

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 10-2/20 on October 29, 2020

President _____ E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Herbion Iceland moss syrup	iceland moss thick extract	syrup	6mg/ml; 150ml glass bottle and measuring spoon	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- quality control (physical/chemical, microbiological), batch releaser, KRKA d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia- bulk manufacturer, packager, Nacionalni laboratorij za zdravje, okolje in hrano (NLZOH), Dalmatinova ulica 3, Novo mesto, 8000, Slovenia- quality control (physical/chemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	19448 29.10.2020
2	Actovegin	deproteinised haemoderivate of calf blood	tablets coated	200mg; (50) in glass container	Takeda Pharmaceuticals LLC, Yaroslavl city, 9 Tekhnoparkovaya street	Russia	Takeda Pharmaceuticals LLC, Usacheva str 2, bld. 1, Moscow 119048	Russia	R	19450 29.10.2020

3	Glucophage XR	metformin (metformin hydrochloride)	tablets prolonged-release	500mg; (30/2x15/) in blister, (60/4x15/) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400, Semoy	France	Merck Serono Limited, Bedfont Cross, Stanwell Road, Feltham, Middlesex, TW14 8NX	UK	R	19451 29.10.2020
4	Glucophage XR	metformin (metformin hydrochloride)	tablets prolonged-released tablet	1000mg; (60/6x10/) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400, Semoy- packager, batch releaser, Merck KGaA, Frankfurter Strasse 250, 64 293 Darmstadt, Germany- bulk manufacturer, quality control	France	Merck Serono Limited, Bedfont Cross, Stanwell Road, Feltham, Middlesex, TW14 8NX	UK	R	19452 29.10.2020

LIST

of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 10-2/20 on October 29, 2020

President _____ E. Amroya

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Skudexa	tramadol (tramadol hydrochloride), dexketoprofen	tablets film-coated	75mg+25mg; (15/1x15/) in blister PA/Aluminium/PVC, (15/1x15/) in blister PVC/PE/PVDC, (15/1x15/) in blister PVC/PVDC	Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden	Germany	Menarini International Operations Luxembourg S.A., 1, avenue de la Gare, 1611	Luxembourg	R/C	19453 29.10.2020

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 10-2/20 on October 29, 2020

President _____ E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Hydrocortison-Richter	hydrocortisone (hydrocortisone acetate), lidocaine (lidocaine hydrochloride)	suspension for injection	25mg/ml+5mg/ml; (1) glass vial 5ml	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	19454 29.10.2020
2	Hexaspray	biclotymol	aerosol for local use	750mg/30g; 30g glass bottle with pump dispenser	Laboratoires Bouchara-Recordati, Parc Mecatronic 03410 Saint Victor	France	Laboratoires Bouchara-Recordati, Immeuble le Wilson, 70 avenue du General de Gaulle, 92800 Puteaux	France	OTC	19455 29.10.2020
3	Nevanac	nepafenac	drops eye (suspension)	1mg/ml; plastic bottle 5ml	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	19456 29.10.2020

4	Hexalyse	biclotymol, lysozyme (lysozyme hydrochloride), enoxolone	tablets orodispersible	5mg+5mg+5mg; (30/3x10/) in blister	Laboratoires Bouchara-Recordati, Parc Mecatronic 03410 Saint Victor	France	Laboratoires Bouchara-Recordati, Immeuble le Wilson, 70 avenue du General de Gaulle, 92800 Puteaux	France	OTC	19457 29.10.2020
5	Kreon 10000	pancreatin (lipase 10000PhEU, amylase 8000 PhEU, protease 600 PhEU)	capsules gastro-resistant	150mg; (20/2x10/) in blister, (20) in plastic container	Abbott Laboratories GmbH, Justus-von-Liebig-Strasse 33, 31535 Neustadt	Germany	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	OTC	19458 29.10.2020
6	Kreon 25000	pancreatin (lipase 25000PhEU, amylase 18000 PhEU, protease 1000 PhEU)	capsules gastro-resistant	300mg; (20/2x10/) in blister, (20) in plastic container	Abbott Laboratories GmbH, Justus-von-Liebig-Strasse 33, 31535 Neustadt	Germany	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	OTC	19459 29.10.2020
7	Kreon 40000	pancreatin (lipase 40000PhEU, amylase 25000 PhEU, protease 1600 PhEU)	capsules gastro-resistant	400mg; (20/2x10/) in blister, (20) in plastic container	Abbott Laboratories GmbH, Justus-von-Liebig-Strasse 33, 31535 Neustadt	Germany	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	OTC	19460 29.10.2020

8	Strepsils with Menthol and Eucalyptus	dichlorobenzyl alcohol, amylmetacresol, levomenthol	lozenges	1,2mg+0,6mg+8mg; (24/2x12/) in blister, (36/3x12/) in blister	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	OTC	19461 29.10.2020
9	Zoledronic acid	zoledronic acid	powder lyophilized for solution for infusion	4mg; (1) glass vial 10ml, (40) glass vials 10ml	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30- quality control, batch releaser, Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30, N2, Belarus- bulk manufacturer, packager	Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	R	19462 29.10.2020
10	Dexdor	dexmedetomidine (dexmedetomidine hydrochloride)	concentrate for solution for infusion	100mcg/ml; (5) ampoules 2ml, (25) ampoules 2ml	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	R	19463 29.10.2020
11	Prenessa	perindopril (perindopril erbumine)	tablets	4mg; (30/3x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	19464 29.10.2020
12	Prenessa	perindopril (perindopril erbumine)	tablets	8mg; (30/3x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	19465 29.10.2020

13	Clavoton 1g	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	875mg+125mg; (14/2x7/) in blister	Medochemie Ltd- Factory B, 48 Iapetou street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupolis street, 3011 Limassol	Cyprus	R	19466 29.10.2020
14	Armenicum	iodine, potassium iodide, lithium chloride, polyvinyl alcohol, dextrin, sodium chloride	capsules	28,76mg+43,14mg+0,72mg+10,79mg+359,53mg+32,36mg; (40/4x10/) in blister, (40) in plastic container	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	'Armenicum+' CJSC, 37 Nalbandayan, Yerevan 0001	Republic of Armenia	R	19467 29.10.2020
15	Arbidol	umifenovir (umifenovir hydrochloride)	capsules	100mg; (10/1x10/) in blister, (20/2x10/) in blister, (40/4x10/) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	19468 29.10.2020
16	Letiram	levetiracetam	tablets coated	250mg; (30/3x10/) in blister, (60/6x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120-batch releaser, Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa, Greece- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19469 29.10.2020

17	Letiram	levetiracetam	tablets coated	500mg; (30/3x10/) in blister, (60/6x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa, Greece- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19470 29.10.2020
18	Letiram	levetiracetam	tablets coated	750mg; (30/3x10/) in blister, (60/6x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa, Greece- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19471 29.10.2020
19	Letiram	levetiracetam	tablets coated	1000mg; (30/3x10/) in blister, (60/6x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa, Greece- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19472 29.10.2020

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 10-2/20 on October 29, 2020

President _____ E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Hydrocortisone	hydrocortisone (hydrocortisone acetate)	ointment eye	5mg/g; 3g aluminium tube	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	R	15337/1/1 29.10.2020
2	Momederm	mometasone (mometasone furoate)	ointment for external use	1mg/g; 15g aluminium tube	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	R	16365/2/1 29.10.2020
3	Neuromultivit	vitamin B1, vitamin B6, vitamin B12	tablets film-coated	100mg+200mg+0,2mg; (20/2x10/) in blister, (100/10x10/) in blister	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach -batch releaser, G.L. Pharma GmbH, Industriestrasse 1, 8502 Lannach, Austria -bulk manufacturer, packager	Austria	Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	OTC	18344/1/ 29.10.2020

4	Septotele total eucalyptus	benzydamine (benzydamine hydrochloride), cetylpyridinium chloride	pastilles	3mg+1mg; (8/1x8/), (16/2x8/), (24/3x8/) and (32/4x8/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto-batch releaser, KRKA d.d., Novo mesto, Ulica Rada Pusenjaka 10, Ljutomer, 9240, Slovenia-bulk manufacturer, packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	16026/1/1 29.10.2020
5	Cetirizine-Asteria Tab. 10mg	cetirizine (cetirizine hydrochloride)	tablets film-coated	10mg; (20/2x10/) in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-Si, Chungcheongbuk-do	Korea South	Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan	Republic of Armenia	OTC	16793/1/1 29.10.2020
6	Temodal	temozolomide	capsules	100mg; (5) sachets	Schering-Plough Labo N.V., Industriepark 30 B-2220, Heist-op-den-Berg-batch releaser, packager, Orion Corporation / Orion Pharma, Tengstrominkatu 8, FI-20360 Turku, Finland-bulk manufacturer	Finland	Merc Sharp & Dohme IDEA GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	R	18301/1/1 29.10.2020
7	Temodal	temozolomide	capsules	140mg; (5) in sachet	Schering-Plough Labo N.V., Industriepark 30 B-2220, Heist-op-den-Berg-batch releaser, packager, Orion Corporation / Orion Pharma, Tengstrominkatu 8, FI-20360 Turku, Finland-bulk manufacturer	Finland	Merc Sharp & Dohme IDEA GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	R	17017/1/1 29.10.2020

8	Temodal	temozolomide	capsules	180mg; (5) in sachet	Schering-Plough Labo N.V., Industriepark 30 B-2220, Heist-op-den-Berg- batch releaser, packager, Orion Corporation / Orion Pharma, Tengstrominkatu 8, FI-20360 Turku, Finland- bulk manufacturer	Finland	Merc Sharp & Dohme IDEA GmbH, Weystrasse 20, 6006 Luzern	Switzerland	R	17018/1/1 29.10.2020
9	Temodal	temozolomide	capsules	250mg; (5) sachets	Schering-Plough Labo N.V., Industriepark 30 B-2220, Heist-op-den-Berg- batch releaser, packager, Orion Corporation / Orion Pharma, Tengstrominkatu 8, FI-20360 Turku, Finland- bulk manufacturer	Finland	Merc Sharp & Dohme IDEA GmbH, Weystrasse 20, 6006 Luzern	Switzerland	R	18302/1/1 29.10.2020
10	Esmeron	rocuronium (rocuronium bromide)	solution for injection	10mg/ml; (10) glass vial 5ml	N.V. Organon, Kloosterstraat 6, 5349 AB Oss- seconadary packager, quality control (microbiological), batch releaser, Siegfried Hameln GmbH, Langes Feld 13, Hameln, Niedersachsen, 31789, Germany- bulk manufacturer, primary packager, quality control (physicochemical)	the Netherlands	Schering-Plough Central East AG, Weystrasse 20, 6000 Lucerne 6	Switzerland	R	18428/1/1 29.10.2020

11	Influcein	oseltamivir (oseltamivir phosphate)	capsules hard	75mg: (10/1x10/) in blister	CJSC Canonpharma production, 105B bldg, 11, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region- quality control (phiscocemical), batch releaser, CJSC Canonpharma production, 105, 105B bldg, 12, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, Russia- bulk manufacturer, primary packager, CJSC Canonpharma production, 105, 105B bldg, 1, 105B bldg, 12, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, Russia- secondary packager, CJSC Canonpharma production, 105, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, Russia- quality control (microbiological)	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Schelkovo district, Moscow region, 141100	Russia	R	18062/1/1 29.10.2020
12	Korold-Asteria	paracetamol, pseudoephedrine (pseudoephedrine hydrochloride), chlorphenamine (chlorphenamine maleate)	tablets film-coated	500mg+30mg+2mg; (20/2x10/) and (100/10x10/) in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-Si, Chungcheongbuk-do	Korea South	Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan	Republic of Armenia	OTC	18757/1/1 29.10.2020

13	Amoxicillin-Asteria Cap. 500mg	amoxicillin (amoxicillin trihydrate)	capsules hard	500mg; (100/10x10/) in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-si, Chungcheongbuk-do- batch releaser, Chong Kun Dang Pharmaceutical Corp, 797-48, Manghyang-ro, Seonggeo-eup, Seobuk-gu, Cheonan-si, Chungcheongnam-do, South Korea- bulk manufacturer, packager	Korea South	Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan	Republic of Armenia	R	17505/1/1 29.10.2020
14	Levicitam	levetiracetam	tablets film-coated	250mg; (30/3x10/) in blister, (60/6x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev f	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	R	18675/1/1 29.10.2020
15	Levicitam	levetiracetam	tablets film-coated	500mg; (30/3x10/) in blister, (60/6x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	R	18676/1/1 29.10.2020

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision 10-2/20 on October 29, 2020

President _____ E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Sinupret	gentiane radix, primulae flos, rumicis herba, sambuci flos, verbenae herba	tablets coated	6mg+18mg+18mg+18mg+ 18mg; (50/2x25/) blisters	Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt	Germany	Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt	Germany	R	14569/1 29.10.2020
2	Duovit	vitamin A, vitamin D3, vitamin C, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin PP, folic acid, vitamin B5, vitamin E, calcium hydrophosphate dihydrate, ferrous fumarate, copper sulfate pentahydrate, zinc sulfate heptahydrate, magnesium lactate dihydrate, manganese sulfate monohydrate, sodium molybdate dihydrate	tablets coated	2,94mg+0,2mg+60mg+1mg+1,2mg+2mg+3mcg+13mg+0,4mg+5mg+10mg+64,5mg+30,3mg+4mg+13,3mg+200mg+3,1mg+0,22mg; (40/4x5+5/5 red+5 blue/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto - batch releaser, KRKA d.d., Novo mesto, Ulica Rada Pusenjaka 10, Ljutomer, 9240, Slovenia-bulk manufacturer, packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	16527/1 29.10.2020

3	Fasigyn	tinidazole	tablets film-coated	500mg; (4/1x4/), in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	R	15422/1 29.10.2020
4	Enterofuryl	nifuroxazide	suspension oral	200mg/5ml; 90ml suspension in 125ml glass bottle and plastic measuring spoon (2.5ml/5ml)	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	R	16380/2 29.10.2020
5	Abasaglar	insulin glargine	solution for injection	100IU/ml; (5) cartridges 3ml	Lilly France S.A.S., Zone Industrielle, 2 rue du Colonel Lilly, 67640 Fegersheim	France	Eli Lilly Regional Operations GmbH., Koelblgasse 8-10, 1030, Vienna	Austria	R	16535/1 29.10.2020
6	Seretide Evohaler	salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)	suspension, pressurised inhalation	25mcg/dose+ 250mcg/dose; 120 dose in aluminium container with pump dispenser	Glaxo Wellcome Production, Zone Industrielle N 2, 23 Rue Lavoisier, 27000 Evreux	France	Laboratoire GlaxoSmithKline, 23 rue Francois Jacob, 92500 Rueil-Malmaison	France	R	18680/1 29.10.2020
7	Gliatilin	choline alfoscerate	capsules	400mg; (14/1x14/) in blister	Italfarmaco S.p.A., Viale Fulvio Testi, 330 - 20126 Milan-batch releaser, packager, Catalent Italy S.p.A., Via Nettunense Km. 20, 100 - 04011 Aprilia (LT), Italy-bulk manufacturer	Italy	Italfarmaco S.p.A., Viale Fulvio Testi, 330 - 20126 Milan	Italy	R	18345/1 29.10.2020

8	Adenuric 80mg	febuxostat	tablets film-coated	80mg; (14/1x14/), (28/2x14/), (56/4x14/) and (84/6x14/) in blister	Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden	Germany	Menarini International O. L. S.A., 1, Avenue de la Gare, 1611	Luxembourg	R	16377/1 29.10.2020
9	Adenuric 120mg	febuxostat	tablets film-coated	120mg; (14/1x14/), (28/2x14/), (56/4x14/) and (84/6x14/) in blister	Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden	Germany	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, 1611	Luxembourg	R	16376/1 29.10.2020
10	Iodomarin 200	potassium iodide	tablets	200mcg; (100/4x25/), in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin-batch releaser, packager, Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin,Germany-bulk manufacturer	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	R	16222/1 29.10.2020
11	Iodomarin 200	potassium iodide	tablets	200mcg; (100/4x25/), in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin - batch releaser, Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden, Germany-bulk manufacturer, primary and secondary packager	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	R	15282/1 29.10.2020
12	Diabeton MR	gliclazide	tablets modified-release	60mg; (30/2x15/) in blister	Les Laboratoires Servier Industrie, 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	14951/1 29.10.2020

13	Diabeton MR	gliclazide	tablets modified-release	60mg; (30/2x15/) in blister	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co Wicklow	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	14952/1 29.10.2020
14	Controloc	pantoprazole (pantoprazole sodium sesquihydrate)	powder for solution for injection	40mg; glass vial	Takeda GmbH, Robert-Bosch-Str. 8, 78224 Singen	Germany	Takeda GmbH, Byk-Gulden str. 2, D-78467, Konstanz	Germany	R	18714/2 29.10.2020
15	Diacarb	acetazolamide	tablets	250mg; (30/3x10/) in blister	Pharmaceutical Works Polpharma S.A., ul. Pelplinska 19, 83-200 Starogard Gdanski	Poland	Pharmaceutical Works Polpharma S.A., ul. Pelplinska 19, 83-200 Starogard Gdanski	Poland	R	15878/1 29.10.2020
16	Zocardis 7,5	zofenopril (zofenopril calcium)	tablets film-coated	7,5mg; (28/2x14/) in blister	A.Menarini Manufacturing Logistics and Services S.r.l., Via Campo Di Pile, 67100 L Aquila	Italy	Menarini International Operations Luxembourg S.A., 1, avenue de la Gare, 1611	Luxembourg	R	15272/1 29.10.2020
17	Zocardis 30	zofenopril (zofenopril calcium)	tablets film-coated	30mg; (28/2x14/) in blister	A.Menarini Manufacturing Logistics and Services S.r.l., Via Campo Di Pile, 67100 L Aquila	Italy	Menarini International Operations Luxembourg S.A., 1, avenue de la Gare, 1611	Luxembourg	R	15273/1 29.10.2020

18	L-Thyroxin 50 Berlin-Chemie	levothyroxine sodium	tablets	50mcg; (50/2x25/) and (100/4x25/) in blister	Berlin-Chemie A.G.,Glienicker Weg 125, D-12489 Berlin-batch releaser, packager, Berlin- Chemie A.G., Tempelhofer Weg 83, D-12347 Berlin,Germany-bulk manufacturer	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	R	18082/1 29.10.2020
19	L-Thyroxin 75 Berlin-Chemie	levothyroxine sodium	tablets	75mcg (50/2x25/) and (100/4x25/) in blister	Berlin-Chemie A.G., Glienicker Weg 125 D- 12489 Berlin - packager, batch releaser (Berlin- Chemie AG, Tempelhofer Weg 83, D-12347 Berlin, Germany - bulk manufacturer)	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	R	17199/2 29.10.2020
20	L-Thyroxin 100 Berlin-Chemie	levothyroxine sodium	tablets	100mcg; (50/2x25/), in blistes, (100/4x25/), in blister	Berlin-Chemie A.G.,Glienicker Weg 125, D-12489 Berlin-batch releaser, packager, Berlin- Chemie A.G., Tempelhofer Weg 83, D-12347 Berlin,Germany-bulk manufacturer	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	R	15391/2 29.10.2020
21	L-Thyroxin 125 Berlin-Chemie	levothyroxine sodium	tablets	125mcg; (50/2x25/) and (100/4x25/) in blister	Berlin-Chemie A.G., Glienicker Weg 125 D- 12489 Berlin - packager, batch releaser (Berlin- Chemie AG, Tempelhofer Weg 83, D-12347 Berlin, Germany - bulk manufacturer)	Germany	for Berlin-Chemie A.G., Glienicker Weg 125 D-12489 Berlin	Germany	R	17198/2 29.10.2020

22	L-Thyroxin 150 Berlin-Chemie	levothyroxine sodium	tablets	150mcg; (50/2x25) and (100/4x25/) in blister	Berlin-Chemie A.G., Glienicker Weg 125 D- 12489 Berlin - packager, batch releaser (Berlin- Chemie AG, Tempelhofer Weg 83, D-12347 Berlin, Germany - bulk manufacturer)	Germany	Berlin-Chemie A.G., Glienicker Weg 125 D-12489 Berlin	Germany	R	17197/2 29.10.2020
23	Arbidol	umifenovir (umifenovir hydrochloride)	capsules	100mg; (10/1x10/) blister, (20/2x10/) blisters, (40/4x10/) blisters	Pharmstandard- Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTCPharm PJSC, 123317, Moscow, Testovskaya str., 10	Russia	OTC	14281/2 29.10.2020
24	Lamictal	lamotrigine	tablets	100mg; (30/3x10/) in blister	GlaxoSmithKline Pharmaceuticals S.A.,189 Grunwaldzka street, 60- 322 Poznan	Poland	GlaxoSmithKline Trading CJSC, 119180, Moscow, Yakimanskaya nab., 2	Russia	R	18748/1 29.10.2020
25	Lorista H	losartan (losartan potassium), hydrochlorothiazide	tablets film- coated	50mg+12,5mg; (28/2x14/) blisters, (28/4x7/) blisters	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	18821/2 29.10.2020
26	Lorista H 100	losartan (losartan potassium), hydrochlorothiazide	tablets film- coated	100mg+12,5mg; (28/2x14/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	17964/2 29.10.2020
27	Lorista HD	losartan (losartan potassium), hydrochlorothiazide	tablets film- coated	100mg+25mg; (28/2x14) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	19348/1 29.10.2020

28	Mexidol	ethylmethylhydroxypyridine succinate	tablets film-coated	125mg; (30/3x10/) in blister, (50/5x10/) in blister	CJSC "ZiO-Zdorovie", 142103, Moscow region, Podolsk, str. Zheleznodorozhnaya, 2	Russia	LLC "RPC "PHARMASOFT", 115407, Moscow,Sudostroitel'naya str., bld. 41, floor 1, premises 12	Russia	R	18448/2 29.10.2020
29	Diprosan	betamethasone (betamethasone dipropionate), betamethasone (betamethasone sodium phosphate)	suspension for injection	5mg/ml+2mg/ml; (5) ampoules 1ml	Schering-Plough Labo N.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Schering-Plough Central East AG, Weyrstrasse 20, CH-6000 Lucerne 6	Switzerland	R	19021/1 29.10.2020
30	Enterofuryl	nifuroxazide	suspension oral	200mg/5ml; 90ml suspension in 125ml glass bottle and plastic measuring spoon (2.5ml/5ml)	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	R	16380/3 29.10.2020
31	Perjeta	pertuzumab	concentrate for solution for infusion	30mg/ml; (1) glass vial 14ml	Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim- bulk manufacturer, primary packager, quality control, batch releaser, F. Hoffmann-La Roche Ltd, 4303 Kaiseraugst, Switzerland- secondary packager	Germany	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070	Switzerland	R	19074/1 29.10.2020
32	Caffetin SC	paracetamol, propyphenazone, caffeine	tablets	250mg+210mg+50mg; (6/1x6/) and (12/2x6/) in strip	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Macedonia	OTC	17217/1 29.10.2020

33	Caffetin	paracetamol, propyphenazone, caffeine, codeine (codeine phosphate)	tablets	250mg+210mg+50mg +7,1mg; (6/1x6/), (12/2x6/), and (10/1x10/) in strip	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Macedonia	R	16384/1 29.10.2020
34	Verapress MR 240 Tablets	verapamil (verapamil hydrochloride)	tablets modified- release	240mg; (28/2x14/) in blister	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB - batch releaser, Dexcel Ltd., 1 Dexcel Street, Or-Akiva 3060000, Israel-bulk manufacturer, packager	UK	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire , NN11 8PB	UK	R	17986/1 29.10.2020
35	Lysobact Complete Spray	lysozyme (lysozyme hydrochloride), cetylpyridinium chloride, lidocaine (lidocaine hydrochloride)	spray	20mg/ml+1,5mg/ml+0 ,5mg/ml; 30ml glass bottle with spraying pump and spray applicator	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	17938/1 29.10.2020
36	Acyclovir Denk 200	aciclovir	tablets	200mg; (25/5x5/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	17984/2 29.10.2020

37	Groprinosin-Richter	inosine pranobex	syrup	50mg/ml; 150ml glass bottle and plastic syringe 0.5ml-5ml	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825-batch releaser, Gedeon Richter Romania S.A., 99-105 Guza Voda str., 540306, Targu-Mures, Romania-bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	15709/1 29.10.2020
38	ACC 200	acetylcysteine	tablets effervescent	200mg; (20) in plastic container	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben-batch releaser, Hermes Pharma Ges.m.b.H, Allgau 36, 9400 Wolfsberg, Austria-bulk manufacturer, packager, quality control	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	18716/3 29.10.2020
39	ACC Long	acetylcysteine	tablets effervescent	600mg; (10) in plastic container	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben-batch releaser, Hermes Arzneimittel GmbH, Hans-Urmiler Ring 52, 82515 Wolfratshausen, Germany-bulk manufacturer, packager, quality control	Germany	Sandoz Pharmaceuticals d.d. Verevskova 57, Ljubljana	Slovenia	OTC	18925/2 29.10.2020

40	Dicloberl retard	diclofenac (diclofenac sodium)	capsules prolonged-release	100mg; (20/2x10/) in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- batch releaser, Hennig Arzneimittel GmbH & Co. KG, Liebigstrasse 1 - 2, 65439 Floersheim am Main, Hessen, Germany- bulk manufacturer, Menarini - Von Heyden GmbH, Leipziger Strasse 7 - 13, 01097 Dresden, Sachsen, Germany- packager, Hennig Arzneimittel GmbH & Co. KG, Liebigstrasse 1 - 2, 65439 Floersheim am Main, Hessen, Germany- quality control (physicochemical), MikroBiologie Kramer GmbH, Odilienplatz 3, 66763 Dillingen Deutschland, Germany- quality control (microbiological)	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin,	Germany	R	19236/1 29.10.2020
41	Tasigna	nilotinib (nilotinib hydrochloride monohydrate)	capsules hard	150mg; (28/7x4/), in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	R	15486/1 29.10.2020
42	Tasigna	nilotinib (nilotinib hydrochloride monohydrate)	capsules hard	200mg; (28/7x4) in blister; (28/2x14) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	18112/1 29.10.2020
43	Clivas	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (30/3x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	R	18320/3/1 29.10.2020
44	Clivas	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (30/3x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	R	18321/3/1 29.10.2020

45	Azitrox	azithromycin (azithromycin dihydrate)	powder for oral suspension	100mg/5ml; 50ml glass bottle with 15.9g powder (for 20ml prepared suspension), measuring spoon and dropper	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTCPharm PJSC, 123317, Moscow, Testovskaya str., 10	Russia	R	14935/2 29.10.2020
46	Azitrox	azithromycin (azithromycin dihydrate)	powder for oral suspension	200mg/5ml; 50ml glass bottle with 15.9g powder (for 20ml prepared suspension), measuring spoon and dropper	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTCPharm PJSC, 123317, Moscow, Testovskaya str., 10	Russia	R	14936/2 29.10.2020
47	Nevanac	nepafenac	drops eye (suspension)	1mg/ml; plastic bottle 5ml	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	15198/3 29.10.2020
48	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	5mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19013/1 29.10.2020
49	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	7,5mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19014/1 29.10.2020

50	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	10mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19015/1 29.10.2020
51	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	15mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19016/1 29.10.2020
52	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	20mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19017/1 29.10.2020
53	Yaz plus	pink tablet-drospirenone, ethinyl estradiol, levomefolate (levomefolate calcium); light orange tablet-levomefolate (levomefolate calcium)	tablets film-coated	pink tablet-3mg+0,02mg+0,451mg; light orange tablet-0,451mg; (28/24 pink tablet+4 light orange tablet/), in blister	Bayer Weimar GmbH & Co. KG, Dobereinerstrasse 20, 99427 Weimar	Germany	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	R	19356/1 29.10.2020

54	Cefichew	cefixime (cefixime trihydrate)	tablets chewable	400mg; (10/1x10/) blister	SRS Pharmaceuticals Pvt. Ltd., Plot No.11 & 12 Kumar Industrial Estate, Gat No. 1251-1261, Alandi-Markal Road, Markal, Pune 412 105	India	SRS Pharmaceuticals Pvt. Ltd., 602, 6th Floor, Marathon Max Bldg. No 2, Mulund Goreagon Link Road L.B.S. Marg, Mulund, Goreagon Link Road L.B.S. Marg, Mulund, Mumbai,400 080	India	R	14218/2 29.10.2020
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