

ROMANIA

Newsletter

Year 26, No. 2 (102), 2nd quarter of 2024

*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, 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

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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Instruction of the Minister of Health No. 6226/2024 on disposal practices for unused and/or expired medicinal waste from the population

Ordinances

Government Emergency Ordinance No. 29/2022 on establishing the institutional framework for the implementation of Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, for the regulation of certain measures, as well as for the amendment of certain regulatory acts in the healthcare field, as further amended and supplemented

Government decisions

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 of the Minister of Health and of the President of the National Health Insurance House no. 564/499/2021 on approval of therapeutic protocols for prescription of medicinal products with International Non-proprietary Names specified in 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, as approved through Government Decision no. 720/2008, and of the methodological norms on their implementation, as further amended and supplemented

Order of the Minister of Health No. 444/2019 on approval of the Rules regarding the establishment, organisation and operation of pharmaceutical units, as further amended and supplemented

Order of the Minister of Health No. 2684/2024 on approval of the Rules for the payment and reimbursement of costs for the conduct of operations for disposal of

expired and/or unused medicinal products from the population, as further amended and supplemented

Medicinal product batches recalled during the 2nd quarter of 2024

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/MAH/parallel import authorisation holder	Batch	Grounds for recall	Proposed action	Date of recall
1	AKYNZEO 300mg/0.5mg capsules	capsules	300mg/0.5 mg	NETUPITANT/ PALONOSETRON	HELSINN BIREX PHARMACEUTICALS LTD., IRELAND	4300164 3	EMA request	Recall upon NAMMDR request	14.06.2024
2	PADUDEN EXPRESS FORTE 400mg soft capsules	soft capsules	400mg	IBUPROFEN	TERAPIA SA, ROMANIA		European Commission Decision (2024)3294 final 10.05.2024	Recall upon NAMMDR request	14.06.2024

Applications for marketing authorisation/marketing authorisation renewal received during the 1st quarter of 2024

In the 1st quarter of 2024, 22 marketing authorisation/marketing authorisation renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

AUTHORISATION	RENEWAL
N02 – Analgesic drugs	S02 – Otologicals
M02 –Topical products for joint and muscular pain	R05 – Cough and cold preparations
J01 – Antibacterial drugs	R01 – Nasal preparations
	C10 – Lipid modifying agents
	C10 – Lipid modifying agents
	C10 – Lipid modifying agents
	C10 – Lipid modifying agents
	N02 – Analgesics
	N05 – Psycholeptics
	N05 – Psycholeptics
	N05 – Psycholeptics
	N05 – Psycholeptics
	N02 – Analgesics
	N02 – Analgesics
	R05 – Cough and cold preparations
	R05 – Cough and cold preparations
	N02 – Analgesics
	J01 – Antibacterial drugs
	A05 – Bile and liver therapy

Medicinal products authorised for marketing during the 1st quarter of 2024

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	ACIDUM ACETYLSALICYLICUM	MAXIPIRIN 500 mg	tablets	500mg	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	15352	2024
2	ACIDUM TRANEXAMICUM	TRANEXAMIC ACID KABI 10 mg/ml	solution for infusion	10mg/ml	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	15372	2024
3	AMISULPRIDUM	MASULTAB 50 mg	tablets	50mg	G.L. PHARMA GMBH	AUSTRIA	15377	2024
4	AMISULPRIDUM	MASULTAB 100 mg	tablets	100mg	G.L. PHARMA GMBH	AUSTRIA	15378	2024
5	AMISULPRIDUM	MASULTAB 200 mg	tablets	200mg	G.L. PHARMA GMBH	AUSTRIA	15379	2024
6	AMISULPRIDUM	MASULTAB 400 mg	tablets	400mg	G.L. PHARMA GMBH	AUSTRIA	15380	2024
7	BUDESONIDUM	BUDENOFALK 4 mg	suppositories	4mg	DR. FALK PHARMA GMBH	GERMANY	15299	2024
8	CALCII FOLINAS	CALCIUM FOLINATE KABI 10 mg/ml	solution for injection/infusion	10mg/ml	FRESENIUS KABI DEUTSCHLAND GMBH	GERMANY	15345	2024
9	CLOFARABINUM	CLOFARABINA VIVANTA 1 mg/ml	concentrate for solution for infusion	1mg/ml	VIVANTA GENERICS S.R.O	THE CZECH REPUBLIC	15320	2024
10	CLOPIDOGRELUM	CLOPIDOGREL MSN 75 mg	film-coated tablets	75mg	MSN LABS EUROPE LIMITED	MALTA	15390	2024
11	COMBINATIONS	BENELYTE	solution for infusion		FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	15347	2024

12	COMBINATIONS	SMOFKABIVEN LOW OSMO PERIPHERAL	emulsion for infusion	100mg/ml	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	15346	2024
13	COMBINATIONS (AMLODIPINUM+ VALSARTANUM)	WAMLOX 5 mg/320 mg	film-coated tablets	5mg/320mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15264	2024
14	COMBINATIONS (AMLODIPINUM+ VALSARTANUM)	WAMLOX 10 mg/320 mg	film-coated tablets	10mg/ 320mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15265	2024
15	COMBINATIONS (BECLOMETASONUM+ FORMOTEROLUM)	BECLOMETAZONA/ FORMOTEROL CIPLA 100/6 micrograms pe doza	pressurised solution for inhalation	100/ 6micrograms/ dose	CIPLA EUROPE NV	BELGIUM	15309	2024
16	COMBINATIONS (CINARIZINUM+ DIMENHIDRINATUM)	AZALONUM 20 mg/40 mg	tablets	20mg/40mg	MEDOCHEMIE LTD.	CYPRUS	15355	2024
17	COMBINATIONS (DORZOLAMIDUM+ TIMOLOLUM)	DORZOLAMIDA/ TIMOLOL MISOM 20 mg/ml+5 mg/ml	eye drops, solution	20mg/ml+ 5mg/ml	MISOM LABS LIMITED	MALTA	15291	2024
18	COMBINATIONS (DORZOLAMIDUM+ TIMOLOLUM)	DORZOLAMIDA/ TIMOLOL MISOM 20 mg/ml+5 mg/ml	eye drops, solution in single-dose recipient	20mg/ml+ 5mg/ml	MISOM LABS LIMITED	MALTA	15376	2024
19	COMBINATIONS (ETONOGESTRELUM+ ETINILESTRADIOLUM)	AIRING 0.120 mg/ 0.015 mg per 24 h	vaginal delivery system	120 mg/ 0.015 mg/24h	AICORE LIFE SCIENCES B.V.	THE NETHERLANDS	15270	2024
20	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	SORTIS PLUS 10 mg/10mg	film-coated tablets	10mg/10mg	VIATRIS HEALTHCARE LIMITED	IRELAND	15292	2024

21	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	SORTIS PLUS 10 mg/20mg	film-coated tablets	10mg/20mg	VIATRIS HEALTHCARE LIMITED	IRELAND	15293	2024
22	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	SORTIS PLUS 10 mg/40mg	film-coated tablets	10mg/40mg	VIATRIS HEALTHCARE LIMITED	IRELAND	15294	2024
23	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	SORTIS PLUS 10 mg/80mg	film-coated tablets	10mg/80mg	VIATRIS HEALTHCARE LIMITED	IRELAND	15295	2024
24	COMBINATIONS (OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM)	SALVO 20 mg/5 mg	film-coated tablets	20mg/5mg	TERAPIA SA	ROMANIA	15325	2024
25	COMBINATIONS (OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM)	SALVO 40 mg/5 mg	film-coated tablets	40mg/5mg	TERAPIA SA	ROMANIA	15326	2024
26	COMBINATIONS (OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM)	SALVO 40 mg/10 mg	film-coated tablets	40mg/10mg	TERAPIA SA	ROMANIA	15327	2024
27	COMBINATIONS (PARACETAMOLUM+ PSEUDOEPHEDRINUM)	REVIGRIP SINUS 500 mg/30 mg	film-coated tablets	500mg/ 30mg	LABORMED PHARMA S.A.	ROMANIA	15274	2024
28	COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM)	PREAMLESSA 2.85 mg/2,5 mg	tablets	2.85mg/2,5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15304	2024
29	COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM)	PREAMLESSA 5.7 mg/5 mg	tablets	5.7mg/5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15305	2024

30	COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	SUVEZEN 10 mg/ 10 mg	film-coated tablets	10mg/10mg	SANOFI ROMANIA SRL	ROMANIA	15348	2024
31	COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	SUVEZEN 20 mg/ 10 mg	film-coated tablets	20mg/10mg	SANOFI ROMANIA SRL	ROMANIA	15349	2024
32	COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	SUVEZEN 40 mg/ 10 mg	film-coated tablets	40mg/10mg	SANOFI ROMANIA SRL	ROMANIA	15350	2024
33	DABIGATRANUM ETEXILATUM	DAROXOMB 75 mg	capsules	75mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15335	2024
34	DABIGATRANUM ETEXILATUM	DAROXOMB 110 mg	capsules	110mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15336	2024
35	DABIGATRANUM ETEXILATUM	DAROXOMB 150 mg	capsules	150mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15337	2024
36	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILAT VIATRIS 75 mg	capsules	75mg	VIATRIS LIMITED	IRELAND	15360	2024
37	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILAT VIATRIS 110 mg	capsules	110mg	VIATRIS LIMITED	IRELAND	15361	2024
38	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILAT VIATRIS 150 mg	capsules	150mg	VIATRIS LIMITED	IRELAND	15362	2024
39	DABIGATRANUM ETEXILATUM	SIANTA 75 mg	capsules	75mg	EGIS PHARMACEUTICA LS PLC.	HUNGARY	15384	2024

40	DABIGATRANUM ETEXILATUM	SIANTA 110 mg	capsules	110mg	EGIS PHARMACEUTICA LS PLC.	HUNGARY	15385	2024
41	DABIGATRANUM ETEXILATUM	SIANTA 150 mg	capsules	150mg	EGIS PHARMACEUTICA LS PLC.	HUNGARY	15386	2024
42	DICLOFENACUM	VOLTAREN 140 mg	medicated plaster	140mg	HALEON ROMANIA S.R.L.	ROMANIA	15308	2024
43	DUTASTERIDUM	ASIUM 0.5 mg	soft capsules	0.5mg	TERAPIA S.A.	ROMANIA	15351	2024
44	ELTROMBOPAG	MINING 25 mg	film-coated tablets	25mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15331	2024
45	ELTROMBOPAG	MINING 50 mg	film-coated tablets	50mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15332	2024
46	EPINEPHRINUM	JEXT 150 micrograms	solution for injection in pre- filled pen	150 micrograms	ALK-ABELLÓ A/S	DENMARK	15391	2024
47	EPINEPHRINUM	JEXT 300 micrograms	solution for injection in pre- filled pen	300 micrograms	ALK-ABELLÓ A/S	DENMARK	15392	2024
48	STANDARDIZED ALLERGENIC EXTRACT OF BIRCH POLLEN	ITULAZAX 12 SQ- BET	Sublingual lyophilisate		ALK-ABELLÓ A/S	DENMARK	15323	2024
49	FINASTERIDUM	FINJUVE PENTRU BARBATI 2.275 mg/ml	cutaneous spray, solution	2.275mg/ml	POLICHEM S.A.	LUXEMBOURG	15354	2024

50	FLUCONAZOLUM	FLUCTOBAR 2 mg/ml	solution for infusion	2mg/ml	RUAL FARM SRL	ROMANIA	15328	2024
51	FLURBIPROFENUM	OROFAR INTENSIV 8.75 mg/dose	oromucosal spray, solution	8.75mg/ dose	STADA M&D S.R.L.	ROMANIA	15280	2024
52	FLUTICASONUM PROPIONAT	FLONASE 50 micrograms/dose	nasal spray, suspension	50 micrograms/ dose	GLAXOSMITHKLI NE CONSUMER HEALTHCARE S.R.L.	ROMANIA	15282	2024
53	FULVESTRANTUM	FULVESTRANT ROMPHARM 250 mg	solution for injection in pre- filled syringe	250mg	ROMPHARM COMPANY S.R.L.	ROMANIA	15341	2024
54	HOMEOPATHIC PRODUCTS	ZEEL	solution for injection		BIOLOGISCHE HEILMITTEL HEEL GMBH	GERMANY	15281	2024
55	IBUPROFENUM	IBUPROFEN NUTRA 200 mg	oral suspension, sachet	200mg	NUTRA ESSENTIAL OTC, S.L.	SPAIN	15329	2024
56	IBUPROFENUM	IBUPROFEN NUTRA 400 mg	oral suspension, sachet	400mg	NUTRA ESSENTIAL OTC, S.L.	SPAIN	15330	2024
57	IBUPROFENUM	IBUPROFEN DR. MAX PHARMA 400 mg	film-coated tablets	400mg	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	15307	2024
58	IBUPROFENUM	SALIPREN 100 mg/g	gel	100mg/g	FITERMAN PHARMA S.R.L.	ROMANIA	15315	2024
59	IBUPROFENUM	IBUPROFEN DR. MAX 20 mg/ml	oral suspension	20mg/ml	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	15319	2024

60	NORMAL HUMAN IMMUNOGLOBULIN	CUTAQUIG 165 mg/ml	subcutaneous solution for injection	165mg/ml	OCTAPharma (IP) SPRL	BELGIUM	15356	2024
61	KETOPROFENUM	KETOPROFEN DOMPÉ 50 mg	coated granules in sachet	50mg	DOMPÉ FARMACEUTICI S.P.A.	ITALY	15371	2024
62	LATANOPROSTUM	VIZILATAN 50 micrograms/ml	eye drops, solution	50micrograms/ml	BAUSCH + LOMB IRELAND LIMITED	IRELAND	15301	2024
63	LETROZOLUM	LETROZOL ACCORD 2.5 mg	film-coated tablets	2.5mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15279	2024
64	LIDOCAINUM	LIDOCAINA KABI 10 mg/ml	solution for injection	10mg/ml	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	15343	2024
65	LIDOCAINUM	LIDOCAINA KABI 20 mg/ml	solution for injection	20mg/ml	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	15344	2024
66	LOPERAMIDUM+ SIMETHICONUM	IMODIUM PLUS 2 mg/125 mg	tablets	2mg/125mg	MCNEIL HEALTHCARE (IRELAND) LIMITED	IRELAND	15285	2024
67	MACROGOLUM	PROCTOLAX 4 g	powder for oral solution in sachet	4g	CASEN RECORDATI, S.L.	SPAIN	15306	2024
68	MACROGOLUM	PROCTOLAX 10 g	powder for oral solution in sachet	10g	CASEN RECORDATI, S.L.	SPAIN	15359	2024

69	MELPHALANUM	MELFALAN ZENTIVA 50 mg	powder and solvent for solution for injection/infusion	50mg	ZENTIVA K.S.	THE CZECH REPUBLIC	15272	2024
70	MEMANTINUM	MEMANTINA TERAPIA 10 mg	film-coated tablets	10mg	TERAPIA SA	ROMANIA	15283	2024
71	MEMANTINUM	MEMANTINA TERAPIA 20 mg	film-coated tablets	20mg	TERAPIA SA	ROMANIA	15284	2024
72	METFORMINUM	METFORMIN ACCORD 750 mg	prolonged- release tablets	750mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15268	2024
73	METFORMINUM	METFORMIN ACCORD 1000 mg	prolonged- release tablets	1000mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15269	2024
74	METHYLPREDNISOLONUM	METILPREDNISOLON ROMPHARM 250 mg	powder and solvent for solution for injection	250mg	ROMPHARM COMPANY S.R.L.	ROMANIA	15262	2024
75	METHYLPREDNISOLONUM	METILPREDNISOLON ROMPHARM 500 mg	powder and solvent for solution for injection	500mg	ROMPHARM COMPANY S.R.L.	ROMANIA	15263	2024
76	MIDAZOLAMUM	MIDAZOLAM SUN 1 mg/ml	solution for injection/infusion in pre-filled syringe	1mg/ml	SUN PHARMACEUTICA L INDUSTRIES EUROPE B.V.	THE NETHERLANDS	15316	2024
77	MIDAZOLAMUM	MIDAZOLAM SUN 2 mg/ml	solution for injection/infusion in pre-filled syringe	2mg/ml	SUN PHARMACEUTICA L INDUSTRIES EUROPE B.V.	THE NETHERLANDS	15317	2024

78	NICOTINUM	NICORETTE ICEMINT 2 mg	medicated chewing gum	2mg	MCNEIL AB	SWEDEN	15302	2024
79	NICOTINUM	NICORETTE ICEMINT 4 mg	medicated chewing gum	4mg	MCNEIL AB	SWEDEN	15303	2024
80	NINTEDANIBUM	PUQOD 100 mg	soft capsules	100mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15310	2024
81	NINTEDANIBUM	PUQOD 150 mg	soft capsules	150mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15311	2024
82	NINTEDANIBUM	NINTEDANIB TEVA 100 mg	soft capsules	100mg	TEVA PHARMACEUTICA LS S.R.L.	ROMANIA	15367	2024
83	NINTEDANIBUM	NINTEDANIB TEVA 150 mg	soft capsules	150mg	TEVA PHARMACEUTICA LS S.R.L.	ROMANIA	15368	2024
84	NINTEDANIBUM	NINTEDANIB STADA 100 mg	soft capsules	100mg	STADA ARZNEIMITTEL AG	GERMANY	15357	2024
85	NINTEDANIBUM	NINTEDANIB STADA 150 mg	soft capsules	150mg	STADA ARZNEIMITTEL AG	GERMANY	15358	2024
86	OXYTOCINUM	OXITOCINA PANPHARMA 5 UI/ml	solution for injection/infusion	5IU/ml	PANPHARMA	FRANCE	15389	2024
87	PANTOPRAZOLUM	PANTOPRAZOL ROMPHARM 40 mg	powder for solution for injection	40mg	ROMPHARM COMPANY S.R.L.	ROMANIA	15342	2024

88	PAZOPANIBUM	PAZOPANIB ACCORD 200 mg	film-coated tablets	200mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15266	2024
89	PAZOPANIBUM	PAZOPANIB ACCORD 400 mg	film-coated tablets	400mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15267	2024
90	HERBS	SINUPRET SIROP JUNIOR 2+	syrup		BIONORICA SE	GERMANY	15322	2024
91	HERBS (LAVENDER)	TAVIPEC FORTE 300 mg	gastroresistant soft capsules	300mg	PHARMAZEUTISC HE FABRIK MONTAVIT GES.M.B.H.	AUSTRIA	15296	2024
92	PREGABALINUM	PREGABALINA VIVANTA 75 mg	capsules	75mg	VIVANTA GENERICS S.R.O.	THE CZECH REPUBLIC	15288	2024
93	PREGABALINUM	PREGABALINA VIVANTA 150 mg	capsules	150mg	VIVANTA GENERICS S.R.O.	THE CZECH REPUBLIC	15289	2024
94	PREGABALINUM	PREGABALINA VIVANTA 300 mg	capsules	300mg	VIVANTA GENERICS S.R.O.	THE CZECH REPUBLIC	15290	2024
95	PREGABALINUM	LUSAMA 82,5 mg	prolonged- release tablets	82.5mg	ARISTO PHARMA GMBH	GERMANY	15373	2024
96	PREGABALINUM	LUSAMA 165 mg	prolonged- release tablets	165mg	ARISTO PHARMA GMBH	GERMANY	15374	2024
97	PREGABALINUM	LUSAMA 330 mg	prolonged- release tablets	330mg	ARISTO PHARMA GMBH	GERMANY	15375	2024
98	SALMETEROLUM+ FLUTICASONUM	EVERIO 25 micrograms/ 50 micrograms/dose	pressurised suspension for inhalation	25micrograms/ 50micrograms/ dose	ZENTIVA, K.S.	THE CZECH REPUBLIC	15381	2024

99	SALMETEROLUM+ FLUTICASONUM	EVERIO 25 micrograms/ 125 micrograms/dose	pressurised suspension for inhalation	25micrograms/ 250microgram s/dose	ZENTIVA, K.S.	THE CZECH REPUBLIC	15382	2024
100	SALMETEROLUM+ FLUTICASONUM	EVERIO 25 micrograms/ 250 micrograms/dose	pressurised suspension for inhalation	25micrograms/ 250microgram s/dose	ZENTIVA, K.S.	THE CZECH REPUBLIC	15383	2024
101	SILDENAFILUM	AZURVIG 12.5 mg/pump	oral suspension	12.5mg/ pump	ALPEN PHARMA GMBH	GERMANY	15312	2024
102	SILDENAFILUM	SILDENAFIL STADA 25 mg	film-coated tablets	25mg	STADA ARZNEIMITTEL AG	GERMANY	15297	2024
103	SILDENAFILUM	SILDENAFIL STADA 50 mg	film-coated tablets	50mg	STADA ARZNEIMITTEL AG	GERMANY	15298	2024
104	SUNITINIBUM	SUNITINIB STADA 12.5 mg	capsules	12.5mg	STADA M&D SRL	ROMANIA	15276	2024
105	SUNITINIBUM	SUNITINIB STADA 25 mg	capsules	25mg	STADA M&D SRL	ROMANIA	15277	2024
106	SUNITINIBUM	SUNITINIB STADA 50 mg	capsules	50mg	STADA M&D SRL	ROMANIA	15278	2024
107	SUNITINIBUM	SUNITINIB VIATRIS 12.5 mg	capsules	12.5mg	VIATRIS LIMITED	IRELAND	15363	2024
108	SUNITINIBUM	SUNITINIB VIATRIS 25 mg	capsules	25mg	VIATRIS LIMITED	IRELAND	15364	2024
109	SUNITINIBUM	SUNITINIB VIATRIS 37.5 mg	capsules	37.5mg	VIATRIS LIMITED	IRELAND	15365	2024

110	SUNITINIBUM	SUNITINIB VIATRIS 50 mg	capsules	50mg	VIATRIS LIMITED	IRELAND	15366	2024
111	SUXAMETHONII CHLORIDUM	SUXAMETONIUM CLORURA AGUETTANT 10 mg/ml	solution for injection in pre- filled syringe	10mg/ml	LABORATOIRE AGUETTANT	FRANCE	15275	2024
112	TEICOPLANINUM	TEICOPLANINA MYLAN 100 mg	powder for solution for injection/infusion sau sol. orala	100mg	MYLAN PHARMACEUTICA LS LIMITED	IRELAND	15338	2024
113	TEICOPLANINUM	TEICOPLANINA MYLAN 200 mg	powder or oral solution for solution for injection/infusion	200mg	MYLAN PHARMACEUTICA LS LIMITED	IRELAND	15339	2024
114	TEICOPLANINUM	TEICOPLANINA MYLAN 400 mg	powder or oral solution for solution for injection/infusion	400mg	MYLAN PHARMACEUTICA LS LIMITED	IRELAND	15340	2024
115	TERIFLUNOMIDUM	TERIFLUNOMIDA TEVA 14 mg	film-coated tablets	14mg	TEVA B.V.	THE NETHERLANDS	15300	2024
116	TESTOSTERONUM	TESTOSTERON EVER PHARMA 1000 mg/4 ml	solution for injection	1000mg/ 4ml	EVER VALINJECT GMBH	AUSTRIA	15353	2024
117	TICAGRELOR	TICAGRELOR SWYSSI 60 mg	film-coated tablets	60mg	SWYSSI AG	GERMANY	15369	2024
118	TICAGRELOR	TICAGRELOR SWYSSI 90 mg	film-coated tablets	90mg	SWYSSI AG	GERMANY	15370	2024
119	BOTOX TYPE A	AZZALURE 125 SPEYWOOD UNITS	powder for solution for injection	125 SPEYWOOD UNITS	IPSEN PHARMA	FRANCE	15273	2024

120	TRABECTEDINUM	TRABECTEDINA STADA 0.25 mg	powder for concentrate for solution for infusion	0.25mg	STADA ARZNEIMITTEL AG	GERMANY	15333	2024
121	TRABECTEDINUM	TRABECTEDINA STADA 1 mg	powder for concentrate for solution for infusion	1mg	STADA ARZNEIMITTEL AG	GERMANY	15334	2024
122	TRIMETAZIDINUM	PREDUCTAL 40 mg	prolonged- release capsules	40mg	LES LABORATOIRES SERVIER	FRANCE	15313	2024
123	TRIMETAZIDINUM	PREDUCTAL 80 mg	prolonged- release capsules	80mg	LES LABORATOIRES SERVIER	FRANCE	15314	2024
124	BCG VACCINE	ONKO BCG 100	powder+solvent for intravesical suspension	100mg/ml	ANISAPHARM DISTRIBUTION S.R	ROMANIA	8	2024
125	LIVE ATTENUATED VARICELLA VACCINE	VARIVAX	powder and solvent for solution for injection in pre- filled syringe		MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	15287	2024
126	VILDAGLIPTINUM	GLYPVILO 50 mg	tablets	50mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15286	2024
127	VORICONAZOLUM	VORAMOL 200 mg	film-coated tablets	200mg	ZENIVA K.S.	THE CZECH REPUBLIC	15324	2024
128	XYLOMETAZOLINUM	ORINOX HA 1 mg/ml	nasal spray, solution	1mg/ml	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	15318	2024
129	XYLOMETAZOLINUM	ORINOX 0.5 mg/ml	nasal spray, solution	0.5mg/ml	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	15387	2024

130	XYLOMETAZOLINUM	ORINOX 1 mg/ml	nasal spray, solution	1mg/ml	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	15388	2024
131	XYLOMETAZOLINUM+ IPRATROPIUM	RHINXYL PLUS 0.5 mg/ml+0.6 mg/ml	nasal spray, solution	0.5mg/ml+0.6mg/ml	TERAPIA S.A.	ROMANIA	15321	2024

Medicamente autorizate prin procedura centralizată, efectuată la nivelul Agenției Europene a Medicamentului (EMA), pentru care s-a notificat intenția de punere pe piață în România în trimestrul I 2024 EMA centrally authorised medicinal products notified for marketing in Romania during the 1st quarter of 2024

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	ETRASIMODUM	VELSIPITY 2 mg	film-coated tablets	2mg	PFIZER EUROPE MA EEIG	BELGIUM	1790	2024
2	PACLITAXELUM	NAVERUCLIF 5 mg/ml	powder for dispersion for infusion	5mg/ml	ACCORD HEALTHCARE S.L.U.	SPAIN	1778	2024
3	ROZANOLIXIZUMABUM	RYSTIGGO 140 mg/ml	solution for injection	140mg/ml	UCB PHARMA S.A.	BELGIUM	1780	2024

4	TRAMETINIBUM	SPEXOTRAS 0,05 mg/ml	powder for oral solution	0.05mg/ml	NOVARTIS EUROPHARM LIMITED	IRELAND	1781	2024
5	USTEKINUMABUM	UZPRUVO 45 mg	solution for injection in pre- filled syringe	45mg/0.5ml	STADA ARZNEIMITTEL AG	GERMANY	1784	2024
6	USTEKINUMABUM	UZPRUVO 90 mg	solution for injection in pre- filled syringe	90mg/ml	STADA ARZNEIMITTEL AG	GERMANY	1784	2024