

ROMANIA

Newsletter

Year 24, No. 3 (95), 3rd 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 No. 249 of 20 July 2022 on approval of Emergency Government Ordinance no. 29/2022 regarding the establishment of an institutional framework and necessary measures for 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, repeal of Directive 2001/20/EC and amendment of certain healthcare regulations;

Ordinances

Ordinance no. 37 of 31 August 2022 on amendment and supplementation of Law No. 95/2006 on healthcare reform and of Law No. 227/2015 regarding the Fiscal code, and on establishment of other measures in the healthcare field;

Orders of the Minister of Health

Order of the Minister of Health no. 2.219 of 14 July 2022 on control by periodic assessment of the medical devices in use, the assessment of the performance of second-hand medical devices put into operation and the issuance of the approval for use of medical devices belonging to the means of intervention for pre-hospital emergency medical care;

Order of the Minister of Health no. 2.242/2022 on approval of the procedure for grant of out-of-scope notices for products which do not fall under the scope 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.

Medicinal product batches recalled during the 3rd quarter of 2022

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/ MAH/PIAH*	Batch	Grounds for recall	Acțiune propusă	Data retragerii
1	Paxeladine 2 mg/ml	syrup	2 mg/ml	oxeladine citrate	Ipsen Consumer Healthcare, France	P17074, P17075, P17076, T00448, T00449, T00452, T00453, T00454, T00455, T06604, T06605, T06606, T06607, T08517, T08518, T08519, T09307, T09308, T00450	presence of impurities	Recall from the market at pharmacy level	14.10.2022
2	Paxeladine 2 mg/ml	syrup	2 mg/ml	oxeladine citrate	Genco Pharmaceuticals, Romania	T066033, U00237, U00238, U00239	presence of impurities	Recall from the market at pharmacy level	14.10.2022
3	Amlodipina Aurobindo 5 mg comprimate	tablets	5 mg	Amlodipine	Aurobindo Pharma Romania S.R.L	ALMI9005-05A	short shelf life	Recall and destruction	13.10.2022
4	Vitafusal soluție perfuzabilă	solution for infusion		combination	Infomed Fluid, Romania	1992001	European Commission Decision no. C(2022)3591-final of 24.06.2022: suspension of MAs for medicinal products containing hydroxyethyl starch (HES), solutions for infusion	Recall from the market at pharmacy level and destruction	28.07.2022

*PIAH - (parallel import authorisation holder)

Applications for marketing authorisation/marketing authorisation renewal received during the 2nd quarter of 2022

20 marketing authorisation/marketing authorisation renewal applications for medicinal products corresponding to the following therapeutic groups were received during the 2nd quarter of 2022:

M01 - ANTI-INFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
A02 - DRUGS FOR ACID RELATED DISORDERS
B01A - ANTITHROMBOTIC AGENTS
J05 - ANTIVIRALS FOR SYSTEMIC USE
L01 - ANTINEOPLASTIC AGENTS
R05 - COUGH AND COLD PREPARATIONS
J05 - ANTIVIRALS FOR SYSTEMIC USE
J05 - ANTIVIRALS FOR SYSTEMIC USE
N06 - PSYCHOANALEPTICS
N06 - PSYCHOANALEPTICS
J01 - ANTIBACTERIALS FOR SYSTEMIC USE
C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
M02 - TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN
A10 - DRUGS USED IN DIABETES
A10 - DRUGS USED IN DIABETES
A10 - DRUGS USED IN DIABETES
J01 - ANTIBACTERIALS FOR SYSTEMIC USE
J01 - ANTIBACTERIALS FOR SYSTEMIC USE

Medicinal products authorised for marketing during the 2nd quarter of 2022

INN	Invented name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
ACIDUM GADOTERICUM	CLARISCAN 0.5 mmols/ml	solution for injection	0.5mmols/ml	GE HEALTHCARE AS	NORWAY	14388	2022
ACIDUM GADOTERICUM	CLARISCAN 0.5 mmols/ml	solution for injection in pre-filled syringe	0.5mmols/ml	GE HEALTHCARE AS	NORWAY	14389	2022
AMBAZONUM	FARINGOSEPT CAFEA	tablets de supt		TERAPIA S.A.	ROMANIA	14491	2022
AMBAZONUM	FARINGOSEPT MIERE ȘI LĂMÂIE	tablets de supt		TERAPIA S.A.	ROMANIA	14493	2022
AMBAZONUM	FARINGOSEPT VANILIE	tablets de supt		TERAPIA S.A.	ROMANIA	14492	2022
BENDAMUSTINUM	BENDAMUSTINA ACCORD 25 mg/ml	concentrate for solution for infusion	25mg/ml	ACCORD HEALTHCARE POLSKA SP. Z. O.O.	POLAND	14484	2022
BILASTINUM	BILASTINA MSN 20 mg	tablets	20mg	MSN LABS EUROPE LIMITED	MALTA	14463	2022
BOSENTANUM	BOSENTAN TERAPIA 125 mg	film-coated tablets	125mg	TERAPIA SA	ROMANIA	14415	2022
BUPIVACAINUM	SANERGY SPINAL 5 mg/ml	solution for injection	5mg/ml	AS GRINDEKS	LATVIA	14436	2022
BUPIVACAINUM	BUPIVACAINA GRINDEKS 5 mg/ml	solution for injection	5mg/ml	AS GRINDEKS	LATVIA	14435	2022
CALCIFEDIOLUM	HIDROFEROL 0.266 mg	soft capsules	0.266mg	FAES FARMA S.A.	SPAIN	14472	2022
CANDESARTANUM CILEXETIL	TANDESAR 32 mg	tablets	32mg	TERAPIA S.A.	ROMANIA	14471	2022

CASPOFUNGINUM	CASPOFUNGINA TERAPIA 50 mg	powder for concentrate for solution for infusion	50mg	TERAPIA S.A.	ROMANIA	14473	2022
CASPOFUNGINUM	CASPOFUNGINA TERAPIA 70 mg	powder for concentrate for solution for infusion	70mg	TERAPIA S.A.	ROMANIA	14474	2022
COMBINATIONS	SOLPADEINE EXTRA 500 mg/12.8 mg/30 mg	effervescent tablets	500mg/12.8mg/ 30mg	PERRIGO ROMANIA S.R.L.	ROMANIA	14516	2022
COMBINATIONS	SMOFKABIVEN EXTRA NITROGEN FARA ELECTROLITI	emulsion for infusion		FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	14454	2022
COMBINATIONS	SMOFKABIVEN EXTRA NITROGEN	emulsion for infusion		FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	14453	2022
COMBINATIONS (AMLODIPINUM+ VALSARTANUM)	DIPPERAM 5 mg/80 mg	film-coated tablets	5mg/80mg	SANDOZ S.R.L.	ROMANIA	14398	2022
COMBINATIONS (AMLODIPINUM+ VALSARTANUM)	DIPPERAM 5 mg/160 mg	film-coated tablets	5mg/160mg	SANDOZ S.R.L.	ROMANIA	14399	2022
COMBINATIONS (AMLODIPINUM+ VALSARTANUM)	DIPPERAM 10 mg/160 mg	film-coated tablets	10mg/160mg	SANDOZ S.R.L.	ROMANIA	14400	2022
COMBINATIONS (ARTICAINUM+ ADRENALINUM)	SEPTANEST CU ADRENALINA 1/100000	solution for injection	40mg/0.01mg/ml	SEPTODONT	FRANCE	14385	2022
COMBINATIONS (ARTICAINUM+ ADRENALINUM)	SEPTANEST CU ADRENALINA 1/200000	solution for injection	40mg/0.005mg/ml	SEPTODONT	FRANCE	14386	2022

COMBINATIONS (BECLOMETASONUM+ FORMOTEROLUM)	FOSTER 200 micrograms/ 6 micrograms	pressurised solution for inhalation	200micrograms/ 6micrograms	CHIESI PHARMACEUTICALS GMBH	AUSTRIA	14482	2022
COMBINATIONS (BECLOMETASONUM+ FORMOTEROLUM)	FOSTER NEXTHALER 200 micrograms/ 6 micrograms	powder for inhalation	200micrograms/ 6micrograms	CHIESI PHARMACEUTICALS GMBH	AUSTRIA	14483	2022
COMBINATIONS (CANDESARTANUM CILEXETIL+HCT)	CANDESARTAN HCT SWYSSI 8 mg/12.5 mg	tablets	8mg/12.5mg	SWYSSI AG	GERMANY	14423	2022
COMBINATIONS (CANDESARTANUM CILEXETIL+HCT)	CANDESARTAN HCT SWYSSI 16 mg/12.5 mg	tablets	16mg/12.5mg	SWYSSI AG	GERMANY	14424	2022
COMBINATIONS (IBUPROFENUM+ PSEUDOEFEDRINUM)	IBUVALEN FLU 200 mg/30 mg	film-coated tablets	200mg/30mg	POLISANO PHARMACEUTICALS S.A.	ROMANIA	14430	2022
COMBINATIONS (IBUPROFENUM+ PSEUDOEFEDRINUM)	IBUSTOP RACEALA SI GRIPA 200 mg/30 mg	soft capsules	200mg/30mg	STADA M&D S.R.L.	ROMANIA	14464	2022
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	CO-PRENESSANEO 5 mg/1.25 mg	tablets	5mg/1.25mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14401	2022
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	CO-PRENESSANEO 10 mg/2.5 mg	tablets	10mg/2.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14402	2022
COMBINATIONS (ROSUVASTATINUM+ VALSARTAMUM)	VALAROX 10 mg/80 mg	film-coated tablets	10mg/80mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14442	2022

COMBINATIONS (ROSUVASTATINUM+ VALSARTAMUM)	VALAROX 20 mg/80 mg	film-coated tablets	20mg/80mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14443	2022
COMBINATIONS (ROSUVASTATINUM+ VALSARTAMUM)	VALAROX 10 mg/160 mg	film-coated tablets	10mg/160mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14444	2022
COMBINATIONS (ROSUVASTATINUM+ VALSARTAMUM)	VALAROX 20 mg/160 mg	film-coated tablets	20mg/160mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14445	2022
COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	SITAGLIPTIN/METFORM IN GRINDEKS 50 mg/850 mg	film-coated tablets	50mg/850mg	AS GRINDEKS.	LATVIA	14411	2022
COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	SITAGLIPTIN/METFORM IN GRINDEKS 50 mg/1000 mg	film-coated tablets	50mg/1000mg	AS GRINDEKS.	LATVIA	14412	2022
COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	SITAGLIPTIN/ METFORMIN TEVA 50 mg/1000 mg	film-coated tablets	50mg/1000 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	14425	2022
COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	JAMESI 50 mg/850 mg	film-coated tablets	50mg/850mg	ZENIVA, K.S.	THE CZECH REPUBLIC	14437	2022
COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	JAMESI 50 mg/1000 mg	film-coated tablets	50mg/1000mg	ZENIVA, K.S.	THE CZECH REPUBLIC	14438	2022
COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	SITAGLIPTIN/ METFORMIN SANDOZ 50 mg/1000 mg	film-coated tablets	50mg/1000mg	SANDOZ S.R.L.	ROMANIA	14504	2022

COMBINATIONS (TELMISARTANUM+ AMLODIPINUM)	TELASSMO 40 mg/5 mg	tablets	40mg/5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14416	2022
COMBINATIONS (TELMISARTANUM+ AMLODIPINUM)	TELASSMO 40 mg/10 mg	tablets	40mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14417	2022
COMBINATIONS (TELMISARTANUM+ AMLODIPINUM)	TELASSMO 80 mg/5 mg	tablets	80mg/5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14418	2022
COMBINATIONS (TELMISARTANUM+ AMLODIPINUM)	TELASSMO 80 mg/10 mg	tablets	80mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14419	2022
COMBINATIONS (TRAMADOLUM+ PARACETAMOLUM)	TRAMADOL/PARACETA MOL ACCORD 37.5 mg/325 mg	effervescent tablets	37.5mg/325mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	14518	2022
DEXPANTHENOLUM	RECREOL 50 mg/g	cream	50mg/g	AS GRINDEKS	LATVIA	14421	2022
DEXPANTHENOLUM	RECREOL 50 mg/g	ointment	50mg/g	AS GRINDEKS	LATVIA	14422	2022
DICLOFENACUM	RAPLON 12.5 mg	film-coated tablets	12.5mg	MEDOCHEMIE LTD	CYPRUS	14439	2022
DULOXETINUM	DULOXETINA PHARMACLAN 30 mg	gastroresistant capsules	30mg	PHARMACLAN S.R.O.	THE CZECH REPUBLIC	14476	2022
DULOXETINUM	DULOXETINA PHARMACLAN 60 mg	gastroresistant capsules	60mg	PHARMACLAN S.R.O.	THE CZECH REPUBLIC	14477	2022
ETORICOXIBUM	IMESOL 30 mg	film-coated tablets	30mg	TERAPIA S.A.	ROMANIA	14500	2022
ETORICOXIBUM	IMESOL 60 mg	film-coated tablets	60mg	TERAPIA S.A.	ROMANIA	14501	2022
ETORICOXIBUM	IMESOL 90 mg	film-coated tablets	90mg	TERAPIA S.A.	ROMANIA	14502	2022
ETORICOXIBUM	IMESOL 120 mg	film-coated tablets	120mg	TERAPIA S.A.	ROMANIA	14503	2022
FIBRINOGEN UMAN	FIBRYGA 1 g	powder and solvent for solution for injection/infusion	1g	OCTAPHARMA (IP) SPRL	BELGIUM	14395	2022

FINGOLIMODUM	FINGOLIMOD DR. REDDY'S 0.5 mg	capsules	0.5mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	14511	2022
IBUPROFENUM	IBUPROFEN B. BRAUN 400 mg	solution for infusion	400mg	B. BRAUN MELSUNGEN AG	GERMANY	14450	2022
IBUPROFENUM	IBUPROFEN B. BRAUN 600 mg	solution for infusion	600mg	B. BRAUN MELSUNGEN AG	GERMANY	14451	2022
IBUPROFENUM	BIOFEN 200 mg	soft capsules	200mg	BIOFARM S.A.	ROMANIA	14498	2022
IBUPROFENUM	BIOFEN FORTE 400 mg	soft capsules	400mg	BIOFARM S.A.	ROMANIA	14499	2022
ICATIBANTUM	ICATIBANT UNIVERSAL FARMA 30 mg	solution for injection in pre- filled syringe	30mg	UNIVERSAL FARMA, S.L.	SPAIN	14427	2022
INDOMETACINUM	INDOSIN 20 mg/g	gel	20mg/g	SINTOFARM S.A.	ROMANIA	14452	2022
INHIBITOR ALFA1 PROTEINAZA UMANA	RYMPHYSIA 500 mg	powder and solvent for solution for infusion	500mg	TAKEDA MANUFACTURING AUSTRIA AG	AUSTRIA	14494	2022
INHIBITOR ALFA1 PROTEINAZA UMANA	RYMPHYSIA 1000 mg	powder and solvent for solution for infusion	1000mg	TAKEDA MANUFACTURING AUSTRIA AG	AUSTRIA	14495	2022
INOSINUM	RESIVIRTAN 100 mg/ml	syrup	100mg/ml	HEALTH-MED SP. Z O. O. SP.J.	POLAND	14394	2022
IVABRADINUM	IVABRADINA TEVA 5 mg	film-coated tablets	5mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	14507	2022
IVABRADINUM	IVABRADINA TEVA 7.5 mg	film-coated tablets	7.5mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	14508	2022
KETOPROFENUM	KETOPROFEN PHARMEXON 25 mg	film-coated tablets	25mg	DOMPE FARMACEUTICI S.P.A.	ITALY	14470	2022

KETOPROFENUM	KETOPROFEN PHARMEXON 25 mg	granule drajefiate în plic	25mg	DOMPE FARMACEUTICI S.P.A.	ITALY	14469	2022
LEVOFLOXACINUM	LEVOFLOXACINA VIOSER 5 mg/ml	solution for infusion	5mg/ml	VIOSER S.A. PARENTERAL SOLUTIONS INDUSTRY	GREECE	14414	2022
LEVOMETHADONUM	LEFISYO 5 mg/ml	oral solution	5mg/ml	ALKALOID - INT D.O.O.	SLOVENIA	14405	2022
LEVOSIMENDANUM	LEVOSIMENDAN KALCEKS 2.5 mg/ml	concentrate for solution for infusion	2.5mg/ml	AKCIJU SABIEDRIBA KALCEKS	LATVIA	14397	2022
LINAGLIPTINUM	SANSIK 5 mg	film-coated tablets	5mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	14496	2022
MESALAZINUM	SALCROZINE 1000 mg	gastroresistant tablets	1000mg	FAES FARMA S.A.	SPAIN	14426	2022
METAMIZOLUM NATRIUM	METAMIZOL KALCEKS 500 mg/ml	solution for injection	500 mg/ml	AS KALCEKS	LATVIA	14519	2022
METAMIZOLUM NATRIUM	ALGOCALMIN 500 mg	film-coated tablets	500mg	ZENTIVA K.S.	THE CZECH REPUBLIC	14462	2022
METRONIDAZOLUM	METRONIDAZOL VIOSER 500 mg/100 ml	solution for infusion	500mg/100ml	VIOSER S.A. PARENTERAL SOLUTIONS INDUSTRY	GREECE	14407	2022
NATRII CITRAS	CIFOBAN 136mmol/l	solution for infusion	136mmol/l	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	GERMANY	14396	2022
NICARDIPINUM	NICARDIPINE AGUETTANT 10mg/10ml	solution for injection	10mg/10ml	HYPERICUM S.R.L.	ROMANIA	724	2022

OFLOXACINUM	UNIFLOX 3 mg/ml	eye/ear drops, solution	3mg/ml	UNIMED PHARMA SPOL. S.R.O.	THE SLOVAK REPUBLIC	14481	2022
OMEPRAZOLUM	OMEPRAZOL MEDREG 10 mg	gastroresistant capsules	10mg	MEDREG S.R.O.	THE CZECH REPUBLIC	14447	2022
OMEPRAZOLUM	OMEPRAZOL MEDREG 20 mg	gastroresistant capsules	20mg	MEDREG S.R.O.	THE CZECH REPUBLIC	14448	2022
OMEPRAZOLUM	OMEPRAZOL MEDREG 40 mg	gastroresistant capsules	40mg	MEDREG S.R.O.	THE CZECH REPUBLIC	14449	2022
ONDANSETRONUM	ZONDARON 2 mg/ml	solution for injection/infusion	2mg/ml	SOPHARMA AD	BULGARIA	14413	2022
OXYBUPROCAINI HYDROCHLORIDUM	BENOXI 4 mg/ml	eye drops, solution	4mg/ml	UNIMED PHARMA SPOL. S.R.O.	THE SLOVAK REPUBLIC	14475	2022
OXYTOCINUM	OFOST 8.3 micrograms/ml	solution for injection/infusion	8.3micrograms/ml	AS GRINDEKS	LATVIA	14428	2022
OXYTOCINUM	OFOST 16.7 micrograms/ml	solution for injection/infusion	16.7micrograms/ml	AS GRINDEKS	LATVIA	14429	2022
PARACETAMOLUM	PARACETAMOL AUROBINDO 500 mg	tablets	500mg	AUROBINDO PHARMA ROMANIA SRL	ROMANIA	14446	2022
PARACETAMOLUM	PACETRAL 500 mg	tablets	500mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	14497	2022
PAZOPANIBUM	PAZOPANIB TEVA 200 mg	film-coated tablets	200mg	TEVA B.V.	HOLLAND	14403	2022
PAZOPANIBUM	PAZOPANIB TEVA 400 mg	film-coated tablets	400mg	TEVA B.V.	HOLLAND	14404	2022
PEMETREXEDUM	PEMETREXED STADA 25 mg/ml	concentrate for solution for infusion	25mg/ml	STADA ARZNEIMITTEL AG	GERMANY	14393	2022
PHENYLEPHRINUM	BIORPHEN 0.1 mg/ml	solution for injection/infusion	0.1mg/ml	SINTETICA GMBH	GERMANY	14478	2022

PHENYLEPHRINUM	BIORPHEN 10 mg/ml	solution for injection	10 mg/ml	SINTETICA GMBH	GERMANY	14479	2022
QUETIAPINUM	QUETIAPINA ACCORD 150 mg	prolonged-release tablets	150mg	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	14480	2022
RILMENIDINUM	TARUZA 1 mg	tablets	1mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	14512	2022
SITAGLIPTINUM	SITAGLIPTIN GRINDEKS 25 mg	film-coated tablets	25mg	AS GRINDEKS.	LATVIA	14408	2022
SITAGLIPTINUM	SITAGLIPTIN GRINDEKS 50 mg	film-coated tablets	50mg	AS GRINDEKS.	LATVIA	14409	2022
SITAGLIPTINUM	SITAGLIPTIN GRINDEKS 100 mg	film-coated tablets	100mg	AS GRINDEKS.	LATVIA	14410	2022
SITAGLIPTINUM	JIDINUM 25 mg	film-coated tablets	25mg	MEDOCHEMIE LIMITED	CYPRUS	14459	2022
SITAGLIPTINUM	JIDINUM 50 mg	film-coated tablets	50mg	MEDOCHEMIE LIMITED	CYPRUS	14460	2022
SITAGLIPTINUM	JIDINUM 100 mg	film-coated tablets	100mg	MEDOCHEMIE LIMITED	CYPRUS	14461	2022
SITAGLIPTINUM	SITAGLIPTINA TIEFENBACHER 25 mg	film-coated tablets	25mg	ALFRED E. TIEFENBACHER GMBH & CO. KG	GERMANY	14520	2022
SITAGLIPTINUM	SITAGLIPTINA TIEFENBACHER 50 mg	film-coated tablets	50mg	ALFRED E. TIEFENBACHER GMBH & CO. KG	GERMANY	14521	2022
SITAGLIPTINUM	SITAGLIPTINA TIEFENBACHER 100 mg	film-coated tablets	100mg	ALFRED E. TIEFENBACHER GMBH & CO. KG	GERMANY	14522	2022
SOLIFENACINUM SUCCINATE	SOLIFENACIN ARISTO 5 mg	film-coated tablets	5mg	ARISTO PHARMA GMBH	GERMANY	14505	2022

SOLIFENACINUM SUCCINATE	SOLIFENACIN ARISTO 10 mg	film-coated tablets	10mg	ARISTO PHARMA GMBH	GERMANY	14506	2022
SUGAMMADEXUM	SUGAMMADEX TEVA 100 mg/ml	solution for injection	100 mg/ml	TEVA PHARMACEUTICAL S.R.L.	ROMANIA	14406	2022
SUNITINIBUM	SUNITINIB ALKALOID-INT 12.5 mg	capsules	12.5mg	ALKALOID - INT D.O.O.	SLOVENIA	14390	2022
SUNITINIBUM	SUNITINIB ALKALOID-INT 25 mg	capsules	25mg	ALKALOID - INT D.O.O.	SLOVENIA	14391	2022
SUNITINIBUM	SUNITINIB ALKALOID-INT 50 mg	capsules	50mg	ALKALOID - INT D.O.O.	SLOVENIA	14392	2022
SUNITINIBUM	SUNITINIB MSN 12.5 mg	capsules	12.5mg	MSN LABS EUROPE LIMITED	MALTA	14455	2022
SUNITINIBUM	SUNITINIB MSN 25 mg	capsules	25mg	MSN LABS EUROPE LIMITED	MALTA	14456	2022
SUNITINIBUM	SUNITINIB MSN 37.5 mg	capsules	37.5mg	MSN LABS EUROPE LIMITED	MALTA	14457	2022
SUNITINIBUM	SUNITINIB MSN 50 mg	capsules	50mg	MSN LABS EUROPE LIMITED	MALTA	14458	2022
TADALAFILUM	TADALAFIL ACCORD 10 mg	film-coated tablets	10mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	14513	2022
TADALAFILUM	TADALAFIL ACCORD 20 mg	film-coated tablets	20mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	14514	2022
TADALAFILUM	TADILECTO 5 mg	film-coated tablets	5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14432	2022
TADALAFILUM	TADILECTO 10 mg	film-coated tablets	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14433	2022

TADALAFILUM	TADILECTO 20 mg	film-coated tablets	20mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14434	2022
TADALAFILUM	ARVALTI 2.5 mg	film-coated tablets	2.5mg	CIPLA EUROPE NV	BELGIUM	14487	2022
TADALAFILUM	ARVALTI 5 mg	film-coated tablets	5mg	CIPLA EUROPE NV	BELGIUM	14488	2022
TADALAFILUM	ARVALTI 10 mg	film-coated tablets	10mg	CIPLA EUROPE NV	BELGIUM	14489	2022
TADALAFILUM	ARVALTI 20 mg	film-coated tablets	20mg	CIPLA EUROPE NV	BELGIUM	14490	2022
TEICOPLANINUM	TEICOPLANINA APTAPHARMA 200 mg	powder and solvent for solution for injection/infusion	200mg	APTA MEDICA INTERNACIONAL D.O.O.	SLOVENIA	14465	2022
TEICOPLANINUM	TEICOPLANINA APTAPHARMA 400 mg	powder and solvent for solution for injection/infusion	400mg	APTA MEDICA INTERNACIONAL D.O.O.	SLOVENIA	14466	2022
TELMISARTANUM	TELMISARTAN AUROBINDO 40 mg	tablets	40mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	14467	2022
TELMISARTANUM	TELMISARTAN AUROBINDO 80 mg	tablets	80mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	14468	2022
TERLIPRESSINUM	ACETAT DE TERLIPRESINA EVER PHARMA 0.2 mg/ml	solution for injection	0.2mg/ml	EVER VALINJECT GMBH	AUSTRIA	14517	2022
TICAGRELOR	PLATEGRA 60 mg	film-coated tablets	60mg	EGIS PHARMACEUTICAL PLC.	HUNGARY	14485	2022
TICAGRELOR	PLATEGRA 90 mg	film-coated tablets	90mg	EGIS PHARMACEUTICAL PLC.	HUNGARY	14486	2022
TICAGRELOR	OREBRITON 60 mg	film-coated tablets	60mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	14509	2022

TICAGRELOR	OREBRITON 90 mg	film-coated tablets	90mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	14510	2022
TRABECTEDINUM	TRABECTEDIN TEVA 0.25 mg	powder for concentrate for solution for infusion	0.25mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	14440	2022
TRABECTEDINUM	TRABECTEDIN TEVA 1 mg	powder for concentrate for solution for infusion	1mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	14441	2022
VACCIN GRIPAL INACTIVAT	INFLUVAC TETRA	suspension for injection in pre-filled syringe		VIATRIS HEALTHCARE LIMITED	IRELAND	14420	2022
VALGANCICLOVIRUM	VALGANCICLOVIR CIPLA 450 mg	film-coated tablets	450mg	CIPLA EUROPE NV	BELGIUM	14387	2022

Medicinal products authorised through centralised procedure by the EMA, notified for marketing in Romania during the 2nd quarter of 2022

INN	Invented name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
AVALGLUCOSIDASUM ALPHA	NEXVIADYME 100 mg	powder for concentrate for solution for infusion	100mg	GENZYME EUROPE B.V.	HOLLAND	1579	2022
CAPMATINIBUM	TABRECTA 150 mg	film-coated tablets	150mg	NOVARTIS EUROPHARM LIMITED	IRELAND	1650	2022
CAPMATINIBUM	TABRECTA 200 mg	film-coated tablets	200mg	NOVARTIS EUROPHARM LIMITED	IRELAND	1650	2022
CILTACABTAGEN AUTOLEUCEL	CARVYKTI 3.2 × 10 ⁶ – 1.0 × 10 ⁸ cells dispersion for infusion	cells dispersion for infusion		JANSSEN CILAG INTERNATIONAL NV	BELGIUM	1648	2022
DOXORUBICINUM	ZOLSKETIL PEGYLATED LIPOSOMAL 2 mg/ml	concentrate for dispersion for infusion	2mg/ml	ACCORD HEALTHCARE S.L.U.	SPAIN	1629	2022
LENALIDOMIDUM	LENALIDOMIDE KRKA 5 mg	capsules	5mg	KRKA D.D. NOVO MESTO	SLOVENIA	1519	2022
LEUPRORELINUM	CAMCEVI 42 mg	prolonged-release suspension for injection	42mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1647	2022

MOSUNETUZUMABUM	LUNSUMIO 1 mg	concentrate for solution for infusion	1mg	ROCHE REGISTRATION GMBH	GERMANY	1649	2022
MOSUNETUZUMABUM	LUNSUMIO 30 mg	concentrate for solution for infusion	30mg	ROCHE REGISTRATION GMBH	GERMANY	1649	2022
OLIPUDASE ALFA	XENPOZYME 20 mg	powder for concentrate for solution for infusion	20mg	GENZYME EUROPE B.V.	HOLLAND	1659	2022
PLANTS (BIRCH)	FILSUVEZ	gel		AMRYT PHARMACEUTICALS DAC	IRELAND	1652	2022
RIMEGEPANT	VYDURA 75 mg	oral lyophilisate	75mg	BIOHAVEN PHARMACEUTICAL IRELAND DAC	IRELAND	1645	2022
SITAGLIPTINUM	SITAGLIPTIN ACCORD 25 mg	film-coated tablets	25mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1633	2022
SITAGLIPTINUM	SITAGLIPTIN ACCORD 50 mg	film-coated tablets	50mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1633	2022
SITAGLIPTINUM	SITAGLIPTIN ACCORD 100 mg	film-coated tablets	100mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1633	2022
TEBENTAFUSP	KIMMTRAK 100 micrograms/0.5 ml	concentrate for solution for infusion	100 µg/0.5 ml	IMMUNOCORE IRELAND LIMITED	IRELAND	1630	2022