

ROMANIA

Newsletter

Year 26, No. 4 (104), 4th 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. 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 the balance sheet

Budget and funding source

Balance sheet

g) The institution's programmes and strategies

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Order of the Minister of Health and of the Director of the Special Telecommunications Service no. 5813/56/2024 regarding the approval of the methodology for data reporting, collecting and processing, including personal data, regarding stocks, commercial operations, prescribing and releasing medicinal products for human use, as well as the data related to their distribution outside the Romanian territory, associated operators and persons empowered by the operator, conditions and access limits to confidential data and information in the electronic reporting system, as well as the way of fulfilling the necessary measures in order to inform the data subjects on the processing operations and the manner of exercising the rights of the persons concerned, in line with the provisions of Art. 8041 (7) of Law 95/2006 on healthcare reform

Order of the Minister of Health no. 194/2015 on approval of the Rules for the evaluation and approval of advertising of medicinal products for human use, as further amended and supplemented

Medicinal product batches recalled during the 4th 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	Diclofenac Terapia 10 mg/g cream	cream	10 mg/g	Diclofenac	Terapia SA, Romania	231138//expiry date 08.2025	Wrong imprinting of the expiry date	Voluntary recall	24.12.2024

Applications for marketing authorisation/marketing authorisation renewal received during the 3rd quarter of 2024

18 marketing authorisation/marketing authorisation renewal applications for medicinal products have been received during the 3rd quarter of 2024, corresponding to the following therapeutic groups:

AUTHORISATION	RENEWAL
J01 – Antibacterials for systemic use	A07 - Antidiarrheals, intestinal antiinflammatory/antiinfective agents
R05 – Cough and cold preparations	J02 – Antimycotics for systemic use
G04 - Urologicals	N02 - Analgesics
J05 – Antivirals for systemic use	C05 - Vasoprotectives
J05 – Antivirals for systemic use	V03 – All other therapeutic products
N02 - Analgesics	A02 – Drugs for acid related disorders
B03 – Antianemic preparations	
B01 – Antithrombotic agents	
J01 - Antibacterials for systemic use	
V03 – All other therapeutic products	
B01 – Antithrombotic agents	
N01 - Anesthetics	

Medicinal products authorised for marketing during the 3rd quarter of 2024

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	ACIDUM URSODEOXYCHOLICUM	ACID URSODEOXYCHOLIC PHARMACEUTICAL INNOVATION 250 mg	capsules	250mg	PHARMACEUTIC AL INNOVATION SERVICES S.L.	SPAIN	155 67	2024
2	ACIDUM URSODEOXYCHOLICUM	ACID URSODEOXYCHOLIC PHARMACEUTICAL INNOVATION 500 mg	capsules	500mg	PHARMACEUTIC AL INNOVATION SERVICES S.L.	SPAIN	155 68	2024
3	ALPRAZOLAMUM	ALPRAZOLAM GRINDEKS 0.25 mg	tablets	0.25mg	AS GRINDEKS	LATVIA	156 08	2024
4	ALPRAZOLAMUM	ALPRAZOLAM GRINDEKS 0.5 mg	tablets	0.5mg	AS GRINDEKS	LATVIA	156 09	2024
5	ALPRAZOLAMUM	ALPRAZOLAM GRINDEKS 1 mg	tablets	1mg	AS GRINDEKS	LATVIA	156 10	2024
6	AMIKACINUM	AMIKACINA NORIDEM 250 mg/ml	solution for injection/infusion	250mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	155 86	2024
7	AMIKACINUM	AMIKACINA NORIDEM 125 mg/ml	solution for injection/infusion	125mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	155 85	2024
8	APIXABANUM	APIXABAN TEVA B.V. 2.5 mg	film-coated tablets	2.5mg	TEVA B.V.	THE NETHERLANDS	155 87	2024
9	APIXABANUM	APIXABAN TEVA B.V. 5 mg	film-coated tablets	5mg	TEVA B.V.	THE NETHERLANDS	155 88	2024

10	APREMILASTUM	BRATITI 30 mg	film-coated tablets	30mg	ADALVO LIMITED	MALTA	155 42	2024
11	APREMILASTUM	BRATITI 10 mg+ 20 mg+30 mg	film-coated tablets	10mg+ 20mg+ 30mg	ADALVO LIMITED	MALTA	155 41	2024
12	CEFTRIAXONUM	CEFTRIAXONA SWYSSI 1 g	powder for solution for injection/infusion	1g	SWYSSI AG	GERMANY	156 12	2024
13	CEFTRIAXONUM	CEFTRIAXONA SWYSSI 2 g	powder for solution for injection/infusion	2g	SWYSSI AG	GERMANY	156 13	2024
14	CLONAZEPAMUM	CLONOTRIL 0.5 mg	tablets	0.5mg	BESMAX PHARMA SOLUTIONS S.R.L.	ROMANIA	10	2024
15	CLONAZEPAMUM	CLONOTRIL 2 mg	tablets	2mg	BESMAX PHARMA SOLUTIONS S.R.L.	ROMANIA	11	2024
16	COMBINATIONS	ASPIGOLA MENTA FARA ZAHAR	lozenges		BAYER S.R.L.	ROMANIA	155 77	2024
17	COMBINATIONS (ACIDUM ACETYLSALICYLICUM+ PARACETAMOLUM+ CAFEINUM)	ANTINEVRALGIC INTENSIV 250 mg/250 mg/50 mg	tablets	250mg/ 250mg/ 50 mg	OPELLA HEALTHCARE ROMANIA S.R.L.	ROMANIA	156 11	2024
18	COMBINATIONS (ATORVASTATINUM+ EZETIMIBUM)	TORVAZIN PLUS 10 mg/10 mg	capsules	10mg/ 10mg	EGIS PHARMACEUTICA LS PLC	HUNGARY	155 33	2024

19	COMBINATIONS (ATORVASTATINUM+ EZETIMIBUM)	TORVAZIN PLUS 20 mg/10 mg	capsules	20 mg/ 10 mg	EGIS PHARMACEUTICA LS PLC	HUNGARY	155 34	2024
20	COMBINATIONS (ATORVASTATINUM+ EZETIMIBUM)	TORVAZIN PLUS 40 mg/10 mg	capsules	40 mg/ 10 mg	EGIS PHARMACEUTICA LS PLC	HUNGARY	155 35	2024
21	COMBINATIONS (AZELASTINUM+ FLUTICASONUM)	LUTONAZE 137 micrograms/ 50 micrograms/dose	nasal spray, suspension	137 micrograms/ 50 micrograms/dose	ZENTIVA, K.S.	THE CZECH REPUBLIC	155 24	2024
22	COMBINATIONS (BENZYDAMINUM+ CETYLPIRIDINII CHLORIDUM)	TANTUM VERDE DUO 1.5 mg/ml + 5 mg/ml	oromucosal spray, solution	1.5mg/ml+ 5mg/ml	ANGELINI PHARMA ÖSTERREICH GMBH	AUSTRIA	155 91	2024
23	COMBINATIONS (DUTASTERIDUM+ TAMSULOSINUM)	DUTAZEN 0.5 mg/0.4 mg	capsules	0.5mg/ 0.4mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	155 25	2024
24	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	EZETIMIB/ ATORVASTATINA SANDOZ 10 mg/10 mg	film-coated tablets	10mg/ 10mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	155 46	2024
25	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	EZETIMIB/ ATORVASTATINA SANDOZ 10 mg/20 mg	film-coated tablets	10mg/ 20mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	155 47	2024
26	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	EZETIMIB/ ATORVASTATINA SANDOZ 10 mg/40 mg	film-coated tablets	10mg/ 40mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	155 48	2024

27	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	EZETIMIB/ ATORVASTATINA SANDOZ 10 mg/80 mg	film-coated tablets	10mg/ 80mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	155 49	2024
28	COMBINATIONS (LEVODOPUM+ CARBIDOPUM)	PARKADOR 250 mg/25 mg	tablets	250mg/ 25mg	ORION CORPORATION	FINLAND	155 65	2024
29	COMBINATIONS (NATRII ALGINAS+ NATRII HYDROGENOCARBONA)	GAVISCON FORTE CU AROMA DE ZMEURA	oral suspension	500mg/ 213mg/ 325mg	RECKITT BENCKISER (ROMANIA) S.R.L.	ROMANIA	155 74	2024
30	COMBINATIONS (NATRII ALGINAS+ NATRII HYDROGENOCARBONA)	GAVISCON FORTE CU AROMA DE FRUCTE DE PADURE	oral suspension in sachet	500mg/ 213mg/ 325mg	RECKITT BENCKISER (ROMANIA) S.R.L.	ROMANIA	155 75	2024
31	COMBINATIONS (NATRII ALGINAS+ NATRII HYDROGENOCARBONA)	GAVISCON FORTE CU AROMA DE FRUCTE DE PADURE	oral suspension	500mg/ 213mg/ 325mg	RECKITT BENCKISER (ROMANIA) S.R.L.	ROMANIA	155 76	2024
32	COMBINATIONS (NATRII ALGINAS+ NATRII HYDROGENOCARBONAS +CALCII CARBONAS)	GAVISCON FORTE CU AROMA DE ZMEURA	oral suspension in sachet	500mg/ 213mg/ 325mg	RECKITT BENCKISER (ROMANIA) S.R.L.	ROMANIA	155 73	2024
33	COMBINATIONS (PARACETAMOLUM+ ACIDUM ASCORBICUM+ PHENYLEPHRINUM)	COLDREX MAXGRIP FRUCTE DE PADURE & MENTOL	powder for oral solution	1000mg+ 70mg+ 10mg	PERRIGO ROMANIA S.R.L.	ROMANIA	156 15	2024
34	COMBINATIONS (VALSARTANUM+ INDAPAMIDUM)	VALOMINDO 160 mg/1.5 mg	modified-release tablets	160mg/ 1.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	155 60	2024

35	DEFERASIROXUM	DEFERASIROX MSN LABORATORIES 90 mg	film-coated tablets	90mg	VIVANTA GENERICS S.R.O.	THE CZECH REPUBLIC	155 61	2024
36	DEFERASIROXUM	DEFERASIROX MSN LABORATORIES 180 mg	film-coated tablets	180mg	VIVANTA GENERICS S.R.O.	THE CZECH REPUBLIC	155 62	2024
37	DEFERASIROXUM	DEFERASIROX MSN LABORATORIES 360 mg	film-coated tablets	360mg	VIVANTA GENERICS S.R.O.	THE CZECH REPUBLIC	155 63	2024
38	DEFERASIROXUM	REDITENS 90 mg	film-coated tablets	90mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	155 19	2024
39	DEFERASIROXUM	REDITENS 180 mg	film-coated tablets	180mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	155 20	2024
40	DEFERASIROXUM	REDITENS 360 mg	film-coated tablets	360mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	155 21	2024
41	DEXIBUPROFENUM	SERACTIL 300 mg	film-coated tablets	300mg	GALENICA PHARMACEUTIC AL INDUSTRY S.A.	GREECE	155 69	2024
42	DEXIBUPROFENUM	SERACTIL 400 mg	film-coated tablets	400mg	GALENICA PHARMACEUTIC AL INDUSTRY S.A.	GREECE	155 70	2024
43	DIMETHYL FUMARATE	DIMETIL FUMARAT MSN 120 mg	gastroresistant capsules	120mg	MSN LABS EUROPE LIMITED	MALTA	155 27	2024
44	DIMETHYL FUMARATE	DIMETIL FUMARAT MSN 240 mg	gastroresistant capsules	240mg	MSN LABS EUROPE LIMITED	MALTA	155 28	2024

45	DIMETHYL FUMARATE	DIMTELZO 120 mg	gastroresistant capsules	120mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	15538	2024
46	DIMETHYL FUMARATE	DIMTELZO 240 mg	gastroresistant capsules	240mg	SANDOZ PHARMACEUTICA LS S.R.L.	ROMANIA	15539	2024
47	DIMETHYL FUMARATE	DIMETIL FUMARAT TEVA 120 mg	gastroresistant capsules	120mg	TEVA PHARMACEUTICA LS S.R.L.	ROMANIA	15601	2024
48	DIMETHYL FUMARATE	DIMETIL FUMARAT TEVA 240 mg	gastroresistant capsules	240mg	TEVA PHARMACEUTICA LS S.R.L.	ROMANIA	15602	2024
49	DIMETHYL FUMARATE	DITAGFENDA 120 mg	gastroresistant capsules	120mg	ADALVO LIMITED	ROMANIA	15603	2024
50	DIMETHYL FUMARATE	DITAGFENDA 240 mg	gastroresistant capsules	240mg	ADALVO LIMITED	ROMANIA	15604	2024
51	DIMETHYL FUMARATE	JAXTERAN 120 mg	gastroresistant capsules	120mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15597	2024
52	DIMETHYL FUMARATE	JAXTERAN 240 mg	gastroresistant capsules	240mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15598	2024
53	DIMETHYL FUMARATE	ARBICEN 120 mg	gastroresistant capsules	120mg	EGIS PHARMACEUTICA LS PLC	HUNGARY	15599	2024
54	DIMETHYL FUMARATE	ARBICEN 240 mg	gastroresistant capsules	240mg	EGIS PHARMACEUTICA LS PLC	HUNGARY	15600	2024

55	DIMETHYL FUMARATE	DIMETIL FUMARAT DR.REDDY'S 120 mg	gastroresistant capsules	120mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	156 05	2024
56	DIMETHYL FUMARATE	DIMETIL FUMARAT DR.REDDY'S 240 mg	gastroresistant capsules	240mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	156 06	2024
57	DIMETINDENUM	CALEMO 1 mg/g	gel	1mg/g	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	155 44	2024
58	ERIBULINUM	ERIBULIN EVER PHARMA 0.44 mg/ml	solution for injection	0.44mg/ml	EVER VALINJECT GMBH	AUSTRIA	155 22	2024
59	ERIBULINUM	NEXERELIN 0.44 mg/ml	solution for injection	0.44mg/ml	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	155 50	2024
60	GADOTERIDOLUM	PROHANCE 0.5 mmol/ml	solution for injection	0.5mmol/ml	BRACCO IMAGING S.P.A.	ITALY	155 58	2024
61	GADOTERIDOLUM	PROHANCE 0.5 mmol/ml	solution for injection in pre- filled syringe	0.5mmol/ml	BRACCO IMAGING S.P.A.	ITALY	155 59	2024
62	HOMEOPATHIC PRODUCTS	VERTIGOHEEL	tablets		BIOLOGISCHE HEILMITTEL HEEL GMBH	GERMANY	155 72	2024
63	HYDROCORTISONUM	HIDROCORTIZON ROMPHARM 100 mg	powder for solution for injection/infusion	100mg	ROMPHARM COMPANY S.R.L.	ROMANIA	155 71	2024
64	IBUPROFENUM	IBUPROFEN BANNER 100 mg	soft chewable capsules	100mg	PATHEON SOFTGELS B.V.	THE NETHERLANDS	155 66	2024
65	IBUPROFENUM	IBUPROFEN STRIDES PHARMA 400 mg	film-coated tablets	400mg	TERAPIA S.A.	ROMANIA	155 37	2024

66	KETOROLACUM TROMETHAMIN	KETOROLAC TROMETAMOL MISOM 5 mg/ml	eye drops, solution	5mg/ml	MISOM LABS LIMITED	MALTA	156 21	2024
67	LORNOXICAMUM	LORNOXICAM ROMPHARM 8 mg	powder and solvent for solution for injection	8mg	ROMPHARM COMPANY S.R.L.	ROMANIA	155 51	2024
68	METAMIZOLUM NATRIUM	METAMIZOL NORIDEM 500 mg/ml	solution for injection/infusion	500mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	155 56	2024
69	METFORMINUM	GLUCOPHAGE XR 750 mg	prolonged- release tablets	750mg	MERCK SANTE S.A.S.	FRANCE	155 31	2024
70	METFORMINUM	GLUCOPHAGE XR 1000 mg	prolonged- release tablets	1000mg	MERCK SANTE S.A.S.	FRANCE	155 32	2024
71	MILRINONUM	MILRINONE ZENTIVA 1mg/ml	solution for injection/infusion	1mg/ml	ZENTIVA K.S.	THE CZECH REPUBLIC	9	2024
72	NILOTINIBUM	NILOTINIB ZENTIVA 150 mg	capsules	150mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	155 89	2024
73	NILOTINIBUM	NILOTINIB ZENTIVA 200 mg	capsules	200mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	155 90	2024
74	NILOTINIBUM	KRUFTON 50 mg	capsules	50mg	EGIS PARMACEUTICA LS PLC	HUNGARY	155 92	2024
75	NILOTINIBUM	KRUFTON 150 mg	capsules	150mg	EGIS PARMACEUTICA LS PLC	HUNGARY	155 93	2024

76	NILOTINIBUM	KRUFTON 200 mg	capsules	200mg	EGIS PARMACEUTICA LS PLC	HUNGARY	155 94	2024
77	PACLITAXELUM	BUGVI 5 mg/ml	powder for dispersion for infusion	5mg/ml	STADA M&D S.R.L.	ROMANIA	156 19	2024
78	PALIPERIDONUM	PARNIDO 3 mg	prolonged- release tablets	3mg	KRKA, D.D., NOVO MESTO	SLOVENIA	155 82	2024
79	PALIPERIDONUM	PARNIDO 6 mg	prolonged- release tablets	6mg	KRKA, D.D., NOVO MESTO	SLOVENIA	155 83	2024
80	PALIPERIDONUM	PARNIDO 9 mg	prolonged- release tablets	9mg	KRKA, D.D., NOVO MESTO	SLOVENIA	155 84	2024
81	PARACETAMOLUM	PARACETAMOL ACCORD 500 mg	effervescent tablets	500mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	155 29	2024
82	PIPERACILLINUM + TAZOBACTAMUM	PITAZ 2 g/0.25 g	powder for solution for infusion	2g/0.25g	MEDOCHEMIE LTD.	CYPRUS	155 45	2024
83	PLANTS (IVY EXTRACT)	STREPTUSS IEDERA 8.25 mg/ml	syrup	8.25mg/ml	RECKITT BENCKISER (ROMANIA) S.R.L.	ROMANIA	156 18	2024
84	PLANTS (PLANTAGO EXTRACT)	STREPTUSS PATLAGINA 30 mg/ml	syrup	30mg/ml	RECKITT BENCKISER (ROMANIA) S.R.L.	ROMANIA	155 36	2024
85	PLANTS (SISYMBRIUM OFFICINALE GRASS EXTRACT)	STREPTUSS BRANCUTA 10 mg	lozenges	10mg	RECKITT BENCKISER (ROMANIA) S.R.L.	ROMANIA	156 17	2024

86	PLANTS (THYME+IVY EXTRACT)	BRONCHIPRET FORTE	oral solution		BIONORICA SE	GERMANY	156 14	2024
87	POSACONAZOLUM	GUDIVIN 100 mg	gastroresistant tablets	100mg	EGIS PARMACEUTICA LS PLC	HUNGARY	155 57	2024
88	ROSUVASTATINUM+ PERINDOPRILUM+ INDAPAMIDUM	ROXIPER 10 mg/4 mg/1.25 mg	film-coated tablets	10mg/ 4mg/1.25mg	KRKA, D.D., NOVO MESTO	SLOVENIA	155 78	2024
89	ROSUVASTATINUM+ PERINDOPRILUM+ INDAPAMIDUM	ROXIPER 10 mg/8 mg/2.5 mg	film-coated tablets	10mg/8mg/ 2.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	155 80	2024
90	ROSUVASTATINUM+ PERINDOPRILUM+ INDAPAMIDUM	ROXIPER 20 mg/4 mg/1.25 mg	film-coated tablets	20mg/4mg/ 1.25mg	KRKA, D.D., NOVO MESTO	SLOVENIA	155 79	2024
91	ROSUVASTATINUM+ PERINDOPRILUM+ INDAPAMIDUM	ROXIPER 20 mg/8 mg/2.5 mg	film-coated tablets	20mg/8mg/ 2.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	155 81	2024
92	SIMETHICONUM	SIMETICONA CLINRES FARMACIJA 240 mg	soft capsules	240mg	CLINRES FARMACIJA D.O.O.	SLOVENIA	156 20	2024
93	SITAGLIPTINUM	JAZETA NOVUM 100 mg	film-coated tablets	100mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	155 64	2024
94	SULTIAMUM	OSPOLOT 20 mg/ml	oral suspension	20mg/ml	DESITIN ARZNEIMITTEL GMBH	GERMANY	155 26	2024
95	TENOFOVIRUM DISOPROXIL	TENOFOVIR DISOPROXIL ACCORDPHARMA 245 mg	film-coated tablets	245mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	155 30	2024

96	VACCIN DIFTERIC,PERTUSSIS, POLIO INACTIVAT	ADACEL POLIO	suspension for injection in pre- filled syringe		SANOFI WINTHROP INDUSTRIE	FRANCE	155 40	2024
97	VACCIN GRIPAL INACTIVAT	INFLUVAC	suspension for injection in pre- filled syringe		VIATRIS HEALTHCARE LIMITED	IRELAND	156 07	2024
98	VACCIN TETANIC ADSORBIT	TETANA	suspension for injection	0.5ml/ dose	INSTYTUT BIOTECHNOLOGI I SUROWIC I SZCZEPIONEK (IBSS) BIOMED S.A.	POLAND	156 16	2024
99	VORICONAZOLUM	VORICONAZOL ACCORD 200 mg	powder for solution for infusion	200mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	155 43	2024
100	VORTIOXETINUM	IRSAML A 5 mg	film-coated tablets	5mg	EGIS PHARMACEUTICA LS PLC.	HUNGARY	155 52	2024
101	VORTIOXETINUM	IRSAML A 10 mg	film-coated tablets	10mg	EGIS PHARMACEUTICA LS PLC.	HUNGARY	155 53	2024
102	VORTIOXETINUM	IRSAML A 15 mg	film-coated tablets	15mg	EGIS PHARMACEUTICA LS PLC.	HUNGARY	155 54	2024
103	VORTIOXETINUM	IRSAML A 20 mg	film-coated tablets	20mg	EGIS PHARMACEUTICA LS PLC.	HUNGARY	155 55	2024

EMA centrally authorised medicinal products notified for marketing in Romania during the 3rd quarter of 2024

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	COMBINATIONS (APADAMTASUM ALFA+ CINAXADAMTASUM ALFA)	ADZYNMA 500 UI	powder and solvent for solution for injection	500IU	TAKEDA MANUFACTURING AUSTRIA AG	AUSTRIA	1837	2024
2	COMBINATIONS (APADAMTASUM ALFA+ CINAXADAMTASUM ALFA)	ADZYNMA 1500 UI	powder and solvent for solution for injection	1500IU	TAKEDA MANUFACTURING AUSTRIA AG	AUSTRIA	1837	2024
3	CROVALIMABUM	PIASKY 340 mg	solution for injection/infusion	340mg	ROCHE REGISTRATION GMBH	GERMANY	1848	2024
4	ELAFIBRANORUM	IQIRVO 80 mg	film-coated tablets	80mg	IPSEN PHARMA	FRANCE	1855	2024
5	ERDAFITINIBUM	BALVERSA 3 mg	film-coated tablets	3mg	JANSSEN-CILAG INTERNATIONAL NV	BELGIUM	1841	2024
6	ERDAFITINIBUM	BALVERSA 4 mg	film-coated tablets	4mg	JANSSEN-CILAG INTERNATIONAL NV	BELGIUM	1841	2024
7	ERDAFITINIBUM	BALVERSA 5 mg	film-coated tablets	5mg	JANSSEN-CILAG INTERNATIONAL NV	BELGIUM	1841	2024
8	NILOTINIBUM	NILOTINIB ACCORD 150 mg	capsules	150mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1845	2024
9	NILOTINIBUM	NILOTINIB ACCORD 200 mg	capsules	200mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1845	2024

10	ODEVIXIBATUM	KAYFANDA 200 micrograms	capsules	200 micrograms	IPSEN PHARMA	FRANCE	1854	2024
11	ODEVIXIBATUM	KAYFANDA 400 micrograms	capsules	400 micrograms	IPSEN PHARMA	FRANCE	1854	2024
12	ODEVIXIBATUM	KAYFANDA 600 micrograms	capsules	600 micrograms	IPSEN PHARMA	FRANCE	1854	2024
13	ODEVIXIBATUM	KAYFANDA 1200 micrograms	capsules	1200 micrograms	IPSEN PHARMA	FRANCE	1854	2024
14	POMALIDOMIDUM	POMALIDOMIDE ZENTIVA 3 mg	capsules	3mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	1830	2024
15	POMALIDOMIDUM	POMALIDOMIDE ZENTIVA 4 mg	capsules	4mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	1830	2024
16	POMALIDOMIDUM	POMALIDOMIDE ACCORD 1 mg	capsules	1mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1831	2024
17	POMALIDOMIDUM	POMALIDOMIDE ACCORD 2 mg	capsules	2mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1831	2024
18	POMALIDOMIDUM	POMALIDOMIDE ACCORD 3 mg	capsules	3mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1831	2024
19	POMALIDOMIDUM	POMALIDOMIDE ACCORD 4 mg	capsules	4mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1831	2024
20	RITUXIMABUM	ITUXREDI 500mg	concentrate for solution for infusion	500mg	REDDY HOLDING GMBH	GERMANY	1861	2024
21	RITUXIMABUM	ITUXREDI 100mg	concentrate for solution for infusion	100mg	REDDY HOLDING GMBH	GERMANY	1861	2024
22	SOTATERCEPTUM	WINREVAIR 45 mg	powder and solvent for	45mg	MERCK SHARP & DOHME B.V.	THE NETHERLANDS	1850	2024

			solution for injection					
23	SOTATERCEPTUM	WINREVAIR 60 mg	powder and solvent for solution for injection	60mg	MERCK SHARP & DOHME B.V.	THE NETHERLANDS	1850	2024
24	USTEKINUMABUM	STEQEYMA 130 mg	concentrate for solution for infusion	130mg	CELLTRION HEALTHCARE HUNGARY KFT.	HUNGARY	1844	2024
25	USTEKINUMABUM	STEQEYMA 45 mg	solution for injection in pre-filled syringe	45mg/0.5ml	CELLTRION HEALTHCARE HUNGARY KFT.	HUNGARY	1844	2024
26	USTEKINUMABUM	STEQEYMA 90 mg	solution for injection in pre-filled syringe	90mg/ml	CELLTRION HEALTHCARE HUNGARY KFT.	HUNGARY	1844	2024
27	ZOLBETUXIMABUM	VYLOY 100 mg	powder for concentrate for solution for infusion	100mg	ASTELLAS PHARMA EUROPE B.V.	THE NETHERLANDS	1856	2024