

*ROMANIA*

*Newsletter*

**Year 24, No. 1 (93), 1<sup>st</sup> quarter of 2022**

*National Agency  
for Medicines and Medical Devices  
of Romania*

- All data herein represent official information and are under direct authority of the National Agency for Medicines and Medical Devices of Romania.
- The entire content of the present publication lies under complete legislative protection of the National Agency for Medicines and Medical Devices of Romania.
- Any use of present publication content for revenue purposes or its marketing without express consent of the National Agency for Medicines and Medical Devices of Romania is forbidden and punishable by law.
- The National Agency for Medicines and Medical Devices of Romania reserves exclusive publishing rights

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. 1.522 of 9 October 2019 on approval of the Regulation for organisation and operation 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)**

**TABLE OF CONTENTS**

**Ordinances**

Emergency Ordinance no. 29 of 23 March 2022 regarding the establishment of an institutional framework and the necessary measures 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, as well as the amendment of certain ruling provisions in the healthcare field

**Regulations**

Commission Implementing Regulation (EU) 2022/20 of 7 January 2022 laying down rules for the application of Regulation (EU) No 536/2014 of the European Parliament and of the Council as regards setting up the rules and procedures for the cooperation of the Member States in safety assessment of clinical trials, in force since 30/01/2022 and shall apply from 31/01/2022;

Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

## Medicinal product batches recalled during the 1<sup>st</sup> quarter of 2022

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/MAH	Batch	Grounds for recall	Proposed action	Date of recall
1	Azacidine betapharm, pulbere pentru suspensie injectabilă,	powder for solution for injection		Azacidine	Betapharm Arzneimittel GmbH, Germany	H200135	voluntary recall at warehouse and pharmacy level – VHP requalification failure	Voluntary recall and destruction	16.03.2022
2	Accuzide 10 mg/12.5 mg comprimate filmate	film-coated tablets	10mg/12.5 mg	Quinapril and hydrochlorothiazide	Pfizer Europe MA EEIG, Belgium	AW8622 CL8723 DC1452 DL8508 EA7790 ET1535 FD9320	recall from the market (warehouses and pharmacies), as a result of obtaining values of nitrosamines above the accepted limit (above the acceptable daily intake of 18 ng/day of N-nitroso-quinapril)	Recall and destruction	22.03.2022
3	Accuzide Forte 20 mg/12.5 mg comprimate filmate	film-coated tablets	20 mg/12.5 mg	Quinapril and hydrochlorothiazide	Pfizer Europe MA EEIG, Belgium	CA2055 CK8056 DN0534 FG9234	recall from the market (warehouses and pharmacies), as a result of obtaining values of nitrosamines above the accepted limit (above the acceptable daily intake of 18 ng/day of N-nitroso-quinapril)	Recall and destruction	22.03.2022
4	Vigantol Oil 0.5 mg/ml picături orale, soluție	oral drops, solution	0.5 mg/ml	Cholecalciferol	P&G Health Germany GmbH, Germany	242279 19LQ101	voluntary recall at warehouse and pharmacy level, following an out-of-specification (OOS) result for parameter „cholecalciferol content"	Voluntary recall and destruction	28.03.2022

**Applications for marketing authorisation/marketing authorisation renewal  
received during the 4<sup>th</sup> quarter of 2021**

In the 4<sup>th</sup> quarter of 2021, **10** marketing authorisation/marketing authorisation renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

N02 - ANALGESICS
A03 - DRUGS FOR FUNCTIONAL BOWEL DISORDERS
B01A – ANTITHROMBOTIC AGENTS
M01 - ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
B01A – ANTITHROMBOTIC AGENTS
B01A – ANTITHROMBOTIC AGENTS
A10 – DRUGS USED IN DIABETES
A10 – DRUGS USED IN DIABETES
B05 – BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS
J01 - ANTIBACTERIALS FOR SYSTEMIC USE
D05 - ANTIPSORIATICS

### Medicinal products authorised for marketing during the 4<sup>th</sup> quarter of 2021

INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
ABACAVIRUM+ LAMIVUDINUM	ABACAVIR/ LAMIVUDINA AUROBINDO 600 mg/300mg	film-coated tablets	600mg/ 300mg		ROMANIA	14193	2021
ACIDUM DEOXYCHOLIC	BELKYRA 10 mg/ml	solution for injection	10mg/ml	ABBVIE LIMITED	IRELAND	14147	2021
AMBROXOLUM	BROXIVAN 3 mg/ml	oral solution	3mg/ml	MEDOCHEMIE LTD.	CYPRUS	14167	2021
AMBROXOLUM	BROXIVAN 6 mg/ml	oral solution	6mg/ml	MEDOCHEMIE LTD.	CYPRUS	14168	2021
AMLODIPINUM	AMLODIPINA MEDREG 5 mg	tablets	5mg	MEDREG S.R.O.	THE CZECH REPUBLIC	14185	2021
AMLODIPINUM	AMLODIPINA MEDREG 10 mg	tablets	10mg	MEDREG S.R.O.	THE CZECH REPUBLIC	14186	2021
AMPICILLINUM + SULBACTAM	AMPICILINA/SULBACT AM APTAPHARMA 1 g/0.5 g	powder for solution for injection/infusion	1g/0.5g	APTA MEDICA INTERNACIONAL D.O.O.	SLOVENIA	14211	2021
AMPICILLINUM + SULBACTAM	AMPICILINA/SULBACT AM APTAPHARMA 2 g/1 g	powder for solution for injection/infusion	2g/1g	APTA MEDICA INTERNACIONAL D.O.O.	SLOVENIA	14212	2021
APIXABANUM	ABOXOMA 2.5 mg	film-coated tablets	2.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14214	2021
APIXABANUM	ABOXOMA 5 mg	film-coated tablets	5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14215	2021
APIXABANUM	ABATIXENT 2.5 mg	film-coated	2.5mg	SANDOZ S.R.L.	ROMANIA	14149	2021

		tablets					
APIXABANUM	ABATIXENT 5 mg	film-coated tablets	5mg	SANDOZ S.R.L.	ROMANIA	14150	2021
APIXABANUM	BANXIOL 2.5 mg	film-coated tablets	2.5mg	VIATRIS LIMITED	IRELAND	14155	2021
APIXABANUM	BANXIOL 5 mg	film-coated tablets	5mg	VIATRIS LIMITED	IRELAND	14156	2021
AZACITIDINUM	VIDACULEM 25 mg/ml	powder for suspension for injection	25mg/ml	ONKOGEN KFT.	HUNGARY	14151	2021
AZITHROMYCINUM	AZITROMICINA AUROBINDO 250 mg	film-coated tablets	250mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	14195	2021
AZITHROMYCINUM	AZITROMICINA AUROBINDO 500 mg	film-coated tablets	500mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	14196	2021
BORTEZOMIBUM	BORTEZOMIB DR. REDDY'S 3.5 mg	powder for solution for injection	3.5mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	14171	2021
COMBINATIONS	THERAFLU MAX RACEALA SI GRIPA 1000 mg/10 mg/70 mg	powder for oral solution	1000mg/10mg/70mg	GLAXOSMITHKLINE CONSUMER HEALTHCARE S.R.L.	ROMANIA	14201	2021
COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	DILORYM 6.25 mg/5mg	film-coated tablets	6.25mg/5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	14229	2021
COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	DILORYM 6.25 mg/7.5mg	film-coated tablets	6.25mg/7.5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	14230	2021
COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	DILORYM 12.5 mg/5mg	film-coated tablets	12.5mg/5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	14231	2021



COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	DILORYM 12.5 mg/7.5mg	film-coated tablets	12.5mg/ 7.5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	14232	2021
COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	DILORYM 25 mg/5mg	film-coated tablets	25mg/5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	14233	2021
COMBINATIONS (CARVEDILOLUM+ IVABRADINUM)	DILORYM 25 mg/7.5mg	film-coated tablets	25mg/ 7.5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	14234	2021
COMBINATIONS (GUAIFENESINUM+ PHENYLEPHRINUM)	COLDREX MAX RACEALA SI TUSE	capsules		HIPOCRATE 2000 S.R.L.	ROMANIA	14162	2021
COMBINATIONS (OXICODONUM+ NALOXONUM)	DOLNADA 10 mg/5 mg	prolonged-release tablets	10mg/5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14136	2021
COMBINATIONS (OXICODONUM+ NALOXONUM)	DOLNADA 20 mg/10 mg	prolonged-release tablets	20mg/ 10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14137	2021
COMBINATIONS (OXICODONUM+ NALOXONUM)	DOLNADA 40 mg/20 mg	prolonged-release tablets	40mg/ 20mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14138	2021
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM+ AMLODIPINUM)	PRINDAL 4 mg/1.25 mg/5 mg	tablets	4 mg/ 1.25 mg/ 5 mg	ZENTIVA K.S.	THE CZECH REPUBLIC	14129	2021
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM+ AMLODIPINUM)	PRINDAL 4 mg/1.25 mg/10 mg	tablets	4 mg/ 1.25 mg/ 10 mg	ZENTIVA K.S.	THE CZECH REPUBLIC	14130	2021

COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM+ AMLODIPINUM)	PRINDAL 8 mg/2.5 mg/5 mg	tablets	8 mg/ 2.5 mg/ 5 mg	ZENTIVA K.S.	THE CZECH REPUBLIC	14131	2021
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM+ AMLODIPINUM)	PRINDAL 8 mg/2.5 mg/10 mg	tablets	8 mg/ 2.5 mg/ 10 mg	ZENTIVA K.S.	THE CZECH REPUBLIC	14132	2021
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	RAMIPRIL/ AMLODIPINA ADAMED 2.5 mg/5 mg	capsules	2.5mg/ 5mg	ADAMED PHARMA S.A.	POLAND	14124	2021
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	RAMIPRIL/ AMLODIPINA ADAMED 5 mg/5 mg	capsules	5mg/5mg	ADAMED PHARMA S.A.	POLAND	14125	2021
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	RAMIPRIL/ AMLODIPINA ADAMED 5 mg/10 mg	capsules	5mg/10mg	ADAMED PHARMA S.A.	POLAND	14126	2021
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	RAMIPRIL/ AMLODIPINA ADAMED 10 mg/5 mg	capsules	10mg/5mg	ADAMED PHARMA S.A.	POLAND	14127	2021
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	RAMIPRIL/ AMLODIPINA ADAMED 10 mg/10 mg	capsules	10mg/ 10mg	ADAMED PHARMA S.A.	POLAND	14128	2021
DEXAMETHASONUM	DEXAMETAZONA KRKA 4 mg	tablets	4mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14158	2021
DEXAMETHASONUM	DEXAMETAZONA KRKA 8 mg	tablets	8mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14159	2021
DEXAMETHASONUM	DEXAMETAZONA KRKA 20 mg	tablets	20mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14160	2021

DEXAMETHASONUM	DEXAMETAZONA KRKA 40 mg	tablets	40mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14161	2021
DIOXID DE CARBON	DIOXID DE CARBON SIAD 100%	liquefied medicinal gas	100%	SIAD ROMANIA S.R.L.	ROMANIA	14208	2021
DUTASTERIDUM	DUTASTERIDA AUROBINDO 0.5 mg	soft capsules	0.5mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	14194	2021
DUTASTERIDUM	DUTRYS 0.5 mg	soft capsules	0.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14153	2021
EMTRICITABINUM+ TENOFIVIRUM DISOPROXIL	EMTRICITABINA/ TENOFIVIR DISOPROXIL STADA 200 mg/245 mg	film-coated tablets	200mg/ 245mg	STADA M&D S.R.L.	ROMANIA	14176	2021
ETOPOSIDUM	ETOPOSID ACCORD 20 mg/ml	concentrate for solution for infusion	20mg/ml	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	14197	2021
ETORICOXIBUM	ETORICOXIB TERAPIA 30 mg	film-coated tablets	30mg	TERAPIA S.A.	ROMANIA	14225	2021
ETORICOXIBUM	ETORICOXIB TERAPIA 60 mg	film-coated tablets	60mg	TERAPIA S.A.	ROMANIA	14226	2021
ETORICOXIBUM	ETORICOXIB TERAPIA 90 mg	film-coated tablets	90mg	TERAPIA S.A.	ROMANIA	14227	2021
ETORICOXIBUM	ETORICOXIB TERAPIA 120 mg	film-coated tablets	120mg	TERAPIA S.A.	ROMANIA	14228	2021
STANDARDIZED ALLERGENIC GRASS POLLEN EXTRACT	GRAZAX 75000 SQ-T	oral lyophilisate	75000SQ- T	ALK-ABELLÓ A/S	DENMARK	14141	2021
EZETIMIBUM	EZETIMIB ACCORD 10 mg	tablets	10mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	14200	2021
FLURBIPROFENUM	FARINGO INTENSIV 8.75 mg	lozenges	8.75mg	TERAPIA S.A.	ROMANIA	14189	2021

GANCICLOVIRUM	GANCICLOVIR ROMPHARM 500 mg	powder for concentrate for solution for infusion	500mg	ROMPHARM COMPANY S.R.L.	ROMANIA	14152	2021
IBUPROFENUM	NUROFEN 200 mg	medicated plaster	200mg	RECKITT BENCKISER (ROMANIA) SRL	ROMANIA	14199	2021
IBUPROFENUM	IBUPROFEN DR. MAX 50 mg/g	gel	50mg/g	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	14145	2021
ICATIBANTUM	ICATIBANT ZENTIVA 30 mg	solution for injection in pre- filled syringe	10mg/ml	ZENTIVA K.S.	THE CZECH REPUBLIC	14175	2021
ICATIBANTUM	ICATIBANT TERAPIA 30 mg	solution for injection in pre- filled syringe	30 mg	TERAPIA S.A.	ROMANIA	14190	2021
ICATIBANTUM	ICATIBANT STADA 30 mg	solution for injection in pre- filled syringe	30mg	STADA M&D S.R.L.	ROMANIA	14178	2021
IRINOTECANUM	IRINOTECAN ACCORD 20 mg/ml	concentrate for solution for infusion	20mg/ml	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	14198	2021
LENALIDOMIDUM	LENALIDOMIDA TERAPIA 5 mg	capsules	5 mg	TERAPIA S.A.	ROMANIA	14180	2021
LENALIDOMIDUM	LENALIDOMIDA TERAPIA 7.5 mg	capsules	7.5 mg	TERAPIA S.A.	ROMANIA	14181	2021
LENALIDOMIDUM	LENALIDOMIDA TERAPIA 10 mg	capsules	10mg	TERAPIA S.A.	ROMANIA	14182	2021
LENALIDOMIDUM	LENALIDOMIDA TERAPIA 15 mg	capsules	15 mg	TERAPIA S.A.	ROMANIA	14183	2021
LENALIDOMIDUM	LENALIDOMIDA TERAPIA 20 mg	capsules	20mg	TERAPIA S.A.	ROMANIA	14184	2021
LENALIDOMIDUM	LENALIDOMIDA AUROBINDO 5 mg	capsules	5mg	AUROBINDO PHARMA ROMANIA	ROMANIA	14202	2021

				S.R.L.			
LENALIDOMIDUM	LENALIDOMIDA AUROBINDO 10 mg	capsules	10mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	14203	2021
LENALIDOMIDUM	LENALIDOMIDA AUROBINDO 15 mg	capsules	15mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	14204	2021
LENALIDOMIDUM	LENALIDOMIDA AUROBINDO 25 mg	capsules	25mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	14205	2021
LINEZOLIDUM	LINEZOLID KRKA 2 mg/ml	solution for infusion	2mg/ml	KRKA, D.D., NOVO MESTO	SLOVENIA	14216	2021
MELDONIUM	MILDRONATE 500 mg	capsules	500mg	AS GRINDEKS	LATVIA	14134	2021
METHOTREXATUM	METOTREXAT SANDOZ 2.5 mg (vezi L01BA01)	tablets	2.5mg	SANDOZ S.R.L.	ROMANIA	14217	2021
MISOPROSTOLUM	ANGUSTA 25 micrograms	tablets	25micro- grams	NORGINE B.V.	HOLLAND	14224	2021
NATRII IODIDUM (131I)	THYROTOP 38-7400 MBq	capsules for therapeutic use	38- 7400MBq	CN UNIFARM S.A.	ROMANIA	14210	2021
NIMESULIDUM	AULIN 30 mg/g	gel	30mg/g	ANGELINI PHARMA ÖSTERREICH GMBH	AUSTRIA	14207	2021
NORADRENALINUM	MYKRONOR 10 micrograms/ml	solution for injection/infusion	10micro- grams/ml	LABORATOIRE AGUETTANT	FRANCE	14139	2021
OMEPRAZOLUM	SAGALIX 10 mg	gastroresistant capsules	10mg	LABORATORIOS LICONSA, S.A.	SPAIN	14220	2021
OMEPRAZOLUM	SAGALIX 20 mg	gastroresistant capsules	20mg	LABORATORIOS LICONSA, S.A.	SPAIN	14221	2021

OMEPRAZOLUM	SAGALIX 40 mg	gastroresistant capsules	40mg	LABORATORIOS LICONSA, S.A.	SPAIN	14222	2021
ONDANSETRONUM	ONDANSETRON KALCEKS 2 mg/ml	solution for injection/infusion	2 mg/ml	AS KALCEKS	LATVIA	14146	2021
PALONOSETRONUM	PALONOSETRON DR. REDDY'S 250 micrograms	solution for injection	250micrograms	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	14166	2021
PALONOSETRONUM	PALONOSETRON KALCEKS 250 micrograms	solution for injection	250 micrograms/ 5 ml	AKCIJU SABIEDRIBA KALCEKS	LATVIA	14213	2021
PERINDOPRILUM	PRENESSANEO 5 mg	tablets	5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14218	2021
PERINDOPRILUM	PRENESSANEO 10 mg	tablets	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14219	2021
PROCAINUM	GEROVITAL H <sup>3</sup> 100mg	film-coated tablets	100mg	ZENTIVA S.A.	ROMANIA	14179	2021
NITROGEN PROTOXIDE	PROTOXID DE AZOT MEDICINAL SIAD	liquefied medicinal gas		SIAD ROMANIA S.R.L.	ROMANIA	14188	2021
RADIOPHARMACEUTICALS	TEKTROTYD 20 micrograms	kit for radiopharmaceutical preparations	20micrograms	NARODOWE CENTRUM BADAN JADROWYCH	POLAND	14135	2021
SITAGLIPTINUM	SITAGLIPTIN DR. REDDY'S 100 mg	film-coated tablets	100mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	14133	2021
SITAGLIPTINUM	LONAMO 50 mg	film-coated tablets	50mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	14169	2021

SITAGLIPTINUM	LONAMO 100 mg	film-coated tablets	100mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	14170	2021
SITAGLIPTINUM	JANSITIN 25 mg	film-coated tablets	25mg	G.L. PHARMA GMBH	AUSTRIA	14172	2021
SITAGLIPTINUM	JANSITIN 50 mg	film-coated tablets	50mg	G.L. PHARMA GMBH	AUSTRIA	14173	2021
SITAGLIPTINUM	JANSITIN 100 mg	film-coated tablets	100mg	G.L. PHARMA GMBH	AUSTRIA	14174	2021
SITAGLIPTINUM	JAGLIX 100 mg	film-coated tablets	100mg	VIATRIS LIMITED	IRELAND	14157	2021
SOLIFENACINUM SUCCINATE	SOLIFENACIN AUROBINDO 10 mg	film-coated tablets	10mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	14192	2021
SOLIFENACINUM SUCCINATE	SOLIFENACIN AUROBINDO 5 mg	film-coated tablets	5mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	14191	2021
SORAFENIBUM	WELDININ 200 mg	film-coated tablets	200mg	EGIS PHARMACEUTICAL PLC.	HUNGARY	14187	2021
SORAFENIBUM	RENIXOLA 200 mg	film-coated tablets	200mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	14206	2021
SUGAMMADEXUM	SUGAMMADEX DR. REDDY'S 100 mg/ml	solution for injection	100 mg/ml	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	14143	2021
TADALAFILUM	REVESTAD 20 mg	film-coated tablets	20mg	STADA M&D S.R.L.	ROMANIA	14148	2021
TAMSULOSINUM	SELDONO 0.4 mg	modified-release capsules	0.4mg	ALKALOID - INT D.O.O.	SLOVENIA	14154	2021
TICAGRELOR	TICAGRELOR STADA 90 mg	film-coated tablets	90mg	STADA M&D S.R.L.	ROMANIA	14142	2021

BOTULINUM TOXIN TYPE A	BOCOUTURE 50 units	powder for solution for injection	50units	MERZ PHARMACEUTICALS GMBH	GERMANY	14164	2021
BOTULINUM TOXIN TYPE A	BOCOUTURE 100 units	powder for solution for injection	100units	MERZ PHARMACEUTICALS GMBH	GERMANY	14165	2021
BOTULINUM TOXIN TYPE A	ALLUZIENCE 200 UNITS Speywood/ml	solution for injection	200 UNITS SPEYWOOD/ml	IPSEN PHARMA	FRANCE	14163	2021
TRIFAROTEN	AKLIEF 50 micrograms/g	cream	50micrograms/g	GALDERMA INTERNATIONAL	FRANCE	14177	2021



**Medicinal products authorised through centralised procedure, performed at the level of the European Medicines Agency (EMA), notified for marketing in Romania during the 4 th quarter of 2021**

<b>INN</b>	<b>Trade name</b>	<b>Pharmaceutical form</b>	<b>Strength</b>	<b>MAH</b>	<b>Holding country</b>	<b>MA no.</b>	
ABROCITINIBUM	CIBINQO 50 mg	film-coated tablets	50mg	PFIZER EUROPE MA EEIG	BELGIUM	1593	2021
ABROCITINIBUM	CIBINQO 200 mg	film-coated tablets	200mg	PFIZER EUROPE MA EEIG	BELGIUM	1593	2021
ABROCITINIBUM	CIBINQO 100 mg	film-coated tablets	100mg	PFIZER EUROPE MA EEIG	BELGIUM	1593	2021
ADALIMUMABUM	HUKYNDRA 40 mg	solution for injection in pre-filled syringe	40mg/0.4ml	STADA ARZNEIMITTEL AG	GERMANY	1589	2021
ADALIMUMABUM	HUKYNDRA 40 mg	solution for injection în stilou injector preumplut	40mg/0.4ml	STADA ARZNEIMITTEL AG	GERMANY	1589	2021
ADALIMUMABUM	HUKYNDRA 80 mg	solution for injection in pre-filled syringe	80mg/0,8ml	STADA ARZNEIMITTEL AG	GERMANY	1589	2021
AMIVANTAMABUM	RYBREVANT 350 mg	concentrate for solution for infusion	350mg	JANSSEN-CILAG INTERNATIONAL NV	BELGIUM	1594	2021
CASIRIVIMABUM+IMDEVIMABUM	RONAPREVE 300 mg + 300 mg	solution for injection/infusion	120mg/ml + 120mg/ml	ROCHE REGISTRATION GMBH	GERMANY	1601	2021
CASIRIVIMABUM+IMDEVIMABUM	RONAPREVE 120mg/ml +	solution for injection/infusion	120mg/ml +	ROCHE REGISTRATION	GERMANY	1601	2021

	120mg/ml		120mg/ml	GMBH			
DIROXIMELUM FUMARAT	VUMERITY 231 mg	gastroresistant capsules	231mg	BIOGEN NETHERLANDS B.V.	HOLLAND	1585	2021
PEGCETACOPLANUM	ASPAVELI 1080 mg	solution for infusion	54mg/ml	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	SWEDEN	1595	2021
PRALSETINIBUM	GAVRETO 100 mg	capsules	100mg	ROCHE REGISTRATION GMBH	GERMANY	1555	2021
REGDANVIMABUM	REGKIRONA 60 mg/ml	concentrate for solution for infusion	60mg/ml	CELLTRION HEALTHCARE HUNGARY KFT.	HUNGARY	1594	2021
SACITUZUMAB GOVITECAN	TRODELVY 200 mg	powder for concentrate for solution for infusion	200mg	GILEAD SCIENCES IRELAND UC	IRELAND	1592	2021
SITAGLIPTINUM	SITAGLIPTIN SUN 25 mg	film-coated tablets	25mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HOLLAND	1598	2021
SITAGLIPTINUM	SITAGLIPTIN SUN 50 mg	film-coated tablets	50mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HOLLAND	1598	2021
SITAGLIPTINUM	SITAGLIPTIN SUN 100 mg	film-coated tablets	100mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HOLLAND	1598	2021

SOTROVIMAB	XEVUDY 500 mg	concentrate for solution for infusion	500mg	GLAXOSMITHKLINE TRADING SERVICES LIMITED	IRELAND	1562	2021
VACC PNEUMOCOCIC POLIZAHARIDIC CONJ. 15-VALENT ADS	VAXNEUVANCE	suspension for injection in pre-filled syringe		MERCK SHARP & DOHME B.V.	HOLLAND	1591	2021
VACC. COVID-19 (recombinant, adjuvanted)	NUVAXOVID	dispersion for injection		NOVAVAX CZ A.S.	THE CZECH REPUBLIC	1618	2021
ZANUBRUTINIBUM	BRUKINSA 80 mg	capsules	80mg	BEIGENE IRELAND LIMITED	IRELAND	1576	2021