

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 3-1/20 on March 13, 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	Norvasc	amlodipine (amlodipine besilate)	tablets	5mg; (30/3x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Baden-Wuerttemberg, Mooswaldallee 1, 79090 Frieburg- packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	R	19129 13.03.2020
2	Norvasc	amlodipine (amlodipine besilate)	tablets	10mg; (30/3x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Baden-Wuerttemberg, Mooswaldallee 1, 79090 Frieburg- packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	R	19130 13.03.2020

3	Emcor 2.5	bisoprolol (bisoprolol fumarate)	coated tablets	2.5mg; (30/3x10/) in blister	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	R	19150 13.03.2020
4	Emcor 5	bisoprolol (bisoprolol fumarate)	coated tablets	5mg; (30/3x10/) in blister	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	R	19151 13.03.2020
5	Zumm-25	dexketoprofen (dexketoprofen trometamol)	tablets film-coated	25mg; (10) in blister	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	OTC	19152 13.03.2020

LIST

of the medicines recommended for the registration (new packaging) by the Center according to the meeting decision N 3-1/20 on March 13, 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	Plavix	clopidogrel (clopidogrel hydrosulfate)	tablets film-coated	75mg; (14/1x14/) in blister, (28/1x28/) in blister	Sanofi Winthrop Industrie, 1, rue de la Vierge, Ambares et Lagrave, 33565 Carbon Blanc cedex	France	Sanofi Pharma Bristol-Myers Squibb SNC 174 Avenue de France-F-75013 Paris	France	R	16916/2 13.03.2020

LIST

of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 3-1/20 on March 13, 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	Forxiga	dapagliflozin	tablets film-coated	10mg; (28/2x14/) in blister	AstraZeneca UK Ltd., Silk Road Business Park, Macclesfield, Cheshire, SK102NA- packager, batch releaser, AstraZeneca Pharmaceuticals LP, 4601 Highway 62 East, Mount Vernon, Indiana, 47620, USA- bulk manufacturer, AstraZeneca AB Gartunavagen, Sodertalje, SE-15185, Sweden- quality control	UK	AstraZeneca AB Gartunavagen, Sodertalje, SE-15185	Sweden	R	19132 13.03.2020

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 3-1/20 on March 13, 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	Emanera	esomeprazole (esomeprazole magnesium)	capsules gastro-resistant	20mg; (7/1x7/) in blister, (14/2x7/) in blister, (15/3x5/) in blister, (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (60/6x10/) 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	19133 13.03.2020
2	Emanera	esomeprazole (esomeprazole magnesium)	capsules gastro-resistant	40mg; (7/1x7/) in blister, (14/2x7/) in blister, (15/3x5/) in blister, (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (60/6x10/) 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	19134 13.03.2020
3	Odeston	hymecromone	tablets	200mg; (50/5x10/) in blister	Adamed Pharma S.A., 5 Marszalka Jozefa Pilsudskiego Str., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza St., 05-152 Czosnow	Poland	OTC	19135 13.03.2020

4	Revit	vitamin A, vitamin B1, vitamin B2, vitamin C	dragee	2500IU+1mg+1mg+35mg; (100) in plastic container without cardboard box, (100) in plastic container in a cardboard box	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	OTC	19136 13.03.2020
5	Lamifast	terbinafine (terbinafine hydrochloride)	tablets	250mg; (14/2x7/) in blister	Birzeit Pharmaceutical Company (BPC), Ramallah, Industrial Zone	Palestine	Pharmacare Int. Co./German Palestinian Joint Venture, Palestine, Ramallah, Almasion, Alnahda str. Jerusalem, P.O. box 51621	Palestine	R	19137 13.03.2020
6	Aerius	desloratadine	syrup	0,5mg/ml; glass bottle 60ml and measuring spoon	Schering-Plough Labo N.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	R	19138 13.03.2020
7	Soluferr	iron (III)-hydroxide sucrose complex	solution for i/v injection or concentrate for solution for infusion	20mg/ml; (5) ampoules 5ml	Help S.A. Pedini, Ioanninon, Ioannina, 45500	Greece	Moosmann Pharmaceuticals LLC, Vanahovit 8, Proshyan v., Ashtarak Ave., Kotayk Marz 2413	Republic of Armenia	R	19139 13.03.2020
8	Omniscan	gadodiamide	solution for i/v injection	287mg/ml (0,5mmol/ml); (10) glass vials 20ml	GE Healthcare Ireland Limited, IDA Business Park, Carrigtwohill, Co. Cork	Ireland	GE Healthcare AS, Nycoveien 1-2, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	R	19140 13.03.2020

9	Sedarex	risperidone	tablets coated	1mg; (30/3x10/) in blister	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	R	19141 13.03.2020
10	Sedarex	risperidone	tablets coated	2mg; (30/3x10/) in blister	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	R	19142 13.03.2020
11	Sedarex	risperidone	tablets coated	4mg; (30/3x10/) in blister	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	R	19143 13.03.2020
12	Grippoflu Extra cold and flu	paracetamol, phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid	powder for oral solution with lemon flavour	0,65g+0,01g+0,02g+0,05g; (3) sachets 13g, (8) sachets 13g	Marbiopharm JSC, 424006, the Republic of Mari El, Yoshkar-Ola, st. Karl Marx 121	Russia	Marbiopharm JSC, 424006, the Republic of Mari El, Yoshkar-Ola, st. Karl Marx 121	Russia	OTC	19144 13.03.2020
13	Grippoflu cold and flu	paracetamol, phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid	powder for oral solution with raspberry flavour	0,325g+0,01g+0,02g+0,05g; (10) sachets 13g	Marbiopharm JSC, 424006, the Republic of Mari El, Yoshkar-Ola, st. Karl Marx 121	Russia	Marbiopharm JSC, 424006, the Republic of Mari El, Yoshkar-Ola, st. Karl Marx 121	Russia	OTC	19145 13.03.2020

14	Co-Sentor	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+12,5mg; (30/3x10/) in blister	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Poland Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	19146 13.03.2020
15	Retabolil	nandrolone (nandrolone decanoate)	solution for injection, oily	50mg/ml; (1) ampoule 1ml	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	19147 13.03.2020
16	Lidocaine 5% ointment	lidocaine	ointment	50mg/g; aluminium tube 15g	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	R	19148 13.03.2020
17	Clopi-Denk 75	clopidogrel (clopidogrel besylate)	tablets film-coated	75mg; (30/3x10/) in blister	Artesan Pharma GmbH & Co. KG, Wendlandstrasse 1, 29439 Luechow	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	19149 13.03.2020

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 3-1/20 on March 13, 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	Metrofungyn	miconazole (miconazole nitrate), metronidazole	capsules vaginal	100mg+100mg; (10/2x5/)	Minskintercaps U.V., 26/3 bild. No2, Inzhenernaya str., 220075, Minsk	Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Belarus	R	18873/1/1 13.03.2020
2	Co-Vamloset	amlodipine (amlodipine besilate), valsartan, hydrochlorothiazide	tablets film-coated	5mg+160mg+12,5mg; (30/3x10/) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	R	18911/1/1 13.03.2020
3	Co-Vamloset	amlodipine (amlodipine besilate), valsartan, hydrochlorothiazide	tablets film-coated	10mg+160mg+12,5mg; (30/3x10/) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	R	18912/1/1 13.03.2020

4	Co-Vamloset	amlodipine (amlodipine besilate), valsartan, hydrochlorothiazide	tablets film-coated	10mg+160mg+25mg; (30/3x10/) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	R	18913/1/1 13.03.2020
5	Convulex	valproic acid	tablets prolonged-release film-coated	300mg; (50) glass or plastic container	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach -batch releaser, G.L. Pharma GmbH, Industriestrasse 1, 8502 Lannach, Austria -bulk manufacturer, packager	Australia	BAUSCH Health Ltd., Shabolovka st. 31, building 5, 115162, Moscow	Russia	R	14343/1/1 13.03.2020
6	Convulex	valproic acid	tablets prolonged-release film-coated	500mg; (50) glass or plastic container	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach -batch releaser, G.L. Pharma GmbH, Industriestrasse 1, 8502 Lannach, Austria -bulk manufacturer, packager	Australia	BAUSCH Health Ltd., Shabolovka st. 31, building 5, 115162, Moscow	Russia	R	14344/1/1 13.03.2020
7	CoPlavix	clopidogrel, acetylsalicylic acid	tablets film-coated	75mg+100mg; (30/3x10/) in blister	Sanofi Winthrop Industrie, 1, rue de la Vierge, Ambares et Lagrave, 33565 Carbon Blanc cedex	France	Sanofi Clir SNC 54, rue La Boetie 75008 Paris	France	R	17195/1/1 13.03.2020
8	Rinostop	xylometazoline (xylometazoline hydrochloride)	spray nasal	0,5mg/ml; plastic vial 15ml	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	14505/1/1 13.03.2020

9	Rinostop	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; plastic vial 15ml	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	14506/1/1 13.03.2020
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of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 3-1/20 on March 13, 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	Lorazepam	lorazepam	tablets	2mg; (24/1x24/) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	R	17745/1 13.03.2020
2	Sedarex	risperidone	tablets coated	1mg; (30/3x10/) blisters	GM Pharmaceuticals Ltd, PSP group 65, Qvemo Phonichala str., Tbilisi	Georgia	GM Pharmaceuticals Ltd, PSP group 65, Qvemo Phonichala str., Tbilisi	Georgia	R	14639/1 13.03.2020
3	Sedarex	risperidone	tablets coated	2mg; (30/3x10/) blisters	GM Pharmaceuticals Ltd, PSP group 65, Qvemo Phonichala str., Tbilisi	Georgia	GM Pharmaceuticals Ltd, PSP group 65, Qvemo Phonichala str., Tbilisi	Georgia	R	14641/1 13.03.2020
4	Sedarex	risperidone	tablets coated	4mg; (30/3x10/) blisters	GM Pharmaceuticals Ltd, PSP group 65, Qvemo Phonichala str., Tbilisi	Georgia	GM Pharmaceuticals Ltd, PSP group 65, Qvemo Phonichala str., Tbilisi	Georgia	R	14640/1 13.03.2020

5	Metformin Denk 850	metformin (metformin hydrochloride)	tablets film-coated	850mg; (30/2x15/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	16229/1 13.03.2020
6	Newkofen	acetylsalicylic acid, paracetamol, caffeine	tablets	200mg+200mg+40mg; (200/20x10/) blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Giga Farm LLC, Gogunts st. 3/5, Gyumri	Republic of Armenia	OTC	13970/2 13.03.2020
7	Dermovate	clobetasol (clobetasol propionate)	cream	0,5mg/g; aluminium tube 25g	GlaxoSmithKline Pharmaceuticals S.A.,189 Grunwaldzka street, 60-322 Poznan	Poland	GlaxoSmithKline Export Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	18211/2 13.03.2020
8	Dermovate	clobetasol (clobetasol propionate)	ointment	0,5mg/g; aluminium tube 25g	GlaxoSmithKline Pharmaceuticals S.A.,189 Grunwaldzka street, 60-322 Poznan f	Poland	GlaxoSmithKline Export Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	18212/2 13.03.2020

9	Solcoseryl	hemodialysate protein-free from calves blood	gel eye	8,3mg/g; aluminum tube 5g	Legacy Pharmaceuticals Switzerland GmbH, Ruhrbergstrasse 21, 4127 Birsfelden	Switzerland	Mylan Healthcare Sp.zo.o., Postepu str. 21B, 02-676 Warsawa	Poland	R	18210/2 13.03.2020
10	Vesomni	tamsulosin (tamsulosin hydrochloride), solifenacin (solifenacin succinate)	tablets film-coated modified-release	6mg+0,4mg; (10/1x10/) in blister, (30/3x10/) in blister	Astellas Pharma Europe B.V., Hogemaat 2, 7942 JG Meppel - packager, batch releaser, Avara Pharmaceutical Technologies Inc., 3300 Marshall Avenue, Norman, OK 73072, USA - bulk manufacturer	the Netherlands	Astellas Pharma Europe B.V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	R	18615/1 13.03.2020
11	Aripegis	aripiprazole	tablets	10mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	14847/1 13.03.2020

12	Aripegis	aripiprazole	tablets	15mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	14848/1 13.03.2020
13	Amlessa	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate)	tablets	4mg+5mg; (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	18007/1 13.03.2020
14	Alotendin	bisoprolol (bisoprolol fumarate), amlodipine (amlodipine besilate)	tablets	5mg+5mg; (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (90/9x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	18843/2 13.03.2020
15	Alotendin	bisoprolol (bisoprolol fumarate), amlodipine (amlodipine besilate)	tablets	5mg+10mg; (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (90/9x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	18844/2 13.03.2020

16	Alotendin	bisoprolol (bisoprolol fumarate), amlodipine (amlodipine besilate)	tablets	10mg+5mg; (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (90/9x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	18845/2 13.03.2020
17	Alotendin	bisoprolol (bisoprolol fumarate), amlodipine (amlodipine besilate)	tablets	10mg+10mg; (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (90/9x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	18846/2 13.03.2020
18	Aripegis	aripiprazole	tablets	10mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	14847/2 13.03.2020
19	Aripegis	aripiprazole	tablets	15mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	14848/2 13.03.2020

20	Safocid	I-fluconazole, II-azithromycin (azithromycin dihydrate), III-secnidazole	I-tablets, II-film-coated tablets, III- film-coated tablets	150mg+1000mg+1000mg; (4/1x4(1-I+1-II+2-III)), in blister	Hemofarm LLC, 249032, Obninsk, Kaluga Region, 62 Kievskoye highway - batch releaser, secondary packager, Lyka Labs Limited, T-139, MIDC Industrial Estate, Tarapur, District Thane 401506, India-bulk manufacturer, primary packager	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	R	15005/3 13.03.2020
21	Tribestan	tribulus terrestris herb dry extract	tablets film-coated	250mg; (60/6x10/) blisters	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	14583/1 13.03.2020
22	Letiram	levetiracetam	tablets coated	250mg; (30/3x10/), in blister and (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	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	15308/1 13.03.2020
23	Letiram	levetiracetam	tablets coated	500mg; (30/3x10/), in blister and (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	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	15307/1 13.03.2020

24	Letiram	levetiracetam	tablets coated	750mg; (30/3x10/), in blister and (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	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	15309/1 13.03.2020
25	Letiram	levetiracetam	tablets coated	1000mg; (30/3x10/), in blister and (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	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	15310/1 13.03.2020
26	Extractum Aloes fluidum	aloe liquid extract	solution for injection	360mg/ml; (10) ampoules 1ml	Yerevan Chemical-Pharmaceutical firm OJSC, Yerevan, Ajaryan street, 2 Line, No6	Republic of Armenia	Yerevan Chemical-Pharmaceutical firm OJSC, Yerevan, Ajaryan street, 2 Line, No6	Republic of Armenia	R	13861/1 13.03.2020
27	Losar-Denk 100	losartan (losartan potassium)	tablets film-coated	100mg; (28/2x14/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	16139/1 13.03.2020

28	Indapamide MB STADA	indapamide	tablets prolonged-release film-coated	1,5mg; (30/3x10/) in blister	Hemofarm LLC, 249032, Obninsk, Kaluga Region, 62 Kievskoye shosse	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	R	18876/1 13.03.2020
29	Sandostatin	octreotide (octreotide acetate)	solution for injection	0,1mg/ml; (5) ampoules 1ml	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	R	16616/2 13.03.2020
30	Ryzodeg FlexTouch	insulin degludec (70%), insulin aspart (30%)	solution for injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd-batch releaser, bulk manufacturer, primary packager, Novo Nordisk A/S, Brennum Park, Hillerod,3400, Denmark-secondary packager	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	R	16745/2 13.03.2020
31	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	250mg+125mg; (20/2x10/) in blister	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	17635/1 13.03.2020

32	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	500mg+125mg; (14/2x7/) in blister	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	17633/1 13.03.2020
33	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	875mg+125mg; (14/2x7/) in blister	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	17634/1 13.03.2020
34	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	powder for oral suspension	125mg/5ml+31,25mg/5ml; 100ml glass bottle	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	17636/1 13.03.2020
35	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	powder for oral suspension with mixed fruit flavour	200mg/5ml+28,5mg/5ml; 70ml glass bottle with measuring device	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	17694/1 13.03.2020
36	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	powder for oral suspension	250mg/5ml+62,5mg/5ml; 100ml glass bottle	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	17637/1 13.03.2020

37	Apo-Atenol	atenolol	tablets	50mg; (30/3x10/) in blister, (100) in plastic container	Apotex Inc., 150 Signet Drive, Toronto, Ontario, M9L 1T9-batch releaser, bulk manufacturer, Apotex Inc., 4100 Weston Road, Toronto, Ontario, M9L 2Y6, Canada -packager	Canada	Apotex Inc., 150 Signet Drive, Toronto, Ontario, M9L 1T9	Canada	R	16722/1 13.03.2020
38	Apo-Atenol	atenolol	tablets	100mg; (30/3x10/) in blister, (100) in plastic container	Apotex Inc., 150 Signet Drive, Toronto, Ontario, M9L 1T9-batch releaser, bulk manufacturer, Apotex Inc., 4100 Weston Road, Toronto, Ontario, M9L 2Y6, Canada -packager	Canada	Apotex Inc., 150 Signet Drive, Toronto, Ontario, M9L 1T9	Canada	R	16723/1 13.03.2020
39	Duphaston	dydrogesterone	tablets film-coated	10mg; (20/1x20/), blister	ABBOTT Biologicals B.V., Veerweg 12, 8121 AA Olst	the Netherlands	ABBOTT Healthcare Products B.V., C.J. van Houtenlaan 36, NL-1381 CP Weesp	the Netherlands	R	15489/2 13.03.2020
40	Milurit	allopurinol	tablets	100mg; (30), (40), (50), (60), (70), (80), (90), (100) and (120) in glass bottle	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	R	17483/2 13.03.2020

41	Milurit	allopurinol	tablets	150mg; (30) glass bottle, (40) glass bottle, (50) glass bottle, (60) glass bottle, (70) glass bottle, (80) glass bottle, (90) glass bottle, (100) glass bottle, (120) glass bottle	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly u. 65- packager, batch releaser, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary-bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	18677/1 13.03.2020
42	Milurit	allopurinol	tablets	200mg; (30) glass bottle, (40) glass bottle, (50) glass bottle, (60) glass bottle, (70) glass bottle, (80) glass bottle, (90) glass bottle, (100) glass bottle, (120) glass bottle	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly u. 65- packager, batch releaser, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary-bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	18678/1 13.03.2020
43	Milurit	allopurinol	tablets	300mg; (30), (40), (50), (60), (70), (80), (90), (100) and (120) in glass bottle	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65 -batch releaser, packager, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary-bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	R	17484/2 13.03.2020

44	Antiflu	paracetamol, phenylephrine (phenylephrine hydrochloride), chlorpheniramine (chlorpheniramine maleate)	tablets film-coated	325mg+5mg+2mg; (12/1x12/) in blister	Contract Pharmacal Corporation, 135 Adams avenue, Hauppauge, New York 11788-batch releaser, packager, Contract Pharmacal Corporation, 160 Commerce Drive Hauppauge, New York 11788, USA-bulk manufacturer	USA	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	16153/1 13.03.2020
45	Metformin Denk 1000	metformin (metformin hydrochloride)	tablets film-coated	1000mg; (30/2x15/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	16230/3 13.03.2020
46	Contractubex	extract cepae, heparin (heparin sodium), allantoin	gel for external use	100mg/g+50IU/g+10mg/g; 20g aluminium tube	Merz Pharma GmbH & Co. KGaA, Ludwigstrasse 22, Reinheim, Hessen, 64354	Germany	Merz Pharmaceuticals GmbH, Eckenheimer Landstrasse 100, 60318 Frankfurt/Main	Germany	OTC	16568/113.03.2020
47	Amorolfine Moosmann Medicated Nail Laquer 5%	amorolfine (amorolfine hydrochloride)	medicated nail laquer	50mg/ml; 3ml glass vial, (10) spatulas, (30) nail files, (30) alcohol swabs	Poul W. Beyvers GmbH, Schaffhausener Strasse 26-34 12099 Berlin	Germany	Moosmann Pharmaceuticals LLC, Vanahovit 8, Proshyan v., Ashtarak Ave., Kotayk Marz 2413	Republic of Armenia	OTC	17943/2 13.03.2020

48	Sandostatin LAR	octreotide (octreotide acetate)	powder for suspension for injection	20mg; glass vial, 2ml solvent in pre-filled syringe, adapter and needle	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein-secondary packager, batch releaser, Sandoz GmbH, Biochemiestrasse 10, 6336 Langkampfen, Austria- bulk manufacturer, primary packager, ABBOTT Biologicals B.V., Veerweg 12, 8121, AA Olst, the Netherlands-solvent manufacturer	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	R	18641/2 13.03.2020
49	Tranexam	tranexamic acid	tablets film-coated	250mg; (10/1x10/) in blister, (30/3x10/) in blister	Obninsk Chemical Pharmaceutical Company CJSC, Kaluga region, Obninsk, str. Kiev highway, 107 bulding	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	R	18484/1 13.03.2020
50	Tranexam	tranexamic acid	tablets film-coated	500mg; (10/1x10/) in blister	Obninsk Chemical Pharmaceutical Company CJSC, Kaluga region, Obninsk, str. Kiev highway, 107 bulding	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	R	18485/1 13.03.2020
51	Panto-Denk 40	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	40mg; (28/2x14/) in blister	Advance Pharma GmbH, Wallenroder str. 8-14, 13435 Berlin	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	17852/1 13.03.2020

52	Apo-Tamox	tamoxifen (tamoxifen citrate)	tablets	10mg; (100) plastic container	Apotex Inc., 3701 Weston Road, Weston, Ontario, M9L 2S8-batch releaser (Apotex Inc., 285 Gary Ray Drive, Weston, Ontario, M9L 1P3, Canada-bulk manufacturer, packager)	Canada	Apotex Inc., 150 Signet Drive, Toronto, Ontario, M9L 1T9	Canada	R	14513/1 13.03.2020
53	Apo-Tamox	tamoxifen (tamoxifen citrate)	tablets	20mg; (100) plastic container	Apotex Inc., 3701 Weston Road, Weston, Ontario, M9L 2S8-batch releaser (Apotex Inc., 285 Gary Ray Drive, Weston, Ontario, M9L 1P3, Canada-bulk manufacturer, packager)	Canada	Apotex Inc., 150 Signet Drive, Toronto, Ontario, M9L 1T9	Canada	R	14514/1 13.03.2020