

ROMANIA

Newsletter

Year 24, No. 4 (96), 4th quarter of 2022

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. 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)

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Laws

Law 293 of 3 November 2022 pentru prevenirea și combaterea cancerului

Law 95/2006 on healthcare reform, republished, as further amended and supplemented

Ordinances

Emergency Ordinance no. 137 of 12 October 2022 on the establishment of the institutional framework and the measures to ensure the application of the provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

Published in: the Official Gazette of Romania no. 995 of 13 October 2022

Government decisions

Government Decision no. 879/2018 regarding the establishment of a National Committee for Limiting Antimicrobial Resistance, as further amended and supplemented

Orders of the Minister of Health

Order of the Minister of Health no. 2845 of 29 September 2022 on approval of the Methodological rules for approval of provisions of Article 13 of Emergency Government Ordinance no. 46/2021 on the establishment of the institutional framework and the measures necessary to ensure the direct application of the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) no. 178/2002 and Regulation (EC) no. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, on registration of custom-made devices placed on the market under their own name by manufacturers based in Romania

Published in: the Official Gazette of Romania no. 977 of 7 October 2022

Order of the Minister of Health no. 3390/2022 on approval of the Methodological rules for approval of provisions of Articles 3 (10), 4 (3) and 6 (2) of Emergency Government Ordinance no. 29/2022 regarding the establishment of the institutional framework and the necessary measures to ensure the application 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 for the amendment of some regulatory acts in the healthcare field

Order of the Minister of Health no. 3467/2022 of 17 November 2022 on approval of the tariffs for the activities carried out by the National Agency for Medicines and Medical Devices of Romania (NAMMDR) in the field of medical devices
Published in: The Official Gazette of Romania, no. 1123 of 22 November 2022

Order of the Minister of Health no. 3539/2022 on approval of the Methodological rules for placement on the market of medical devices and registration of economic operators into the European database on medical devices (EUDAMED), as well as into the national database, and on waiver from compliance assessment procedures

Order of the Minister of Health no. 3969/2022 on approval of the Methodological Rules for assessment, designation and notification of the bodies assessing medical device compliance, as well as for monitoring and reassessment of notified bodies

Order of the Minister of Health no. 888/2014 on approval of fees payable to the National Agency for Medicines and Medical Devices for services related to medicinal products for human use, as further amended and supplemented

Medicinal product batches recalled during the 4th quarter of 2022

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/MA H	Batch	Grounds for recall	Proposed action	Date of recall
1	MONURAL 3 g granules for oral solution	granules for oral solution	3g	fosfomicin trometamol	ZAMBON S.p.A., Italy	380524, 380525, 378786, 378787, 378788, 3787889, 377746, 377534, 377533, 378260, 377208, 377209, 376410, 374491, 3820238, 382039, 382145, 382146, 382147, 382174, 382640, 382641,	decision to reject the manufacturer's price proposed by the MAH	Voluntary recall	23.11.2022

**Applications for marketing authorisation/marketing authorisation renewal
received during the 3rd quarter of 2022**

In the 3rd quarter of 2022, 4 marketing authorisation/marketing authorisation renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

M01 - ANTI-INFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
M02 - TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN
H02 - CORTICOSTEROIDS FOR SYSTEMIC USE
G01 - GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS

Medicinal products authorised for marketing during the 3rd quarter of 2022

INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
ABIRATERONUM	ABIRATERONA SUN 500 mg	film-coated tablets	500mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HOLLAND	145 95	2022
ABIRATERONUM	ABIRATERONA TEVA 500 mg	film-coated tablets	500mg	TEVA B.V.	HOLLAND	146 70	2022
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOKSIKLAV 875 mg/125 mg	film-coated tablets	1000mg	LEK PHARMACEUTICALS D.D.	SLOVENIA	145 23	2022
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOKSIKLAV 400 mg/57 mg/5 ml	powder for oral suspension	400mg/ 57mg/5ml	LEK PHARMACEUTICALS D.D.	SLOVENIA	146 59	2022
ANIDULAFUNGINUM	ANIDULAFUNGINA TEVA 100 mg	powder for concentrate for solution for infusion	100mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	146 86	2022
AZACITIDINUM	ETRAGA 25 mg/ml	powder for suspension for injection	25mg/ml	STADA M&D S.R.L.	ROMANIA	146 08	2022
BENZYDAMINUM	OROCALMIN 1.5 mg/ml	oromucosal spray, solution	1.5 mg/ml	ZENTIVA, K.S.	THE CZECH REPUBLIC	145 49	2022

BENZYDAMINUM	OROCALMIN 3 mg/ml	oromucosal spray, solution	3mg/ml	ZENTIVA, K.S.	THE CZECH REPUBLIC	145 50	2022
BILASTINUM	BILASTINA AUROBINDO 20 mg	tablets	20mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	146 37	2022
BILASTINUM	BORENAR 6 mg/ml	eye drops, solution	6mg/ml	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LUXEMBURG	146 61	2022
CABAZITAXELUM	CABAZITAXEL G.L. PHARMA 20 mg/ml	concentrate for solution for infusion	20mg/ml	G.L. PHARMA GMBH	AUSTRIA	146 05	2022
CANDESARTANUM CILEXETIL	CASARO 8 mg	tablets	8mg	MEDREG S.R.O.	THE CZECH REPUBLIC	145 90	2022
CANDESARTANUM CILEXETIL	CASARO 16 mg	tablets	16mg	MEDREG S.R.O.	THE CZECH REPUBLIC	145 91	2022
CANDESARTANUM CILEXETIL	CASARO 32 mg	tablets	32mg	MEDREG S.R.O.	THE CZECH REPUBLIC	145 92	2022
CASPOFUNGINUM	CASPOFUNGINA MYLAN 50 mg	powder for concentrate for solution for infusion	50mg	MYLAN PHARMACEUTICALS LIMITED	IRELAND	146 71	2022
CASPOFUNGINUM	CASPOFUNGINA MYLAN 70 mg	powder for concentrate for solution for infusion	70mg	MYLAN PHARMACEUTICALS LIMITED	IRELAND	146 72	2022
CASPOFUNGINUM	CASPOFUNGINA ROMPHARM 50 mg	powder for concentrate for solution for	50mg	ROMPHARM COMPANY S.R.L.	ROMANIA	146 16	2022

		infusion					
CEFAZOLINUM	CEFAZOLINA ATB 1 g	powder for solution for injection/infusion	1g	ANTIBIOTICE S.A.	ROMANIA	145 83	2022
CLINDAMYCINUM	CLINDAMYCIN - MIP 150 mg/ml	solution for injection/infusion	150 mg/ml	MIP PHARMA GMBH	GERMANY	145 56	2022
CLOBETASOLUM	CLOBETAZOL ATB 0.5 mg/g	cream	0.5mg/g	ANTIBIOTICE S.A.	ROMANIA	145 81	2022
CLOPIDOGRELUM	CLOPIDOGREL MEDREG 75 mg	film-coated tablets	75mg	MEDREG S.R.O.	THE CZECH REPUBLIC	145 93	2022
COLECALCIFEROLUM	BONFAL 5000 IU	film-coated tablets	5000IU	WORWAG PHARMA GMBH & CO. KG	GERMANY	146 02	2022
COLECALCIFEROLUM	BONFAL 10000 IU	film-coated tablets	10000IU	WORWAG PHARMA GMBH & CO. KG	GERMANY	146 03	2022
COLECALCIFEROLUM	BONFAL 20000 IU	film-coated tablets	20000IU	WORWAG PHARMA GMBH & CO. KG	GERMANY	146 04	2022
COMBINATIONS	ZIFEX COMPLEX	ovules		ANTIBIOTICE S.A.	ROMANIA	146 26	2022
COMBINATIONS	SEPTOFAR MIERE SI LAMAIE 0.6 mg/1.2 mg	tablets	0.6mg/ 1.2mg	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	145 68	2022
COMBINATIONS	NEIRAXIN	solution for injection		AS KALCEKS	LATVIA	145 43	2022
COMBINATIONS	ADDAVEN	concentrate for solution for infusion		FRESENIUS KABI AB	SWEDEN	146 58	2022

COMBINATIONS	MICROLAX	rectal solution		MCNEIL HEALTHCARE (IRELAND) LIMITED	IRELAND	146 56	2022
COMBINATIONS	ALIFLUSIN 500 mg/200 mg/4 mg	effervescent granules	500mg/ 200mg/4mg	NATUR PRODUKT ZDROVIT SP. Z O.O.	POLAND	146 66	2022
COMBINATIONS	ALIFLUSIN 500 mg/200 mg/4 mg	effervescent tablets	500mg/ 200mg/4mg	NATUR PRODUKT ZDROVIT SP. Z O.O.	POLAND	146 67	2022
COMBINATIONS (BIMATOPROSTUM + TIMOLOLUM)	BIMATOPROST/TIMOLOL ROMPHARM 0.3 mg/5 mg/ml	eye drops, solution	0.3mg/ 5mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	145 28	2022
COMBINATIONS (FOSLEVODOPUM+ FOSCARBIDOPUM)	PRODUODOPA 240 mg/ml+12 mg/ml	solution for infusion	240mg/ml+12 mg/ml	ABBVIE DEUTSCHLAND GMBH & CO. KG	GERMANY	146 82	2022
COMBINATIONS (IRBERSARTANUM+ HYDROCHLOROTHIA- ZIDUM)	IZGREV 150 mg/12.5 mg	film-coated tablets	150mg/ 12.5 mg	SWYSSI AG	GERMANY	146 00	2022
COMBINATIONS (IRBERSARTANUM+ HYDROCHLOROTHIA- ZIDUM)	IZGREV 300 mg/12.5 mg	film-coated tablets	300mg/ 12.5 mg	SWYSSI AG	GERMANY	146 01	2022
COMBINATIONS (PARACETAMOLUM+ IBUPROFENUM)	INFLANOR PLUS 500 mg/200 mg	film-coated tablets	500mg/ 200mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	145 34	2022
COMBINATIONS (PARACETAMOLUM+ PHENYLEPHRINUM)	TANTUMGRIP CU GUST DE PORTOCALA 600 mg/10 mg	powder for oral solution, sachet	600mg/ 10mg	ANGELINI PHARMA ÖSTERREICH GMBH	AUSTRIA	146 29	2022

COMBINATIONS (PARACETAMOLUM+ PHENYLEPHRINUM)	TANTUMGRIP CU GUST DE LAMAIE SI MIERE 600 mg/10 mg	powder for oral solution, sachet	600mg/ 10mg	ANGELINI PHARMA ÖSTERREICH GMBH	AUSTRIA	146 28	2022
COMBINATIONS (PIOGLITAZONUM + METFORMINUM)	SIMEBETES 50 mg/1000 mg	film-coated tablets	50mg/ 1000mg	ALFRED E. TIEFENBACHER GMBH & CO. KG	GERMANY	145 30	2022
COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	TWICOR 10 mg/10 mg	film-coated tablets	10mg/10mg	VIATRIS HEALTHCARE LIMITED	IRELAND	146 88	2022
COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	TWICOR 20 mg/10 mg	film-coated tablets	20mg/10mg	VIATRIS HEALTHCARE LIMITED	IRELAND	146 89	2022
COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	SIMEBETES 50 mg/850 mg	film-coated tablets	50mg/ 850mg	ALFRED E. TIEFENBACHER GMBH & CO. KG	GERMANY	145 29	2022
COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	SITAGLIPTIN/CLORHIDRAT DE METFORMIN PHARMAZAC 50 mg/850 mg	film-coated tablets	50mg/ 850mg	PHARMAZAC S.A.	CYPRUS	145 60	2022
COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	SITAGLIPTIN/CLORHIDRAT DE METFORMIN PHARMAZAC 50 mg/1000 mg	film-coated tablets	50mg/ 1000mg	PHARMAZAC S.A.	CYPRUS	145 61	2022
COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	LONAMO DUO 50 mg/850 mg	film-coated tablets	50mg/ 850mg	EGIS PHARMACEUTIC ALS P.L.C.	HUNGARY	146 49	2022
COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	LONAMO DUO 50 mg/1000 mg	film-coated tablets	50mg/ 1000mg	EGIS PHARMACEUTIC ALS P.L.C.	HUNGARY	146 50	2022

COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	SITAGLIPTINA/ METFORMIN DR. REDDY'S 50 mg/850 mg	film-coated tablets	50mg/ 850mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	146 77	2022
COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	SITAGLIPTINA/ METFORMIN DR. REDDY'S 50 mg/1000 mg	film-coated tablets	50mg/ 1000mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	146 78	2022
DABIGATRANUM ETEXILATUM	WASEDOC 75 mg	capsules	75mg	TERAPIA SA	ROMANIA	145 73	2022
DABIGATRANUM ETEXILATUM	WASEDOC 110 mg	capsules	110mg	TERAPIA SA	ROMANIA	145 74	2022
DABIGATRANUM ETEXILATUM	WASEDOC 150 mg	capsules	150mg	TERAPIA SA	ROMANIA	145 75	2022
DASATINIBUM	DARUPH 16 mg	film-coated tablets	16mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	146 40	2022
DASATINIBUM	DARUPH 40 mg	film-coated tablets	40mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	146 41	2022
DASATINIBUM	DARUPH 55 mg	film-coated tablets	55mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	146 42	2022
DASATINIBUM	DARUPH 63 mg	film-coated tablets	63mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	146 43	2022
DASATINIBUM	DARUPH 79 mg	film-coated tablets	79mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	146 44	2022
DASATINIBUM	DARUPH 111 mg	film-coated tablets	111mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	146 45	2022
DESLORATADINUM	DESLORATADINA AUROBINDO 5 mg	film-coated tablets	5mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	146 65	2022
DIMETINDENUM	FREST 1 mg/g	gel	1mg/g	AS GRINDEKS.	LATVIA	145 70	2022

ENTECAVIRUM	ENTECAVIR SANDOZ 0.5 mg	film-coated tablets	0.5mg	SANDOZ S.R.L.	ROMANIA	146 54	2022
ENTECAVIRUM	ENTECAVIR SANDOZ 1 mg	film-coated tablets	1mg	SANDOZ S.R.L.	ROMANIA	146 55	2022
ERLOTINIBUM	FOKLEROS 100 mg	film-coated tablets	100mg	ALKALOID-INT D.O.O.	SLOVENIA	146 31	2022
ERLOTINIBUM	FOKLEROS 150 mg	film-coated tablets	150mg	ALKALOID-INT D.O.O.	SLOVENIA	146 32	2022
EZETIMIBUM	LIPOBON 10 mg	tablets	10mg	EGIS PHARMACEUTIC ALS PLC	HUNGARY	146 87	2022
FENOFIBRATUM	FENOFIBRAT TERAPIA 145 mg	film-coated tablets	145mg	TERAPIA S.A.	ROMANIA	146 51	2022
FLUDEOXIGLUKOZA (18F)	FDG-RMC 185 MBq/ml	solution for injection	185MBq/ml	RUDER MEDIKOL CIKLOTRON D.O.O.	CROATIA	145 69	2022
FULVESTRANTUM	FULVESTRANT CIPLA 250 mg	solution for injection in pre- filled syringe	250mg	CIPLA EUROPE NV	BELGIUM	145 77	2022
GLICLAZIDUM	GLICLAZIDA MEDREG 60 mg	prolonged- release tablets	60mg	MEDREG S.R.O.	THE CZECH REPUBLIC	146 85	2022
HEXAMIDINUM	ZAMIDINE 1 mg/ml	eye drops, solution	1mg/ml	LABORATOIRES THEA	ROMANIA	146 57	2022
IBUPROFENUM	BUPROFESS 200 mg	oral powder	200mg	STADA M&D S.R.L.	ROMANIA	145 51	2022
IBUPROFENUM	BUPROFESS 400 mg	oral powder	400mg	STADA M&D S.R.L.	ROMANIA	145 52	2022
IBUPROFENUM	IBUPROFEN NUTRA ESSENTIAL 20 mg/ml	oral suspension	20mg/ml	NUTRA ESSENTIAL OTC S.L.	SPAIN	146 30	2022

IBUPROFENUM	PADUDEN RAPID FORTE 400 mg	film-coated tablets	400mg	TERAPIA SA	ROMANIA	145 94	2022
IBUPROFENUM	LAROFEN FORTE 400 mg	film-coated tablets	400mg	LAROPHARM S.R.L.	ROMANIA	145 82	2022
IBUPROFENUM	PADUDEN JUNIOR 40 mg/ml	oral suspension	40mg/ml	TERAPIA S.A.	ROMANIA	146 06	2022
IBUPROFENUM	PADUDEN EXPRESS FORTE 400 mg	soft capsules	400mg	TERAPIA SA	ROMANIA	146 24	2022
IBUPROFENUM	PADUDEN EXPRESS 200 mg	soft capsules	200mg	TERAPIA SA	ROMANIA	146 23	2022
IBUPROFENUM	BUPROFESS RAPID 200 mg	film-coated tablets	200mg	STADA M&D S.R.L.	ROMANIA	146 09	2022
IBUPROFENUM	BUPROFESS RAPID 400 mg	film-coated tablets	400mg	STADA M&D S.R.L.	ROMANIA	146 10	2022
IBUPROFENUM	IBUPROFEN HELCOR 400 mg	film-coated tablets	400mg	AC HELCOR PHARMA S.R.L.	ROMANIA	146 46	2022
IBUPROFENUM	BUPROFESS 400 mg	soft capsules	400mg	STADA M&D S.R.L.	ROMANIA	146 62	2022
IBUPROFENUM	IBUPROFEN STRIDES 400 mg	soft capsules	400mg	STRIDES PHARMA (CYPRUS) LIMITED	CYPRUS	146 73	2022
IBUPROFENUM	IBUPROFEN CATALENT 200 mg	soft capsules	200mg	CATALENT GERMANY EBERBACH GMBH	GERMANY	146 91	2022
IBUPROFENUM	IBUPROFEN CATALENT 400 mg	soft capsules	400mg	CATALENT GERMANY EBERBACH GMBH	GERMANY	146 92	2022

IMUNOGLOBULINA ANTI-D	RHESONATIV 750 UI/ml	solution for injection	750IU/ml	OCTAPHARMA (IP) SPRL	BELGIUM	145 24	2022
IODIDUM	HEVASCOL 480 mg I/ml	solution for injection	480mg I/ml	GUERBET	FRANCE	146 19	2022
IPIDACRINUM	IPIGRIX 20 mg	tablets	20mg	AS GRINDEKS	LATVIA	146 33	2022
IPIDACRINUM	IPIGRIX 5 mg/ml	solution for injection	5mg/ml	AS GRINDEKS	LATVIA	146 34	2022
IPIDACRINUM	IPIGRIX 15 mg/ml	solution for injection	15mg/ml	AS GRINDEKS	LATVIA	146 35	2022
ISOTRETINOINUM	SOTRET 10 mg	soft capsules	10mg	TERAPIA S.A.	ROMANIA	146 68	2022
ISOTRETINOINUM	SOTRET 20 mg	soft capsules	20mg	TERAPIA S.A.	ROMANIA	146 69	2022
ISOTRETINOINUM	ISOTRETINOIN BAILLEUL 10 mg	soft capsules	10mg	LABORATOIRES BAILLEUL S.A.	LUXEMBURG	145 54	2022
ISOTRETINOINUM	ISOTRETINOIN BAILLEUL 20 mg	soft capsules	20mg	LABORATOIRES BAILLEUL S.A.	LUXEMBURG	145 55	2022
IVABRADINUM	RAENOM 5 mg	film-coated tablets	5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	146 52	2022
IVABRADINUM	RAENOM 7.5 mg	film-coated tablets	7.5 mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	146 53	2022
IVABRADINUM	FELOCORD 5 mg	film-coated tablets	5mg	TERAPIA S.A.	ROMANIA	145 26	2022
IVABRADINUM	FELOCORD 7.5 mg	film-coated tablets	7.5 mg	TERAPIA S.A.	ROMANIA	145 27	2022
KETOCONAZOLUM	KETOCONAZOL SLAVIA 20 mg/ml	shampoo	20mg/ml	SLAVIA PHARM S.R.L.	ROMANIA	146 25	2022

KETOPROFENUM	KETOPROFEN PHARMEXONE 50 mg	granules for oral solution, sachet	50mg	PHARMEXON CONSULTING S.R.O.	THE CZECH REPUBLIC	145 99	2022
KETOTIFENUM	KETAZED 0.25 mg/ml	eye drops, solution	0.25mg/ml	HORUS PHARMA	FRANCE	145 59	2022
LACOSAMIDUM	KANILAD 50 mg	film-coated tablets	50mg	MEDOCHEMIE LTD.	CYPRUS	145 85	2022
LACOSAMIDUM	KANILAD 100 mg	film-coated tablets	100mg	MEDOCHEMIE LTD.	CYPRUS	145 86	2022
LACOSAMIDUM	KANILAD 150 mg	film-coated tablets	150mg	MEDOCHEMIE LTD.	CYPRUS	145 87	2022
LACOSAMIDUM	KANILAD 200 mg	film-coated tablets	200mg	MEDOCHEMIE LTD.	CYPRUS	145 88	2022
LACOSAMIDUM	LACOSAMIDA TEVA 50 mg	film-coated tablets	50mg	TEVA PHARMACEUTIC ALS S.R.L.	ROMANIA	146 11	2022
LACOSAMIDUM	LACOSAMIDA TEVA 100 mg	film-coated tablets	100mg	TEVA PHARMACEUTIC ALS S.R.L.	ROMANIA	146 12	2022
LACOSAMIDUM	LACOSAMIDA TEVA 150 mg	film-coated tablets	150mg	TEVA PHARMACEUTIC ALS S.R.L.	ROMANIA	146 13	2022
LACOSAMIDUM	LACOSAMIDA TEVA 200 mg	film-coated tablets	200mg	TEVA PHARMACEUTIC ALS S.R.L.	ROMANIA	146 14	2022
LACOSAMIDUM	LACOSAMIDA FRESENIUS KABI 10 mg/ml	solution for infusion	10mg/ml	FRESENIUS KABI ROMANIA SRL	ROMANIA	145 64	2022
LAPATINIBUM	LAPATINIB STADA 250 mg	film-coated tablets	250mg	STADA M&D S.R.L.	ROMANIA	146 07	2022

LATANOPROSTUM	MONOPOST 50 micrograme/ml	eye drops, solution	50 micro- grame/ml	LABORATOIRES THEA	FRANCE	145 62	2022
LEFLUNOMIDUM	LEFLUNOMIDA AUROBINDO 10 mg	film-coated tablets	10mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	146 80	2022
LEFLUNOMIDUM	LEFLUNOMIDA AUROBINDO 20 mg	film-coated tablets	20mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	146 81	2022
LINEZOLIDUM	LINEZOLID AUROBINDO 2 mg/ml	solution for infusion	2mg/ml	EUGIA PHARMA (MALTA) LTD.	MALTA	146 83	2022
LOPERAMIDUM	LOPERAMID DR. MAX 2 mg	capsules	2mg	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	145 46	2022
LOPINAVIRUM+ RITONAVIRUM	LOPINAVIR/RITONAVIR ACCORD 200 mg/50 mg	film-coated tablets	200mg/ 50mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	145 42	2022
MENOTROPINUM	MENOPUR 600 UI	solution for injection in pre- filled pen	600IU	FERRING GMBH	GERMANY	145 65	2022
MENOTROPINUM	MENOPUR 1200 UI	solution for injection in pre- filled pen	1200IU	FERRING GMBH	GERMANY	145 66	2022
MENOTROPINUM	MENOPUR 75 UI	powder and solvent for solution for injection	75UI	FERRING GMBH	GERMANY	145 67	2022
MEROPENEMUM	MEROPENEM APTAPHARMA 500 mg	powder for solution for injection/infusion	500mg	APTA MEDICA INTERNACIONAL D.O.O.	SLOVENIA	146 17	2022

MEROPENEMUM	MEROPENEM APTAPHARMA 1000 mg	powder for solution for injection/infusion	1000mg	APTA MEDICA INTERNACIONAL D.O.O.	SLOVENIA	146 18	2022
MEROPENEMUM	MEROPENEM STERISCIENCE 500 mg	powder for solution for injection/infusion	500mg	STERISCIENCE B.V.	HOLLAND	145 39	2022
MEROPENEMUM	MEROPENEM STERISCIENCE 1000 mg	powder for solution for injection/infusion	1000mg	STERISCIENCE B.V.	HOLLAND	145 40	2022
METFORMINUM	ZENOFOR 1000 mg	film-coated tablets	1000mg	ZENTIVA, K.S.	ROMANIA	145 58	2022
MITOMICINUM	MITOMICINA ACCORD 40 mg	powder for solution for injection/infusion	40mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	146 79	2022
MOXIFLOXACINUM	MOXIFLOXACINA ROMPHARM 400 mg/250 ml	solution for infusion	400mg/ 250ml	ROMPHARM COMPANY S.R.L.	ROMANIA	145 57	2022
MOXIFLOXACINUM	KIMOKS 400 mg	film-coated tablets	400mg	ALKALOID-INT D.O.O.	SLOVENIA	146 60	2022
NITROGLYCERINUM	NITRONAL 1 mg/ml	solution for infusion	1mg/ml	CHIMIMPORTEXP ORT-PLURIMEX S.R.L.	ROMANIA	145 84	2022
OMEPRAZOLUM	OMEPRAZOL ANTIBIOTICE 20 mg	gastroresistant capsules	20mg	ANTIBIOTICE S.A.	ROMANIA	145 36	2022
OMEPRAZOLUM	NOVOGAST 20 mg	gastroresistant capsules	20mg	ANTIBIOTICE S.A.	ROMANIA	145 35	2022
OMEPRAZOLUM	OMEPRAZOL ROMPHARM 40 mg	powder for solution for infusion	40mg	ROMPHARM COMPANY S.R.L.	ROMANIA	146 20	2022

PANTOPRAZOLUM	ZENCOPAN 40 mg	powder for solution for injection	40mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	145 25	2022
PARACETAMOLUM	PARACETAMOL FARMALIDER 500 mg	tablets	500mg	FARMALIDER S.A.	SPAIN	145 71	2022
PARACETAMOLUM	PARACETAMOL FARMALIDER 1000 mg	tablets	1000mg	FARMALIDER S.A.	SPAIN	145 72	2022
PEMETREXEDUM	PEMETREXED AUROBINDO 500 mg	powder for concentrate for solution for infusion	500 mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	146 84	2022
PERINDOPRILUM	PERINDOPRIL ARGININA TERAPIA 5 mg	film-coated tablets	5mg	TERAPIA S.A.	ROMANIA	145 47	2022
PERINDOPRILUM	PERINDOPRIL ARGININA TERAPIA 10 mg	film-coated tablets	10mg	TERAPIA S.A.	ROMANIA	145 48	2022
PERINDOPRILUM	PRICORON 5 mg	film-coated tablets	5mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	146 38	2022
PERINDOPRILUM	PRICORON 10 mg	film-coated tablets	10mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	146 39	2022
PIPERACILLINUM + TAZOBACTAMUM	PERASIN 2 g/0.25 g	powder for solution for infusion	2g/0.25g	ANTIBIOTICE S.A.	ROMANIA	146 47	2022
PIPERACILLINUM + TAZOBACTAMUM	PERASIN 4 g/0.50 g	powder for solution for infusion	4g/0.50g	ANTIBIOTICE S.A.	ROMANIA	146 48	2022
PLANTE	SINUPRET SIROP JUNIOR 2+	syrup		BIONORICA SE	GERMANY	146 21	2022
PLANTE (EXTRACT DE IEDERA)	ALYSSUM 7 mg/ml	syrup	7mg/ml	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	145 89	2022

PRUCALOPRIDUM	STERCORE 1 mg	film-coated tablets	1mg	MEDOCHEMIE LIMITED	CYPRUS	146 63	2022
PRUCALOPRIDUM	STERCORE 2 mg	film-coated tablets	2mg	MEDOCHEMIE LIMITED	CYPRUS	146 64	2022
RANOLAZINUM	RANOLAZINA ELC GROUP S.R.O. 375 mg	prolonged-release tablets	375mg	ELC GROUP S.R.O	THE CZECH REPUBLIC	145 78	2022
RANOLAZINUM	RANOLAZINA ELC GROUP S.R.O. 500 mg	prolonged-release tablets	500mg	ELC GROUP S.R.O	THE CZECH REPUBLIC	145 79	2022
RANOLAZINUM	RANOLAZINA ELC GROUP S.R.O. 750 mg	prolonged-release tablets	750mg	ELC GROUP S.R.O	THE CZECH REPUBLIC	145 80	2022
RASAGILINUM	RASAGILINA ZENTIVA 1 mg	tablets	1mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	146 27	2022
SILDENAFILUM	SILDENAFIL MEDREG 100 mg	film-coated tablets	100mg	MEDREG S.R.O.	THE CZECH REPUBLIC	145 38	2022
SILDENAFILUM	SILDENAFIL AUROBINDO 20 mg	film-coated tablets	20mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	146 36	2022
SITAGLIPTINUM	SITAGLIPTINA SANDOZ 100 mg	film-coated tablets	100mg	SANDOZ S.R.L.	ROMANIA	145 37	2022
SITAGLIPTINUM	MELIGLIX 25 mg	film-coated tablets	25mg	PHARMAZAC S.A.	CYPRUS	145 31	2022
SITAGLIPTINUM	MELIGLIX 50 mg	film-coated tablets	50mg	PHARMAZAC S.A.	CYPRUS	145 32	2022
SITAGLIPTINUM	MELIGLIX 100 mg	film-coated tablets	100mg	PHARMAZAC S.A.	CYPRUS	145 33	2022
SITAGLIPTINUM	SITAGLIPTINA AUROBINDO 50 mg	film-coated tablets	50mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	146 74	2022

SITAGLIPTINUM	SITAGLIPTINA AUROBINDO 100 mg	film-coated tablets	100mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	146 75	2022
SPIRONOLACTONUM	SPIRONOLACTONA MEDREG 25 mg	film-coated tablets	25mg	MEDREG S.R.O	THE CZECH REPUBLIC	146 22	2022
TAMSULOSINUM	TAMSULOSIN MEDREG 0.4 mg	prolonged- release capsules	0.4mg	MEDREG S.R.O.	THE CZECH REPUBLIC	145 63	2022
TENOFOVIRUM DISOPROXIL	TENOFOVIR DISOPROXIL ACCORD 245 mg	film-coated tablets	245mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	145 41	2022
TIGECYCLINUM	TIGECICLINA ATB 50 mg	powder for solution for infusion	50mg	ANTIBIOTICE S.A.	ROMANIA	145 76	2022
VANCOMYCINUM	VANCOMICINA ATB 500 mg	powder for concentrate for solution for infusion	500mg	ANTIBIOTICE S.A.	ROMANIA	145 44	2022
VANCOMYCINUM	VANCOMICINA ATB 1000 mg	powder for concentrate for solution for infusion	1000mg	ANTIBIOTICE S.A.	ROMANIA	145 45	2022
VERDE DE INDOCIANINA	VERDYE 5 mg/ml	powder for solution for injection	5mg/ml	DIAGNOSTIC GREEN GMBH	GERMANY	146 90	2022

EMA centrally authorised medicinal products notified for marketing in Romania during the 3rd quarter of 2022

INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
ASCIMINIBUM	SCSEMBLIX 20 mg	film-coated tablets	20mg	NOVARTIS EUROPHARM LIMITED	IRELAND	1670	2022
ASCIMINIBUM	SCSEMBLIX 40 mg	film-coated tablets	40mg	NOVARTIS EUROPHARM LIMITED	IRELAND	1670	2022
BEVACIZUMABUM	VEGZELMA 25 mg/ml	concentrate for solution for infusion	25mg/ml	CELLTRION HEALTHCARE HUNGARY KFT.	HUNGARY	1667	2022
COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	SITAGLIPTIN/METFORMIN HYDROCHLORIDE ACCORD 50 mg/850 mg	film-coated tablets	50mg/850mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1661	2022
COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	SITAGLIPTIN/METFORMIN HYDROCHLORIDE ACCORD 50 mg/1000 mg	film-coated tablets	50mg/1000mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1661	2022
EFGARTIGIMOD ALFA	VYVGART 20 mg/ml	concentrate for solution for infusion	20 mg/ml	ARGENX BV	BELGIUM	1674	2022
ERTAPENEMUM	ERTAPENEM SUN 1 g	powder for concentrate for solution for infusion	1g	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HOLLAND	1656	2022

FARICIMABUM	VABYSMO 120 mg/ml	solution for injection	120mg/ml	ROCHE REGISTRATION GMBH	GERMANY	1683	2022
GANIRELIXUM	GANIRELIX GEDEON RICHTER 0.25 mg/0.5 ml	solution for injection in pre-filled syringe	0.25 mg/0.5 ml	GEDEON RICHTER PLC.	HUNGARY	1658	2022
LENACAPAVIRUM	SUNLENCA 464 mg	solution for injection	464mg	GILEAD SCIENCES IRELAND UC	IRELAND	1671	2022
LENACAPAVIRUM	SUNLENCA 300 mg	film-coated tablets	300mg	GILEAD SCIENCES IRELAND UC	IRELAND	1671	2022
SUGAMMADEXUM	SUGAMMADEX FRESENIUS KABI 100 mg/ml	solution for injection	100mg/ml	FRESENIUS KABI DEUTSCHLAND GMBH	GERMANY	1663	2022
TEZEPelumabum	TEZSPIRE 210 mg	solution for injection in pre-filled syringe	110mg/ml	ASTRAZENECA AB	SWEDEN	1677	2022
TIRZEPATIDUM	MOUNJARO 2.5 mg	solution for injection in pre-filled pen	2.5 mg	ELI LILLY NEDERLAND B.V.	HOLLAND	1685	2022
TIRZEPATIDUM	MOUNJARO 5 mg	solution for injection in pre-filled pen	5mg	ELI LILLY NEDERLAND B.V.	HOLLAND	1685	2022
TIRZEPATIDUM	MOUNJARO 7.5 mg	solution for injection in pre-filled pen	7.5 mg	ELI LILLY NEDERLAND B.V.	HOLLAND	1685	2022
TIRZEPATIDUM	MOUNJARO 10 mg	solution for injection in pre-filled pen	10mg	ELI LILLY NEDERLAND B.V.	HOLLAND	1685	2022

TIRZEPATIDUM	MOUNJARO 12.5 mg	solution for injection in pre-filled pen	12.5 mg	ELI LILLY NEDERLAND B.V.	HOLLAND	1685	2022
TIRZEPATIDUM	MOUNJARO 15 mg	solution for injection in pre-filled pen	15mg	ELI LILLY NEDERLAND B.V.	HOLLAND	1685	2022
VUTRISIRANUM	AMVUTTRA 25 mg	solution for injection in pre-filled syringe	50mg/ml	ALNYLAM NETHERLANDS B.V.	HOLLAND	1681	2022