

ROMANIA

Newsletter

Year 22, No. 4 (88), 4th quarter of 2020

*National Agency
for Medicines and Medical Devices
of Romania*

Medicinal product batches recalled during the 4th quarter of 2020

Applications for marketing authorisation/marketing authorisation renewal received during the 3rd quarter of 2020

Medicinal products authorised for marketing during the 3rd quarter of 2020

EMA centrally authorised medicinal products notified for marketing in Romania during the 3rd quarter of 2020

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TABLE OF CONTENTS

Medicinal product batches recalled during the 4th quarter of 2020	5
Applications for marketing authorisation/marketing authorisation renewal received during the 3rd quarter of 2020	8
Medicinal products authorised for marketing during the 3rd quarter of 2020	9
EMA centrally authorised medicinal products notified for marketing in Romania during the 3rd quarter of 2020	28

Medicinal product batches recalled during the 4th quarter of 2020

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Proposed action	Date of recall
1	Irinotecan Accord 20 mg/ml	concentrate for solution for infusion	20 mg/ml	irinotecan	Accord Healthcare Polska SP. Z.O.O., Poland	X21211	Recall following a quality noncompliance	Recall and destruction	25.08.2020
2	Entecavir Zentiva K.s. 0.5 mg	film-coated tablets	0.5 mg	entecavir	Zentiva SA, Romania/Zentiva K.S. The Czech Republic	all batches	Voluntary recall from the market, following withdrawal of the medicinal product from CaNaMed and the Public National Prices Catalogue from 01.07.2020	Voluntary recall and destruction	06.10.2020
3	Entecavir Zentiva K.s. 1 mg	film-coated tablets	1 mg	entecavir	Zentiva SA, Romania/Zentiva K.S. The Czech Republic	all batches	Voluntary recall from the market, following withdrawal of the medicinal product from CaNaMed and the Public National Prices Catalogue from 01.07.2020	Voluntary recall and destruction	06.10.2020
4	Bortezomib Zentiva 3.5 mg	powder for solution for injection	3.5 mg	bortezomib	Synthon HiSPAIN SL, SPAIN/Zentiva K.S. The Czech Republic	all batches	Voluntary recall from the market, following withdrawal of the medicinal product	Voluntary recall and destruction	06.10.2020

							from CaNaMed and the Public National Prices Catalogue from 01.07.2020		
5	Tenofovir Disoproxil Zentiva 245 mg	film-coated tablets	245 mg	tenofovir disoproxil	Zentiva SA, Romania/Zentiva K.S. The Czech Republic	all batches	Voluntary recall from the market, following withdrawal of the medicinal product from CaNaMed and the Public National Prices Catalogue from 01.07.2020	Voluntary recall and destruction	06.10.2020
6	Nitrofurantoina Arena 100 mg	tablets	100 mg	Nitrofurantoina	Arena Group SA, Romania	2051218	recall following an out of specification result for parameter "g% dissolution", following testing of the relevant parameters within the Yearly Sampling and Testing Plan for 2019	Recall and destruction	07.10.2020
7	Zerbaxa ® 1 g /0.5 g	powder for concentrate for solution for injection	1 g / 0.5 g	combinations (ceftolozan+ tazobactam)	Arvato Distribution GmbH, Germany/ Merck Sharp&Dohme	T024378	voluntary recall from the market, at pharmacy level, as a precautionary measure,	Voluntary recall and destruction	31.12.2020

					B.V. Holland		following conduct of routine sterility tests for other batches (not distributed in Romania) which have identified a bacterial contamination		
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**Applications for marketing authorisation/marketing authorisation renewal
received during the 3rd quarter of 2020**

In the 3rd quarter of 2020, 20 marketing authorisation/marketing authorisation renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

ATC CODE
M01 - ANTI-INFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
M01 - ANTI-INFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
M01 - ANTI-INFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
A07 - ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS
A07 - ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS
A07 - ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS
D01 - ANTIFUNGALS FOR DERMATOLOGICAL USE
M01 - ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
N02 - ANALGESICS
N02 - ANALGESICS
N05 - PSYCHOLEPTICS
C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
J01 - ANTIBACTERIALS FOR SYSTEMIC USE
H02 - CORTICOSTEROIDS FOR SYSTEMIC USE
N01 - ANESTHETICS
P02 - ANTHELMINTICS
R07 - OTHER RESPIRATORY SYSTEM PRODUCTS

Medicinal products authorised for marketing during the 3rd quarter of 2020

INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
ABACAVIRUM/LAMIVUDINUM	ABACAVIR LAMIVUDINA TEVA	film-coated tablets	600 mg/ 300 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	13367	2020
ACETYLCYSTEINUM	ACC MIERE SI LAMAIE	powder for oral suspension	200mg	HEXAL AG	GERMANY	13385	2020
ACETYLCYSTEINUM	ACC MIERE SI LAMAIE	powder for oral suspension	600mg	HEXAL AG	GERMANY	13386	2020
ACICLOVIRUM	ACICLOVIR LAROPHARM	tablets	200 mg	LAROPHARM S.R.L.	ROMANIA	13315	2020
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC SANTA	tablets	500mg	SANTA S.A,	ROMANIA	13423	2020
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC BIOFARM	tablets	500 mg	BIOFARM S.A.	ROMANIA	13360	2020
ACIDUM ACETYLSALICYLICUM	ASCARD	film-coated gastroresistant tablets	75mg	ARENA GROUP S.A.	ROMANIA	13359	2020
ACIDUM URSODEOXYCHOLICUM	URSOGRIX	capsules	250mg	AS GRINDEKS	LITHUANIA	13464	2020

ALBENDAZOLUM	ZENTEL	oral suspension	400 mg/10 ml	GLAXOSMITHKLINE (IRELAND) LIMITED	GREAT BRITAIN	13365	2020
AMLODIPINUM/ VALSARTANUM	AMLOPIDINA VALSARTAN ZENTIVA	film-coated tablets	5mg/80mg	ZENTIVA ks	THE CZECH REPUBLIC	13415	2020
AMLODIPINUM/ VALSARTANUM	AMLOPIDINA VALSARTAN ZENTIVA	film-coated tablets	5mg/160mg	ZENTIVA ks	THE CZECH REPUBLIC	13416	2020
AMLODIPINUM/ VALSARTANUM	AMLOPIDINA VALSARTAN ZENTIVA	film-coated tablets	10mg/160mg	ZENTIVA ks	THE CZECH REPUBLIC	13417	2020
APOMORPHINE HYDROCHLORIDE	APO- GO	solution for infusion	5mg/ml	STADA ARZNEIMITTEL AG	GERMANY	13420	2020
ARIPIRAZOLUM	EXPLEMED	tablets	5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	13466	2020
ARIPIRAZOLUM	EXPLEMED	tablets	10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	13467	2020
ARIPIRAZOLUM	EXPLEMED	tablets	15mg	EGIS PHARMACEUTICALS PLC	HUNGARY	13468	2020
ARIPIRAZOLUM	EXPLEMED	tablets	30mg	EGIS PHARMACEUTICALS PLC	HUNGARY	13469	2020

ARIPIPRAZOLUM	EXPLEMED ODT	orodispersible tablets	5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	13470	2020
ARIPIPRAZOLUM	EXPLEMED ODT	orodispersible tablets	10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	13471	2020
ARIPIPRAZOLUM	EXPLEMED ODT	orodispersible tablets	15mg	EGIS PHARMACEUTICALS PLC	HUNGARY	13472	2020
ARIPIPRAZOLUM	EXPLEMED ODT	orodispersible tablets	30mg	EGIS PHARMACEUTICALS PLC	HUNGARY	13473	2020
ARIPIPRAZOLUM	ARIPIPRAZOL ACCORD HEALTHCARE	orodispersible tablets	10mg	ACCORD HEALTHCARE POLKA Sp.z o.o.	POLAND	13488	2020
ARIPIPRAZOLUM	ARIPIPRAZOL ACCORD HEALTHCARE	orodispersible tablets	15mg	ACCORD HEALTHCARE POLKA Sp.z o.o.	POLAND	13489	2020
BETAXOLOLUM	BETOPTIC S	eye drops, suspension	2.5 mg/ml	NOVARTIS PHARMA GmbH	GERMANY	13500	2020
BIMATOPROSTUM	BIMATOPROST MYLAN	eye drops, solution	0.1mg/ml	MYLAN S.A.S.	FRANCE	13453	2020
BIMATOPROSTUM/ TIMOLOLUM	BIMATOPROST/ TIMOLOL SIFI	eye drops, solution	0.3mg/5mg/ ml	SIFI S.p.A.	ITALY	13462	2020
BISACODILUM	BISACODIL ARENA	gastroresistant	10 mg	ARENA GROUP S.A.	ROMANIA	13309	2020

		tablets					
BISOPROLOL FUMARATE/ PERINDOPRILUM ARGININE	COSYREL	film-coated tablets	5mg/5mg	LES LAB. SERVIER	FRANCE	13494	2020
BISOPROLOL FUMARATE/ PERINDOPRILUM ARGININE	COSYREL	film-coated tablets	5mg/10mg	LES LAB. SERVIER	FRANCE	13495	2020
BISOPROLOL FUMARATE/PERINDOPRILUM ARGININE	COSYREL	film-coated tablets	10mg/5mg	LES LAB. SERVIER	FRANCE	13496	2020
BISOPROLOL FUMARATE/ PERINDOPRILUM ARGININE	COSYREL	film-coated tablets	10mg/10mg	LES LAB. SERVIER	FRANCE	13497	2020
BORTEZOMIBUM	BORTEGA	powder for solution for injection	3.5 mg	HEATON k.s.	THE CZECH REPUBLIC	13326	2020
BORTEZOMIBUM	BORTEZOMIB BIOTECH	powder for solution for injection	3.5mg	BIOTECH PHARMA LIMITED	GREAT BRITAIN	13431	2020
BORTEZOMIBUM	BORTEZOMIB ACTAVIS	powder for solution for injection	3.5mg	ACTAVIS GROUP PTC	ISLANDA	13444	2020
BUDESONIDUM/ FORMOTEROL FUMARAT	SYMBICORT	pressurised inhalation solution	80mcg/ 2.25mcg	ASTRAZENECA PHARMA SRL	ROMANIA	13369	2020

CALCIUM GLUCONATE	GLUCONAT DE CALCIU ZENTIVA	solution for injection	95mg/ml	ZENTIVA S.A.	ROMANIA	13308	2020
CEFUROXIMUM AXETIL	CEFUROXIMA AUROBINDO	film-coated tablets	250mg	AUROBINDO PHARMA LIMITED	MALTA	13427	2020
CEFUROXIMUM AXETIL	CEFUROXIMA AUROBINDO	film-coated tablets	500mg	AUROBINDO PHARMA LIMITED	MALTA	13428	2020
CLORHEXIDINUM GLUCONAS	CORSODYL MINT MOUTHWASH	mouthwash	0.2/100 ml	GLAXOSMITHKLINE CONSUMER HEALTHCARE	ROMANIA	13382	2020
CLOTRIMAZOLUM	CLOTRIMAZOL BIOFARM	cutaneous solution	10.87 mg/ml	BIOFARM S.A.	ROMANIA	13336	2020
COMBINATIONS	LIPERTANCE	film-coated tablets	10mg/5mg/5mg	LES LAB. SERVIER IND.	FRANCE	13328	2020
COMBINATIONS	LIPERTANCE	film-coated tablets	20mg/5mg/5mg	LES LAB. SERVIER IND.	FRANCE	13329	2020
COMBINATIONS	LIPERTANCE	film-coated tablets	20mg/10mg/5mg	LES LAB. SERVIER IND.	FRANCE	13330	2020
COMBINATIONS	LIPERTANCE	film-coated tablets	20mg/10mg/10mg	LES LAB. SERVIER IND.	FRANCE	13331	2020
COMBINATIONS	LIPERTANCE	film-coated tablets	40mg/10mg/10mg	LES LAB. SERVIER IND.	FRANCE	13332	2020
COMBINATIONS	RINOMOL PLUS	tablets		SANTA S.A.	ROMANIA	13339	2020
COMBINATIONS	OCTENISEPT	cutaneous solution	1 mg/ml + 20 mg/ml	SCHULKE & MAYR GmbH	GERMANY	13346	2020

COMBINATIONS	RINONEF T	nasal drops, solution	5 mg/ml+ 5 mg/ml	TIS FARMACEUTIC S.A.	ROMANIA	13361	2020
COMBINATIONS	COLEBIL	lozenges		BIOFARM S.A.	ROMANIA	13377	2020
COMBINATIONS	HEMORZON	ointment		ANTIBIOTICE S.A.	ROMANIA	13383	2020
COMBINATIONS	OLYGRIP ZI SI NOAPTE	tablets		McNeil Healthcare (Ireland) Limited	IRELAND	13392	2020
COMBINATIONS	GRIPPOSTAD ZI	capsules		STADA ARZNEIMITTEL AG	GERMANY	13485	2020
DEFERASIROXUM	DEFERASIROX ALVOGEN	film-coated tablets	90 mg	ALVOGN PHARMA TRADIND EUROPE	BULGARIA	13374	2020
DEFERASIROXUM	DEFERASIROX ALVOGEN	film-coated tablets	180 mg	ALVOGN PHARMA TRADIND EUROPE	BULGARIA	13375	2020
DEFERASIROXUM	DEFERASIROX ALVOGEN	film-coated tablets	360 mg	ALVOGN PHARMA TRADIND EUROPE	BULGARIA	13376	2020
DESLORATADINUM	DESLORATADINA FITERMAN	oral solution	0.5 mg/ml	FITERMAN PHARMA SRL	ROMANIA	13358	2020
DEXPANTHENOLUM	RECREOL	cream	50 mg/g	AS GRINDEKS	LETONIA	13399	2020
DEXPANTHENOLUM	RECREOL	ointment	50 mg/g	AS GRINDEKS	LETONIA	13400	2020
DIACEREINUM	DIAFLEX	capsules	50 mg	ROMPHARM COMPANY S.R.L.	ROMANIA	13313	2020
DICLOFENACUM DIETHYLAMINE	VOLTAREN FORTE	gel	23.2 mg/ml	GLAXOSMITHKLINE CONSUMER HEALTHCARE	ROMANIA	13380	2020

DICLOFENACUM SODIUM	DICLOFENAC HYPERION	cream	10 mg/g	HYPERION S.A.	ROMANIA	13364	2020
DICLOFENACUM SODIUM	DICLOFENAC CHIRMIS	gel	10 mg/g	CHIRMIS FARMIMPEX SRL	ROMANIA	13458	2020
DICLOFENACUM SODIUM	DICLOFENAC TIS	gel	10mg/g	TIS FARMACEUTIC S.A.	ROMANIA	13456	2020
DIMETINDENUM MALEATE	CALEMO	gel	1mg/g	DR MAX PHARMA sro	THE CZECH REPUBLIC	13347	2020
DIOSMINUM	REVADA	tablets	600 mg	RECORDATI ROMANIA SRL	ROMANIA	13455	2020
DIVERSE	APA PENTRU PREPARATE INJECTABILE B BRAUN	solution for injection		B. BRAUN MEDICAL S.A.	ROMANIA	13502	2020
DULOXETINUM HYDROCHLORIDE	DULODET	gastroresistant capsules	30 mg	EGIS PHARMA. PLC	HUNGARY	13396	2020
DULOXETINUM HYDROCHLORIDE	DULODET	gastroresistant capsules	60 mg	EGIS PHARMA. PLC	HUNGARY	13397	2020
DULOXETINUM HYDROCHLORIDE	DULSEVIA	gastroresistant capsules	90 mg	KRKA D.D. NOVO MESTO	SLOVENIA	13366	2020
DUTASTERIDUM	MAXTRID	capsules	0.5 mg	STADA ARZNEIMITTEL AG	GERMANY	13401	2020
DUTASTERIDUM/ TAMSULOSINUM HYDROCHLORIDE	RIMRIL	capsules	0.5 mg/0,4mg	HEATON K.S	THE CZECH REPUBLIC	13352	2020

ENALAPRILUM + NITRENDIPINUM	ENEAS	tablets	10+20 mg	GALENICA S.A.	GREECE	13337	2020
EPLERENONUM	EPLERENON MSN	film-coated tablets	25 mg	VIVANTA GENERICS sro	THE CZECH REPUBLIC	13438	2020
EPLERENONUM	EPLERENON MSN	film-coated tablets	50 mg	VIVANTA GENERICS sro	THE CZECH REPUBLIC	13439	2020
ESTRADIOLUM HEMYHIDRATE	ESTRADIOL RICHTER	vaginal tablets	10 µg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	13484	2020
ETORICOXIBUM	KOSTAROX	film-coated tablets	30 mg	SANDOZ S.R.L.	ROMANIA	13370	2020
ETORICOXIBUM	KOSTAROX	film-coated tablets	60 mg	SANDOZ S.R.L.	ROMANIA	13371	2020
ETORICOXIBUM	KOSTAROX	film-coated tablets	90 mg	SANDOZ S.R.L.	ROMANIA	13372	2020
ETORICOXIBUM	KOSTAROX	film-coated tablets	120 mg	SANDOZ S.R.L.	ROMANIA	13373	2020
ETORICOXIBUM	DOLOXIB	film-coated tablets	60 mg	ZENTIVA k.s.	THE CZECH REPUBLIC	13474	2020
ETORICOXIBUM	DOLOXIB	film-coated tablets	90 mg	ZENTIVA k.s.	THE CZECH REPUBLIC	13475	2020
ETORICOXIBUM	DOLOXIB	film-coated tablets	120 mg	ZENTIVA k.s.	THE CZECH REPUBLIC	13476	2020
EVEROLIMUS	EVEROLIMUS/ PHARMAZAC	tablets	2.5 mg	PHARMAZAC S.A.	GREECE	13481	2020

EVEROLIMUS	EVEROLIMUS/ PHARMAZAC	tablets	5 mg	PHARMAZAC S.A.	GREECE	13482	2020
EVEROLIMUS	EVEROLIMUS/ PHARMAZAC	tablets	10 mg	PHARMAZAC S.A.	GREECE	13483	2020
EZETIMIBUM	CEXADO	tablets	10 mg	ZENTIVA S.A.	ROMANIA	13391	2020
FENTANYLUM CITRATE	FENTANIL KALCEKS	solution for injection	50 µg/ml	AS KALCEKS	LATVIA	13451	2020
FULVESTRANTUM	FULVESTRANT SANDOZ	solution for injection	250 mg/5ml	SANDOZ S.R.L.	ROMANIA	13441	2020
GALANTAMINUM	REMINYL	oral solution	4 mg/ml	JANSSEN PHARMACEUTICA NV	BELGIUM	13381	2020
GEMCITABINUM HYDROCHLORIDE	GEMCITABINE SUN	solution for infusion	10 mg/ml	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HOLLAND	13450	2020
GLUCOZA ANHIDRA	GLUCOSTERIL	solution for infusion	5g/100 ml	FRESENIUS KABI DEUTSCHLAND GMBH	GERMANY	13343	2020
GLUCOZA ANHIDRA	GLUCOSTERIL	solution for infusion	10g/100 ml	FRESENIUS KABI DEUTSCHLAND GMBH	GERMANY	13344	2020
HALOPERIDOLUM	HALOPERIDOL ARENA	oral solution	2 mg/ml	ARENA GROUP S.A.	ROMANIA	13424	2020

HOMEOPATE	OSANIT ERUPTII DENTARE	granules homeopate		DR. A. & L. SCHMIDGALLA	AUSTRIA	13363	2020
HYOSCINUM BUTYLBROMIDE	SCOBUSAL	compr.	10 mg	SLAVIA PHARM S.R.L.	ROMANIA	13421	2020
IBUPROFENUM	IBALGIN FORTE	film-coated tablets	400 mg	ZENTIVA k.s.	ROMANIA	13314	2020
IBUPROFENUM	IBUPROFEN ALKALOID-INT	film-coated tablets	200 mg	ALKALOID d.o.o. LJUBLJANA	SLOVENIA	13388	2020
IBUPROFENUM	IBUPROFEN ALKALOID-INT	film-coated tablets	400 mg	ALKALOID d.o.o. LJUBLJANA	SLOVENIA	13389	2020
IBUPROFENUM	NUROFEN IMMEDIA	film-coated tablets	400 mg	RECKITT BENCKISER HEALTHCARE INTERNAIONAL	UK	13480	2020
IBUPROFENUM + PARACETAMOL	BIOFEN EXTRA 400 mg/325 mg	film-coated tablets	400 mg/325mg	BIOFARM S.A.	ROMANIA	13435	2020
IBUPROFENUM/ PARACETAMOLUM	PADUDEN DUO	film-coated tablets	200mg/500m g	TERAPIA S.A	ROMANIA	13460	2020
IBUPROFENUM/ PSEUDOEFEDRINUM CLORHIDRATUM	IBUGRIP PLUS	film-coated tablets	200mg/30mg	LAROPHARM S.R.L.	ROMANIA	13362	2020
IBUPROFENUM/ PSEUDOEPHEDRINUM HYDROCHLORIDE	IBUSINUS	film-coated tablets	200/30mg	SOLACIUM PHARMA	ROMANIA	13503	2020

INDAPAMIDUM/ AMLOPIDINUM	NATRIXAM	modified-release tablets	1.5mg/5mg	LES LAB. SERVIER IND.	FRANCE	13490	2020
INDAPAMIDUM/ AMLOPIDINUM	NATRIXAM	modified-release tablets	1.5mg/10mg	LES LAB. SERVIER IND.	FRANCE	13491	2020
INDAPAMIDUM/ AMLOPIDINUM	FLUDEXAM	modified-release tablets	1.5mg/5mg	LES LAB. SERVIER IND.	FRANCE	13492	2020
INDAPAMIDUM/ AMLOPIDINUM	FLUDEXAM	modified-release tablets	1.5mg/10mg	LES LAB. SERVIER IND.	FRANCE	13493	2020
INDOMETACINUM	INDOMETACIN SINTOFARM	suppositories	50mg	SINTOFARM S.A.	ROMANIA	13345	2020
KETOTIFENUM FUMARATE	KETOTIFEN LAROPHARM	tablets	1mg	LAROPHARM S.R.L.	ROMANIA	13316	2020
LEVOCETIRIZINUM DIHYDROCHLORIDUM	XYZAL	oral drops, solution	5mg/ml	UCB PHARMA S.p.A.	GERMANY	13501	2020
LEVOFLOXACINUM/ DEXAMETHASONUM	DUCRESSA	eye drops, solution	5mg+ 1mg/ml	SANTEN OY	FINLAND	13368	2020
LORATADINUM	LORATADINA SINTOFARM	tablets	10mg	SINTOFARM S.A.	ROMANIA	13426	2020
LORATADINUM	LORATADINA SLAVIA	tablets	10mg	SLAVIA PHARM S.R.L.	ROMANIA	13422	2020
MEDROXYPROGESTERONUM ACETATE	SAYANA	suspension for injection	104mg	PFIZER EUROPE MA EEIG	BELGIUM	13356	2020
MEDROXYPROGESTERONUM ACETATE	SAYANAJECT	suspension for injection	104mg	PFIZER EUROPE MA EEIG	BELGIUM	13357	2020

MEMANTINUM HYDROCHLORIDE	MIRVEDOL	film-coated tablets	10mg	GEDEON RICHTER PLC.	HUNGARY	13414	2020
MENOTROPHINUM	MERIOFERT	powder and solvent for solution for injection	75 IU	IBSA FARMACEUTICI	ITALY	13402	2020
MENOTROPHINUM	MERIOFERT	powder and solvent for solution for injection	150 IU	IBSA FARMACEUTICI	ITALY	13403	2020
MENOTROPHINUM	MERIOFERT PFS	powder and solvent for solution for injection	150 IU	IBSA FARMACEUTICI	ITALY	13405	2020
MENOTROPHINUM	MERIOFERT PFS	powder and solvent for solution for injection	75 IU	IBSA FARMACEUTICI	ITALY	13404	2020
MEROPENEMUM	MEROPENEM AUROBINDO	powder for concentrate solution for infusion/ injection	500mg	AUROBINDO PHARMA LTD	UK	13418	2020
MEROPENEMUM	MEROPENEM AUROBINDO	powder for concentrate solution for infusion/	1g	AUROBINDO PHARMA LTD	UK	13419	2020

		injection					
METAMIZOLUM SODIUM	ALGOCALMIN	oral drops, solution	500mg/ml	ZENTIVA k.s.	THE CZECH REPUBLIC	13432	2020
METOPROLOLUM SUCCINAS	BLOXAZOC	prolonged-release tablets	25mg	KRKA D.D. NOVO MESTO	SLOVENIA	13446	2020
METOPROLOLUM SUCCINAS	BLOXAZOC	prolonged-release tablets	50mg	KRKA D.D. NOVO MESTO	SLOVENIA	13447	2020
METOPROLOLUM SUCCINAS	BLOXAZOC	prolonged-release tablets	100mg	KRKA D.D. NOVO MESTO	SLOVENIA	13448	2020
METOPROLOLUM SUCCINAS	BLOXAZOC	prolonged-release tablets	200mg	KRKA D.D. NOVO MESTO	SLOVENIA	13449	2020
MIDAZOLAMUM	MIDAZOLAM ACCORD	solution for injection (pre-filled syringes)	1mg/ml	ACCORD HEALTHCARE LIMITED	UK	13498	2020
NITROXOLINUM	NITROXOLINA- MIP	capsules	250mg	MIP PHARMA GmbH	ROMANIA	13379	2020
OCTENIDINEUM/ PHENOXYETHANOL	OCTEANGIN	drops	2.6 mg	M.C.M. Klosterfrau GmbH	GERMANY	13393	2020
OLANZAPINUM	BLOONIS	film-coated tablets	5mg	ZENTIVA k.s.	GREECE	13320	2020
OLANZAPINUM	BLOONIS	film-coated tablets	10mg	ZENTIVA k.s.	GREECE	13321	2020
OLANZAPINUM	BLOONIS	orodispersible	10mg	ZENTIVA k.s.	GREECE	13322	2020

		tablets					
OLANZAPINUM	BLOONIS	orodispersible tablets	15mg	ZENTIVA k.s.	GREECE	13323	2020
OLANZAPINUM	BLOONIS	orodispersible tablets	20mg	ZENTIVA k.s.	GREECE	13324	2020
OXACEPROLUM	ARTROMED	film-coated tablets	200 mg	MIP PHARMA GmbH	GERMANY	13445	2020
OXYTOCINUM	OFOST	solution for injection/perf.	10 IU/ml	AS GRINDEKS	LITHUANIA	13440	2020
PANTOPRAZOLUM	SELTRAZ	gastroresistant tablets	20 mg	DR. REDDY'S LABORATORIES ROMANIA	ROMANIA	13478	2020
PARACETAMOLUM	PARACETAMOL INFANT	tablets	160 mg	FARMACIST MAN SRL	ROMANIA	13341	2020
PARACETAMOLUM	PARACETAMOL SINTOFARM	tablets	500 mg	SINTOFARM S.A.	ROMANIA	13457	2020
PARACETAMOLUM + CLORPHENIRAMINUM MALEATE	RINOMOL	tablets	500mg/3mg	SANTA S.A.	ROMANIA	13338	2020
PARACETAMOLUM + PSEUDOEPHEDRINE HYDROCHLORIDE	SINUFEN	film-coated tablets	500mg/30mg	LAROPHARM S.R.L.	ROMANIA	13425	2020
PEMETREXED DISODIUM	PEMETREXED SANDOZ	concentrate for solution for	25mg/ml	SANDOZ S.R.L.	ROMANIA	13452	2020

		infusion					
PEMETREXEDUM DISODIUM	PEMETREXED TEVA	powder for concentrate solution for infusion	500mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	13442	2020
PEMETREXEDUM DISODIUM	PEMETREXED TEVA	powder for concentrate solution for infusion	1000mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	13443	2020
PERINDOPRILUM ARGININE + AMLOPIDINUM	VIACORAM	tablets	3.5mg/2.5mg	LES LAB. SERVIER	FRANCE	13350	2020
PERINDOPRILUM ARGININE + AMLOPIDINUM	VIACORAM	tablets	7mg/5mg	LES LAB. SERVIER	FRANCE	13351	2020
PLANTE	PLANTOGAST	oral drops, solution		BAYER S.R.L.	ROMANIA	13310	2020
PLANTE	UVACTIV	capsules		FITERMAN PHARMA SRL	ROMANIA	13479	2020
POSACONAZOLUM	POSACONAZOL STADA	gastroresistant tablets	100mg	STADA M&D SRL	ROMANIA	13319	2020
PREGABALINUM	PRAGIOLA	capsules	25mg	KRKA D.D. NOVO MESTO	SLOVENIA	13406	2020
PREGABALINUM	PRAGIOLA	capsules	50mg	KRKA D.D. NOVO MESTO	SLOVENIA	13407	2020

PREGABALINUM	PRAGIOLA	capsules	75mg	KRKA D.D. NOVO MESTO	SLOVENIA	13408	2020
PREGABALINUM	PRAGIOLA	capsules	100mg	KRKA D.D. NOVO MESTO	SLOVENIA	13409	2020
PREGABALINUM	PRAGIOLA	capsules	150mg	KRKA D.D. NOVO MESTO	SLOVENIA	13410	2020
PREGABALINUM	PRAGIOLA	capsules	200mg	KRKA D.D. NOVO MESTO	SLOVENIA	13411	2020
PREGABALINUM	PRAGIOLA	capsules	225mg	KRKA D.D. NOVO MESTO	SLOVENIA	13412	2020
PREGABALINUM	PRAGIOLA	capsules	300mg	KRKA D.D. NOVO MESTO	SLOVENIA	13413	2020
PRODUSE BIOLOGICE	ACARIZAX	Oral lyophilisate	12 SQ-HOM	ALK - ABELLO A/S	DENMARK	13325	2020
PRODUSE BIOLOGICE	FIBRYGA	powder and solvent for solution for infusion	1 g	OCTAPHARMA GmbH	AUSTRIA	13461	2020
PRODUSE BIOLOGICE	XEOMIN	powder for solution for injection	200 IU	MERZ PHARMACEUTICALS GMBH	GERMANY	13463	2020
PROPAFENONUM HYDROCHLORIDE	PROPANORM	solution for injection	35mg/10ml	PRO.MED.CS PRAHA a.s.	THE CZECH REPUBLIC	13312	2020
PROPOFOLUM	PROPOFOL MCT/LCT	emulsion for injection/infusion	10 mg/ml	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	13433	2020

PROPOFOLUM	PROPOFOL MCT/LCT	emulsion for injection/infusion	20 mg/ml	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	13434	2020
RANITIDINUM HYDROCHLORIDE	RANITIDINA ARENA	film-coated tablets	150mg	ARENA GROUP S.A.	ROMANIA	13340	2020
RIFAMPICINA/IZONIAZIDA	SINERDOL Iso	capsules	300mg/150mg	ANTIBIOTICE S.A.	ROMANIA	13454	2020
RISEDRONATE SODIUM	RISEDRONAT AUROBINDO	film-coated tablets	75mg	AUROBINDO PHARMA LTD	ITALY	13327	2020
RISEDRONATUM SODIUM	ACTONEL	gastroresistant tablets	35mg	THERAMEX IRELAND LIMITED	IRELAND	13390	2020
RITONAVIRUM	RITONAVIR SANDOZ	film-coated tablets	100mg	SANDOZ S.R.L.	ROMANIA	13436	2020
ROSUVASTATINUM CALCIUM	ROSI	film-coated tablets	10mg	SWISSI AG	GERMANY	13353	2020
ROSUVASTATINUM CALCIUM	ROSI	film-coated tablets	20mg	SWISSI AG	GERMANY	13354	2020
ROSUVASTATINUM CALCIUM	ROSI	film-coated tablets	40mg	SWISSI AG	GERMANY	13355	2020
SACCHAROMYCES BOULARDII	ENTEROL	oral powder	250 mg	BIOCODEX	FRANCE	13342	2020
SILODOSINUM	SILODOSIN ACCORD	capsules	4mg	ACCORD HEALTHCARE S.L.U.	SPAIN	13333	2020
SILODOSINUM	SILODOSIN ACCORD	capsules	8 mg	ACCORD	SPAIN	13334	2020

				HEALTHCARE S.L.U.			
SODIUM CHLORIDE	CLORURA DE SODIU FRESENIUS	solution for infusion	0.9 g/ 100 ml	FRESENIUS KABI DEUTSCHLAND GMBH	GERMANY	13499	2020
SOLIFENACINUM SUCCINATUM	VESICARE	oral suspension	1mg/ml	ASTELLAS PHARMA EUROPE BV	HOLLAND	13437	2020
SOMATROPINUM	SAIZEN	solution for injection	5.83 mg/ml	MERCK ROMANIA SRL	ROMANIA	13317	2020
SOMATROPINUM	SAIZEN	solution for injection	8 mg/ml	MERCK ROMANIA SRL	ROMANIA	13318	2020
SORAFENIBUM TOSYLATE	SORAFENIB STADA	film-coated tablets	200 mg	STADA M&D SRL	ROMANIA	13387	2020
SORAFENIBUM TOSYLATE	SORAFENIB SANDOZ	film-coated tablets	200 mg	SANDOZ GmbH	AUSTRIA	13429	2020
SORAFENIBUM TOSYLATE	SORAFENIB ZENTIVA	film-coated tablets	200 mg	ZENTIVA k.s.	THE CZECH REPUBLIC	13430	2020
SORAFENIBUM TOSYLATE	SORAFENIB DR. REDDY'S	tablets	200 mg	DR. REDDY'S LABORATORIES	ROMANIA	13477	2020
SORAFENIBUM TOSYLATE	SORAFENIB MYLAN	film-coated tablets	200 mg	MYLAN IRELAND LIMITED	IRELAND	13465	2020
TETRACYCLINUM HYDROCHLORIDE	HEMORZON	suppositories		ANTIBIOTICE S.A.	ROMANIA	13384	2020

TIANEPTINUM SODIUM	STATIVAL	lozenges	12.5mg	ANPHARM PRZEDSIĘBIORSTW O FARMACEUTYCZNE S.A.	POLAND	13378	2020
TIOTROPIUM BROMIDE/OLODATEROLUM HYDROCHLORIDE	YANIMO RESPIMAT	inhalation solution	2.5mcg/ 2.5mcg	BOEHRINGER INGELHEIM INT. GMBH	GERMANY	13398	2020
TOPOTECANUM HYDROCHLORIDE	TOPOTECAN ALVOGEN	concentrate for solution for injection	4 mg	ALVOGEN IPCO S.A.R.L.	BULGARIA	13395	2020
TOPOTECANUM HYDROCHLORIDE	TOPOTECAN ALVOGEN	concentrate for solution for injection	1 mg	ALVOGEN IPCO S.A.R.L.	BULGARIA	13394	2020
TRIMETAZIDINUM DIHYDROCHLORIDUM	TRIMETAZIDINA LPH	film-coated tablets	20 mg	LABORMED PHARMA S.A.	ROMANIA	13335	2020
VILDAGLIPTIMUN/ METFORMINUM	MELKART DUO	film-coated tablets	50mg/850mg	G.L PHARMA GMBH	AUSTRIA	13348	2020
VILDAGLIPTIMUN/ METFORMINUM	MELKART DUO	film-coated tablets	50mg/1000m g	G.L PHARMA GMBH	AUSTRIA	13349	2020
VORICONAZOLUM	VORAMOL	film-coated tablets	200mg	ALVOGEN ROMANIA	ROMANIA	13487	2020
VORICONAZOLUM	VORICONAZOL ZENTIVA	powder for solution for infusion	200 mg	ZENTIVA K.S.	THE CZECH REPUBLIC	13486	2020

EMA centrally authorised medicinal products notified for marketing in Romania during the 3rd quarter of 2020

INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA number	
ALPELISIB	PIQRAY 150 mg	film-coated tablets	150mg	NOVARTIS EUROPHARM LIMITED	IRELAND	1455	2020
ALPELISIB	PIQRAY 200 mg	film-coated tablets	200mg	NOVARTIS EUROPHARM LIMITED	IRELAND	1455	2020
ALPELISIB	PIQRAY 50 mg+200mg	film-coated tablets	50mg, 200mg	NOVARTIS EUROPHARM LIMITED	IRELAND	1455	2020
CABAZITAXELUM	CABAZITAXEL ACCORD 20 mg/ml	concentrate for solution for infusion	20mg/ml	ACCORD HEALTHCARE S.L.U.	SPAIN	1448	2020
ENTRECTINIBUM	ROZLYTREK 100 mg	capsules	100mg	ROCHE REGISTRATION GMBH	GERMANY	1460	2020
ENTRECTINIBUM	ROZLYTREK 200 mg	capsules	200mg	ROCHE REGISTRATION GMBH	GERMANY	1460	2020
INDACATEROLUM+ GLICOPIRONIUM BROMIDUM+ MOMETASONUM	ENERZAIR BREEZHALER 114 micrograms/ 46 micrograms/ 136 micrograms	Inhalation powder capsules	114µg+46 µg +136 µg	NOVARTIS EUROPHARM LIMITED	IRELAND	1438	2020
REMEDSIVIRUM	VEKLURY 100 mg	concentrate for solution for infusion	5mg/ml	GILEAD SCIENCES IRELAND UC	IRELAND	1459	2020

REMDESIVIRUM	VEKLURY 100 mg	powder for concentrate for solution for infusion	100mg	GILEAD SCIENCES IRELAND UC	IRELAND	1459	2020
TEZACAFTORUM+ IVACAFTORUM+ ELEXACAFTORUM	KAFTRIO 75 mg/ 50 mg/100 mg	film-coated tablets	100mg/ 50mg/ 75mg	VERTEX PHARMACEUTICALS (IRELAND) LIMITED	IRELAND	1468	2020
TRASTUZUMABUM	ZERCEPAC 150mg	powder for concentrate for solution for infusion	150mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1456	2020