEZOMIB EVER PHARMA 2.5 mg/ml	solution for injection	2.5mg/ml	EVER VALINJECT GMBH	AUSTRIA	14860	2023	01
18	BUTYLSCOPOLAMMONII BROMIDUM	BYSIMIN 20 mg/ml	solution for injection	20mg/ml	MEDOCHEMIE LTD.	CYPRUS	14859	2023	01
19	CABAZITAXELUM	CABAZITAXEL STADA 20 mg/ml	concentrate for solution for infusion	20mg/ml	STADA M&D SRL	ROMANIA	14868	2023	01
20	CHLORTALIDONUM	ULDIULAN 12.5 mg	tablets	12.5mg	G.L. PHARMA GMBH	AUSTRIA	14871	2023	01
21	CHLORTALIDONUM	ULDIULAN 25 mg	tablets	25mg	G.L. PHARMA GMBH	AUSTRIA	14872	2023	01
22	CHLORTALIDONUM	ULDIULAN 50 mg	tablets	50mg	G.L. PHARMA GMBH	AUSTRIA	14873	2023	01
23	COMBINAȚII	PLENVU	powder for oral solution		NORGINE B.V.	HOLLAND	14857	2023	01
24	COMBINAȚII (BACITRACINUM+ NEOMICINUM)	ZINBA 250IU/5000IU/g	ointment	250IU/5000IU/g	ANTIBIOTICE S.A.	ROMANIA	14833	2023	01
25	COMBINAȚII (CIPROFLOXACINUM+ FLUOCINOLONUM)	CEXIDAL 3 mg/0.25 mg/ml	ear drops, solution in single dose recipient	3mg/0.25mg/ml	LABORATORI OS SALVAT S.A.	SPAIN	14854	2023	01
26	COMBINAȚII (PARACETAMOLUM+ GUAIFENESINUM+ PHENYLEPHRINUM)	COLDREX RACEALA SI TUSE 500 mg/200 mg/10 mg	powder for oral solution	500mg/200mg/10mg	PERRIGO ROMANIA S.R.L.	ROMANIA	14903	2023	01

27	COMBINAȚII (SOLIFENACINUM SUCCINATE+ TAMSULOSINUM)	ZELIFTAN 6 mg/0.4 mg	modified-release tablets	6mg/ 0.4mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	1489 1	2023	01
28	COMBINAȚII (SOLIFENACINUM SUCCINATE+ TAMSULOSINUM)	SOLIFENACIN/ TAMSULOSIN TEVA 6 mg/0.4 mg	modified-release tablets	6mg/ 0.4mg	TEVA B.V.	HOLLAND	1490 0	2023	01
29	COMBINAȚII (VILDAGLIPTINUM+ METFORMINUM)	DALTEX 50 mg/850 mg	film-coated tablets	50mg/ 850mg	MEDOCHEMIE LTD.	CYPRUS	1483 9	2023	01
30	COMBINAȚII (VILDAGLIPTINUM+ METFORMINUM)	DALTEX 50 mg/1000 mg	film-coated tablets	50mg/ 1000mg	MEDOCHEMIE LTD.	CYPRUS	1484 0	2023	01
31	DASATINIBUM	DASATINIB STADA 20 mg	film-coated tablets	20mg	STADA M&D SRL	ROMANIA	1491 9	2023	01
32	DASATINIBUM	DASATINIB STADA 50 mg	film-coated tablets	50mg	STADA M&D SRL	ROMANIA	1492 0	2023	01
33	DASATINIBUM	DASATINIB STADA 100 mg	film-coated tablets	100mg	STADA M&D SRL	ROMANIA	1492 1	2023	01
34	DESLORATADINUM	DASERGIN 5 mg	film-coated tablets	5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1496 4	2023	01
35	DEXMEDETOMIDINUM	DEXMEDETOMIDINA EVER VALINJECT 100 micrograme/ml	concentrate for solution for infusion	100micro- grams/ml	EVER VALINJECT GMBH	AUSTRIA	1495 9	2023	01
36	DICLOFENACUM	DICLOFENAC SLAVIA 10 mg/g	gel	10mg/g	SLAVIA PHARM S.R.L.	ROMANIA	1489 8	2023	01

37	DIOXID DE CARBON	DIOXID DE CARBON LINDE 100%	medicinal gas, liquified	100%	LINDE GAZ MAGYARORSZ AG ZRT.	HUNGARY	1496 7	2023	01
38	ENOXAPARINUM	HEPAXANE 10000 UI (100 mg)/1 ml	solution for injection in pre- filled syringe	10000IU (100mg)/ 1ml	CHEMI S.P.A	ITALY	1493 6	2023	01
39	ENOXAPARINUM	HEPAXANE 12000 UI (120 mg)/0.8 ml	solution for injection in pre- filled syringe	12000IU (120mg)/ 0.8ml	CHEMI S.P.A	ITALY	1493 7	2023	01
40	ENOXAPARINUM	HEPAXANE 15000 UI (150 mg)/1 ml	solution for injection in pre- filled syringe	15000IU (150mg)/ 1ml	CHEMI S.P.A	ITALY	1493 8	2023	01
41	ENOXAPARINUM	HEPAXANE 2000 UI (20 mg)/0.2 ml	solution for injection in pre- filled syringe	2000IU (20mg)/ 0.2ml	CHEMI S.P.A	ITALY	1493 2	2023	01
42	ENOXAPARINUM	HEPAXANE 4000 UI (40 mg)/0.4 ml	solution for injection in pre- filled syringe	4000IU (40mg)/ 0.4ml	CHEMI S.P.A	ITALY	1493 3	2023	01
43	ENOXAPARINUM	HEPAXANE 6000 UI (60 mg)/0.6 ml	solution for injection in pre- filled syringe	6000IU (60mg)/ 0.6ml	CHEMI S.P.A	ITALY	1493 4	2023	01
44	ENOXAPARINUM	HEPAXANE 8000 UI (80 mg)/0.8 ml	solution for injection in pre- filled syringe	8000IU (80mg)/ 0.8ml	CHEMI S.P.A	ITALY	1493 5	2023	01
45	ENTECAVIRUM	ENTECAVIR LABORMED 0.5 mg	film-coated tablets	0.5mg	LABORMED PHARMA S.A.	ROMANIA	1483 7	2023	01
46	ENTECAVIRUM	ENTECAVIR LABORMED 1 mg	film-coated tablets	1mg	LABORMED PHARMA S.A.	ROMANIA	1483 8	2023	01

47	EPINEPHRINUM	JEXT 150 micrograme	solution for injection in pre-filled pen	150 micrograms	ALK-ABELLÓ A/S	DENMARK	14896	2023	01
48	EPINEPHRINUM	JEXT 300 micrograme	solution for injection in pre-filled pen	300 micrograms	ALK-ABELLÓ A/S	DENMARK	14897	2023	01
49	ERTAPENEMUM	ERTAPENEM AUROBINDO 1 g	powder for concentrate for solution for infusion	1g	EUGIA PHARMA (MALTA) LTD.	MALTA	14895	2023	01
50	ETOFENAMATUM	ETOFENAMAT PHAGECON 100 mg/g	gel	100mg/g	PHAGECON - SERVICOS E CONSULTORIA FARMACEUTICA LDA	PORTUGAL	14906	2023	01
51	FERRI CARBOXYMALTOSUM	XABOGARD 50 mg fer/ml	solution for injection/infusion	50mg/ml	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	14841	2023	01
52	FLUMAZENILUM	FLUMAZENIL PANPHARMA 0.1 mg/ml	solution for injection/infusion	0.1mg/ml	PANPHARMA	FRANCE	14894	2023	01
53	FUROSEMIDUM	FUROSEMID HAMELN 10 mg/ml	solution for injection	10mg/ml	HAMELN PHARMA GMBH	GERMANY	14889	2023	01
54	GOSERELINUM	RESELIGO 3.6 mg	implant in pre-filled syringe	3.6mg	LABORMED PHARMA S.A.	ROMANIA	14901	2023	01

55	GOSERELINUM	RESELIGO 10.8 mg	implant in pre-filled syringe	10.8mg	LABORMED PHARMA S.A.	ROMANIA	14902	2023	01
56	HOMEOPATE	MEDICAMENTE HOMEOPATICE UNITARE PLANTEXTRAKT	oral drops, solution		PLANTEXTRA KT S.R.L.	ROMANIA	14890	2023	01
57	IBUPROFENUM	NUROFEN MINEXPRESS 400 mg	soft capsules	400mg	RECKITT BENCKISER (ROMANIA) SRL	ROMANIA	14870	2023	01
58	IMUNOGLOBULINA UMANA ANTI-CITOMEGALOVIRUS	CYTOTECT CP BIOTEST 100 U/ml	solution for infusion	100U/ml	BIOTEST PHARMA GMBH	GERMANY	14855	2023	01
59	LENALIDOMIDUM	LENALIDOMIDA LABORMED 5 mg	capsules	5mg	LABORMED PHARMA S.A.	ROMANIA	14926	2023	01
60	LENALIDOMIDUM	LENALIDOMIDA LABORMED 10 mg	capsules	10mg	LABORMED PHARMA S.A.	ROMANIA	14927	2023	01
61	LENALIDOMIDUM	LENALIDOMIDA LABORMED 15 mg	capsules	15mg	LABORMED PHARMA S.A.	ROMANIA	14928	2023	01
62	LENALIDOMIDUM	LENALIDOMIDA LABORMED 25 mg	capsules	25mg	LABORMED PHARMA S.A.	ROMANIA	14929	2023	01
63	LENALIDOMIDUM	LENALIDOMIDA STADA 2.5 mg	capsules	2.5mg	STADA M&D SRL	ROMANIA	14939	2023	01
64	LENALIDOMIDUM	LENALIDOMIDA STADA 5 mg	capsules	5mg	STADA M&D SRL	ROMANIA	14940	2023	01
65	LENALIDOMIDUM	LENALIDOMIDA STADA 7.5 mg	capsules	7.5mg	STADA M&D SRL	ROMANIA	14941	2023	01
66	LENALIDOMIDUM	LENALIDOMIDA STADA 10 mg	capsules	10mg	STADA M&D SRL	ROMANIA	14942	2023	01

67	LENALIDOMIDUM	LENALIDOMIDA STADA 15 mg	capsules	15mg	STADA M&D SRL	ROMANIA	1494 3	2023	01
68	LENALIDOMIDUM	LENALIDOMIDA STADA 20 mg	capsules	20mg	STADA M&D SRL	ROMANIA	1494 4	2023	01
69	LENALIDOMIDUM	LENALIDOMIDA STADA 25 mg	capsules	25mg	STADA M&D SRL	ROMANIA	1494 5	2023	01
70	LISDEXAMFETAMINUM	LISDEXAMFETAMINA ADALVO 20 mg	capsules	20 mg	ADALVO LIMITED	MALTA	1490 7	2023	01
71	LISDEXAMFETAMINUM	LISDEXAMFETAMINA ADALVO 30 mg	capsules	30 mg	ADALVO LIMITED	MALTA	1490 8	2023	01
72	LISDEXAMFETAMINUM	LISDEXAMFETAMINA ADALVO 40 mg	capsules	40 mg	ADALVO LIMITED	MALTA	1490 9	2023	01
73	LISDEXAMFETAMINUM	LISDEXAMFETAMINA ADALVO 50 mg	capsules	50 mg	ADALVO LIMITED	MALTA	1491 0	2023	01
74	LISDEXAMFETAMINUM	LISDEXAMFETAMINA ADALVO 60 mg	capsules	60 mg	ADALVO LIMITED	MALTA	1491 1	2023	01
75	LISDEXAMFETAMINUM	LISDEXAMFETAMINA ADALVO 70 mg	capsules	70 mg	ADALVO LIMITED	MALTA	1491 2	2023	01
76	LISDEXAMFETAMINUM	LISDEXAMFETAMINA STADA 20 mg	capsules	20mg	STADA M&D S.R.L.	ROMANIA	1491 3	2023	01
77	LISDEXAMFETAMINUM	LISDEXAMFETAMINA STADA 30 mg	capsules	30mg	STADA M&D S.R.L.	ROMANIA	1491 4	2023	01

78	LISDEXAMFETAMINUM	LISDEXAMFETAMINA STADA 40 mg	capsules	40mg	STADA M&D S.R.L.	ROMANIA	1491 5	2023	01
79	LISDEXAMFETAMINUM	LISDEXAMFETAMINA STADA 50 mg	capsules	50mg	STADA M&D S.R.L.	ROMANIA	1491 6	2023	01
80	LISDEXAMFETAMINUM	LISDEXAMFETAMINA STADA 60 mg	capsules	60mg	STADA M&D S.R.L.	ROMANIA	1491 7	2023	01
81	LISDEXAMFETAMINUM	LISDEXAMFETAMINA STADA 70 mg	capsules	70mg	STADA M&D S.R.L.	ROMANIA	1491 8	2023	01
82	LISINOPRILUM	LISINOPRIL GRINDEKS 5 mg	tablets	5mg	AS GRINDEKS	LATVIA	1494 6	2023	01
83	LISINOPRILUM	LISINOPRIL GRINDEKS 10 mg	tablets	10mg	AS GRINDEKS	LATVIA	1494 7	2023	01
84	LISINOPRILUM	LISINOPRIL GRINDEKS 20 mg	tablets	20mg	AS GRINDEKS	LATVIA	1494 8	2023	01
85	MACROGOLUM	PROCTOLAX 10 g	powder for oral solution, sachet	10g	CASEN RECORDATI, S.L.	SPAIN	1496 1	2023	01
86	MENOTROPINUM	MERIOFERT PFS 900IU	powder and solvent for solution for injection	900IU	IBSA FARMACEUTI CI ITALY SRL	ITALY	1486 9	2023	01
87	MEROPENEMUM	MEROPENEM APTAPHARMA 2000 mg	powder for solution for infusion	2000mg	APTA MEDICA INTERNACION AL D.O.O.	SLOVENIA	1489 2	2023	01
88	MEROPENEMUM	MEROPENEM KALCEKS 500 mg	powder for solution for injection/infusion	500mg	AS KALCEKS	LATVIA	1494 9	2023	01
89	MEROPENEMUM	MEROPENEM KALCEKS 1 g	powder for solution for	1g	AS KALCEKS	LATVIA	1495 0	2023	01

			injection/infusion						
90	METFORMINUM	XUVELEX XR 500 mg	prolonged-release tablets	500 mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	14861	2023	01
91	METFORMINUM	XUVELEX XR 750 mg	prolonged-release tablets	750 mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	14862	2023	01
92	METFORMINUM	XUVELEX XR 1000 mg	prolonged-release tablets	1000 mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	14863	2023	01
93	METFORMINUM	METFORMIN TEVA 500 mg	film-coated tablets	500mg	TEVA B.V.	HOLLAND	14865	2023	01
94	METFORMINUM	METFORMIN TEVA 1000 mg	film-coated tablets	1000mg	TEVA B.V.	HOLLAND	14866	2023	01
95	OMEPRAZOLUM	OMEPRAZOL ZENTIVA 40 mg	powder for solution for infusion	40mg	ZENTIVA K.S.	THE CZECH REPUBLIC	14850	2023	01
96	PEMETREXEDUM	PEMETREXED ZENTIVA 25 mg/ml	concentrate for solution for infusion	25mg/ml	ZENTIVA K.S.	THE CZECH REPUBLIC	14851	2023	01
97	PLANTE	BRONCHIPRET TP	film-coated tablets		BIONORICA SE	GERMANY	14853	2023	01
98	PLERIXAFORUM	PLERIXAFOR ONKOGEN 20 mg/ml	solution for injection	20mg/ml	ONKOGEN KFT.	HUNGARY	14960	2023	01
99	RAMIPRILUM	RAMIPRIL-AC 2.5 mg	tablets	2.5mg	AC HELCOR PHARMA S.R.L.	ROMANIA	14834	2023	01

100	RAMIPRILUM	RAMIPRIL-AC 5 mg	tablets	5mg	AC HELCOR PHARMA S.R.L.	ROMANIA	14835	2023	01
101	RAMIPRILUM	RAMIPRIL-AC 10 mg	tablets	10mg	AC HELCOR PHARMA S.R.L.	ROMANIA	14836	2023	01
102	RIVAROXABANUM	XILTESS 2.5 mg	film-coated tablets	2.5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	14880	2023	01
103	RIVAROXABANUM	XILTESS 10 mg	film-coated tablets	10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	14881	2023	01
104	RIVAROXABANUM	XILTESS 15 mg	film-coated tablets	15mg	EGIS PHARMACEUTICALS PLC	HUNGARY	14882	2023	01
105	RIVAROXABANUM	XILTESS 20 mg	film-coated tablets	20mg	EGIS PHARMACEUTICALS PLC	HUNGARY	14883	2023	01
106	RIVAROXABANUM	RIVAROXABAN STADA 15 mg	capsules	15mg	STADA M&D S.R.L.	ROMANIA	14874	2023	01
107	RIVAROXABANUM	RIVAROXABAN STADA 20 mg	capsules	20mg	STADA M&D S.R.L.	ROMANIA	14875	2023	01
108	RIVAROXABANUM	RIVAROXABAN STADA 15mg+20 mg	capsules	15mg+20 mg	STADA M&D S.R.L.	ROMANIA	14876	2023	01
109	RIVAROXABANUM	RIVAROXABAN TERAPIA 2.5 mg	film-coated tablets	2.5mg	TERAPIA S.A.	ROMANIA	14922	2023	01
110	RIVAROXABANUM	RIVAROXABAN TERAPIA 10 mg	film-coated tablets	10mg	TERAPIA S.A.	ROMANIA	14923	2023	01

111	RIVAROXABANUM	RIVAROXABAN TERAPIA 15 mg	film-coated tablets	15mg	TERAPIA S.A.	ROMANIA	1492 4	2023	01
112	RIVAROXABANUM	RIVAROXABAN TERAPIA 20 mg	film-coated tablets	20mg	TERAPIA S.A.	ROMANIA	1492 5	2023	01
113	RIVAROXABANUM	ENKIA 15 mg	film-coated tablets	15mg	MEDOCHEMIE LTD.	CYPRUS	1495 1	2023	01
114	RIVAROXABANUM	ENKIA 20 mg	film-coated tablets	20mg	MEDOCHEMIE LTD.	CYPRUS	1495 2	2023	01
115	SELEGILINUM	SELEGOS	tablets	5mg	MEDOCHEMIE LTD.	CYPRUS	1488 5	2023	01
116	SUNITINIBUM	SUNITINIB TEVA 12.5 mg	capsules	12.5mg	TEVA PHARMACEUTICA LS S.R.L.	ROMANIA	1495 3	2023	01
117	SUNITINIBUM	SUNITINIB TEVA 25 mg	capsules	25mg	TEVA PHARMACEUTICA LS S.R.L.	ROMANIA	1495 4	2023	01
118	SUNITINIBUM	SUNITINIB TEVA 50 mg	capsules	50mg	TEVA PHARMACEUTICA LS S.R.L.	ROMANIA	1495 5	2023	01
119	Tc 99m - PERTECHNETATE	TEKCIS 2-50 GBq	radionuclide generator	2-50GBq	CIS BIO INTERNATION AL	FRANCE	1493 1	2023	01
120	TERIFLUNOMIDUM	AREGALU 14 mg	film-coated tablets	14mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1486 7	2023	01
121	TERIFLUNOMIDUM	BOXARID 14 mg	film-coated tablets	14mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	1486 4	2023	01
122	TERIFLUNOMIDUM	TERIFLUNOMIDA ZENTIVA 14 mg	film-coated tablets	14mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	1489 3	2023	01

123	TERIFLUNOMIDUM	TERIFLUNOMIDA MSN 14 mg	film-coated tablets	14mg	MSN LABS EUROPE LIMITED	MALTA	1493 0	2023	01
124	TESTOSTERONUM	TESTOSTERON TEVA 1000 mg/4 ml	solution for injection	1000mg/ 4ml	TEVA B.V.	HOLLAND	1489 9	2023	01
125	VINORELBINUM	VINORELBINA ACCORD 20 mg	soft capsules	20mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	1487 7	2023	01
126	VINORELBINUM	VINORELBINA ACCORD 30 mg	soft capsules	30mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	1487 8	2023	01
127	VINORELBINUM	VINORELBINA ACCORD 80 mg	soft capsules	80mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	1487 9	2023	01
128	XYLOMETAZOLINUM	RHINXYL HA 0.5 mg/ml	nasal spray, solution	0.5mg/ml	TERAPIA S.A.	ROMANIA	1495 6	2023	01
129	XYLOMETAZOLINUM	RHINXYL HA 1 mg/ml	nasal spray, solution	1mg/ml	TERAPIA S.A.	ROMANIA	1495 7	2023	01
130	XYLOMETAZOLINUM+ DEXPANTHENOLUM	OLYNTH DUO 1 mg/ml+50 mg/ml	nasal spray, solution	1mg/ml+ 50mg/ml	MCNEIL HEALTHCARE (IRELAND) LIMITED	IRELAND	1490 4	2023	01

EMA centrally authorised medicinal products notified for marketing in Romania during the 1st quarter of 2023

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.		
1.	COMBINAȚII (SITAGLIPTINUM+ METFORMINUM)	SITAGLIPTIN/CLORHIDRAT DE METFORMIN SUN 50 mg/850 mg	film-coated tablets	50mg/ 850mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HOLLAN D	17 20	2023	01
2.	COMBINAȚII (SITAGLIPTINUM+ METFORMINUM)	SITAGLIPTIN/CLORHIDRAT DE METFORMIN SUN 50 mg/1000 mg	film-coated tablets	50mg/ 1000mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HOLLAN D	17 20	2023	01

3.	TREMELIMUMABUM	IMJUDO 20 mg/ml	concentrate for solution for infusion	20mg/ml	ASTRAZENECA AB	SWEDEN	17 13	2023	01
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