

## LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 1-1/20 on January 31, 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	Levomycetin	chloramphenicol	tablets	500mg; (10/1x10/) in blister	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	R	19079 31.01.2020
2	Ortophen Tatpharm	diclofenac (diclofenac sodium)	tablets gastro-resistant	25mg; (30/3x10/) in blister, (30/2x15/) in blister	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	R	19080 31.01.2020
3	Peo	ceftriaxone (ceftriaxone sodium)	powder for solution for i/m and i/v injection	1000mg; glass vial	Laboratorio Reig Jofre, S.A., Jarama 111 Poligono Industrial, Toledo, 45007 Toledo	Spain	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	R	19081 31.01.2020
4	Zalasta	olanzapine	tablets	5mg; (28/4x7/) in blister, (56/8x7/) in blister	KRKA Polska Sp. z o.o., ul. Rownolegla 5, Warszawa, 02-235	Poland	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mest	Slovenia	R	19082 31.01.2020

5	Zalasta	olanzapine	tablets	10mg; (28/4x7/) in blister, (56/8x7/) in blister	KRKA Polska Sp. z o.o., ul. Rownolegla 5, Warszawa, 02-235	Poland	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	19083 31.01.2020
6	Iod	iodine	solution for external use	50mg/ml; glass bottle 25ml	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	OTC	19084 31.01.2020
7	Ceftriaxone	ceftriaxone (ceftriaxone sodium)	powder for solution for injection	1000mg; (10) glass vials	CR GoSun Pharma, No. 2 Kaifeng Road Street Avenue, Shangmeilin, Futian District, Shenzhen, Guangdong	China	CR GoSun Pharma, No. 2 Kaifeng Road Street Avenue, Shangmeilin, Futian District, Shenzhen, Guangdong	China	R	19085 31.01.2020
8	Propofol-Lipuro	propofol	emulsion for i/v injection	10mg/ml; (5) ampoules 20ml	B.Braun Melsungen AG, Carl-Braun-Strasse 1, Melsungen, Hessen, 34212	Germany	B.Braun Melsungen AG, Carl-Braun-Strasse 1,34212 Melsungen	Germany	R	19086 31.01.2020
9	Propofol-Lipuro	propofol	emulsion for i/v injection	10mg/ml; (10) glass vials 50ml	B.Braun Melsungen AG, Carl-Braun-Strasse 1, Melsungen, Hessen, 34212	Germany	B.Braun Melsungen AG, Carl-Braun-Strasse 1,34212 Melsungen	Germany	R	19087 31.01.2020

LIST

of the medicines recommended for the registration (new packaging) by the Center according to the meeting decision N 1-1/20 on January 31, 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	Detralex	diosmin, hesperidin	tablets film-coated	900mg+100mg; (18/2x9/) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	17509/2 30.10.2019
2	Plavix	clopidogrel (clopidogrel hydrosulfate)	tablets film-coated	75mg; (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	16916/1 31.01.2020
3	Bepanthen	dexpanthenol	ointment	50mg/g; aluminium tube 30g, aluminium tube 100g	GP Grenzach Produktions GmbH, Emil-Barell-Strasse 7, D-79639 Grenzach-Wyhlen	Germany	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	18643/1 31.01.2020

LIST

of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 1-1/20 on January 31, 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	Prevenar 13	pneumococcal polysaccharide conjugate vaccine (pneumococcal polysaccharide serotype 1, pneumococcal polysaccharide serotype 3, pneumococcal polysaccharide serotype 4, pneumococcal polysaccharide serotype 5, pneumococcal polysaccharide serotype 6A, pneumococcal polysaccharide serotype 6B, pneumococcal polysaccharide serotype 7F, pneumococcal polysaccharide serotype 9V, pneumococcal polysaccharide serotype 14, pneumococcal polysaccharide serotype 18C, pneumococcal polysaccharide serotype 19A, pneumococcal polysaccharide serotype 19F, pneumococcal polysaccharide serotype 23F)	suspension for injection	2.2mcg/dose+2.2mcg/dose+2.2mcg/dose+2.2mcg/dose+4.4mcg/dose+2.2mcg/dose+2.2mcg/dose+2.2mcg/dose+2.2mcg/dose+2.2mcg/dose; (1) prefilled syringe 0,5ml, (10) prefilled syringes 0,5ml	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, 2870- secondary packager, batch releaser, Pfizer Ireland Pharmaceuticals, Grange Castle Business Park, Clondalkin, Dublin 22, Ireland- bulk manufacturer, primary packager, quality control	Belgium	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	R	19089 31.01.2020

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 1-1/20 on January 31, 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	Amlofil 5	amlodipine (amlodipine besilate)	tablets	5mg; (100/10x10/) in strip	Fourrts (India) Laboratories Pvt. Ltd., Vandalur Road, Kelambakkam, Kancheepuram-603 103, Tamilnadu	India	Fourrts (India) Laboratories Pvt. Ltd., Vandalur Road, Kelambakkam, Kancheepuram-603 103, Tamilnadu	India	R	19090 31.01.2020
2	Amlofil 10	amlodipine (amlodipine besilate)	tablets	10mg; (100/10x10/) in strip	Fourrts (India) Laboratories Pvt. Ltd., Vandalur Road, Kelambakkam, Kancheepuram-603 103, Tamilnadu	India	Fourrts (India) Laboratories Pvt. Ltd., Vandalur Road, Kelambakkam, Kancheepuram-603 103, Tamilnadu	India	R	19091 31.01.2020
3	BacTRONN Forte	sulfamethoxazole, trimethoprim	tablets	800mg+160mg; (10/1x10/) in blister, (20/2x10/) in blister, (100/10x10/) in blister, (50) in jar, (100) in jar, (500) in jar	Medicon Pharmaceuticals Ltd, Industrial Plot No.17/A-1, Avenue 1, Block-D, Section-10, Mirpur, Dhaka-1216	Bangladesh	Medicon Pharmaceuticals Ltd, Industrial Plot No.17/A-1, Avenue 1, Block-D, Section-10, Mirpur, Dhaka-1216	Bangladesh	R	19092 31.01.2020

4	Airtal	aceclofenac	tablets film-coated	100mg; (20/2x10/) in blister, (60/6x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	19093 31.01.2020
5	Ibuprofen Medana	ibuprofen	suspension oral with strawberry flavour	20mg/ml; plastic container 100ml and measuring syringe, plastic container 120ml and measuring syringe	Medana Pharma S.A., 98-200 Sieradz, W. Lokietka 10-batch releaser, Medana Pharma S.A., str. Polskiej Organizacji Wojskowej 57, 98-200 Sieradz, Poland-bulk manufacturer, packager, quality control	Poland	Medana Pharma S.A., 98-200 Sieradz, W. Lokietka 10	Poland	OTC	19094 31.01.2020
6	Avastin	bevacizumab	concentrate for solution for infusion	25mg/ml; (1) glass vial 16ml	Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim- bulk manufacturer, primary packager, quality control, batch releaser, F. Hoffmann-La Roche Ltd., Wurmisweg CH-4303 Kaiseraugst, Switzerland-secondary packager	Germany	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	R	19095 31.01.2020
7	Avastin	bevacizumab	concentrate for solution for infusion	25mg/ml; (1) glass vial 4ml	Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim- bulk manufacturer, primary packager, quality control, batch releaser, F. Hoffmann-La Roche Ltd., Wurmisweg CH-4303 Kaiseraugst, Switzerland-secondary packager	Germany	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	R	19096 31.01.2020

8	Septanest with adrenaline 1/100000	articaine (articaine hydrochloride), adrenaline (adrenaline bitartrate)	solution for injection	40mg/ml+10mcg/ml; (50/5x10/) cartridges 1,7ml	Septodont, 58 rue du Pont de Creteil, 94100 Saint-Maur- des- Fosses	France	Septodont, 58 rue du Pont de Creteil, 94100 Saint- Maur- des- Fosses	France	R	19097 31.01.2020
9	Pamiray 370 Injection	iopamidol	solution for injection	370mg iodine/ml; glass vial 100ml	Dongkook Pharmaceutical Co., Ltd. 33-19, Yongso 2-gil, Gwanghyewon-myeon, Jincheon-gun, Chungcheongbuk-do	Korea South	Dongkook Pharmaceutical Co., Ltd. 7, Teheran-ro 108-gil, Gangnam-gu, Seou	Korea South	R	19098 31.01.2020
10	Betadinok	povidone-iodine	solution for external use	100mg/ml; plastic vial 20ml, plastic vial 30ml, plastic vial 75ml, plastic container 1000ml	NOKI JV LTD Co., Nor-Kharberd, Ararat region	Republic of Armenia	NOKI JV LTD Co., Nor-Kharberd, Ararat region	Republic of Armenia	OTC	19099 31.01.2020
11	Rinofluimucil	acetylcysteine, tuaminoheptane (tuaminoheptane sulfat)	spray nasal	10mg/ml+5mg/ml; glass bottle with nebulizer 10ml	Zambon S.P.A., Via della Chimica, 9, Vicenza, 36100	Italy	Zambon S.P.A., Via Lillo del Duca, 10, Bresso, 20091	Italy	OTC	19100 31.01.2020
12	Climaxan homeopathic	cimicifuga racemosa C200, lachesis mutus C50, apis mellifica C200	tablets	(20/1x20/) in blister, (40/2x20/) in blister	NPF Materia Medica Holding LLC, 54, Buguruslanskaya st., Chelyabinsk 454139	Russia	NPF Materia Medica Holding LLC, 9 bld., 3rd Samotyochny per., Moscow 127473	Russia	OTC	19101 31.01.2020

13	Espumisan L	simeticone	emulsion oral	40mg/ml; glass vial-dropper 30ml	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	Berlin-Chemie A.G. (Menarini Group), Glienicker Weg 125, 12489 Berlin	Germany	OTC	19102 31.01.2020
14	Snup	xylometazoline (xylometazoline hydrochloride)	spray nasal	0,5mg/ml; plastic bottle 15ml (150 dose)	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel- batch releaser, Famar Health Care Services Madrid, S.A.U., Avenida de Leganes, 62, Alcorcon, 28923 Madrid, Spain- bulk manufacturer, packager, quality control	Germany	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel	Germany	OTC	19103 31.01.2020
15	Snup	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; plastic bottle 15ml (150 dose)	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel- batch releaser, Famar Health Care Services Madrid, S.A.U., Avenida de Leganes, 62, Alcorcon, 28923 Madrid, Spain- bulk manufacturer, packager, quality control	Germany	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel	Germany	OTC	19104 31.01.2020
16	Xefocam	lornoxicam	tablets film- coated	8mg; (10/1x10) in blister	Takeda GmbH, Lehnitz str. 70-98, 16515 Oranienburg	Germany	Takeda Austria GmbH, St. Peter strasse 25, 4020 Linz	Austria	R	19105 31.01.2020



17	Espumisan	simeticone	capsules soft	40mg; (25/1x25/) in blister	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- packager, quality control, batch releaser, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany- bulk manufacturer	Germany	Berlin-Chemie A.G. (Menarini Group), Glienicker Weg 125, 12489 Berlin	Germany	OTC	19106 31.01.2020
18	Visipaque	iodixanol	solution for injection	320mg iodine/ml; (10) plastic vials 50ml	GE Healthcare Ireland Limited, IDA Business Park, Carrigtwohill, Cork, T45 AV60	Ireland	GE Healthcare AS, Nycoveien 1-2, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	R	19107 31.01.2020
19	Visipaque	iodixanol	solution for injection	320mg iodine/ml; (10) plastic vials 100ml	GE Healthcare Ireland Limited, IDA Business Park, Carrigtwohill, Cork, T45 AV60	Ireland	GE Healthcare AS, Nycoveien 1-2, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	R	19108 31.01.2020
20	Allochol	cattle bile dried, dried garlic, charcoal activated, nettle leaves	tablets coated	80mg+40mg+25mg+5mg; (10/1x10/) in blister, (50) plastic container	Irbitskiy himfarmzavod OJSC, 124-a, K. Marksa str., Irbit, St. Sverdlovsk, 623856	Russia	Irbitskiy himfarmzavod OJSC, 172, Kirova str., Irbit, St. Sverdlovsk, 623856	Russia	OTC	19109 31.01.2020
21	Folic Acid	folic acid	tablets	1mg; (50/5x10) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, No3/2, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	R	19110 31.01.2020

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 1-1/20 on January 31, 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	Multi-tabs Kid	vitamin A, vitamin D3, vitamin E, vitamin B1, vitamin B2, vitamin B6, vitamin B12, nicotinamide, pantothenic acid, folic acid hydrate, vitamin C, iron, zinc, copper, manganese, chromium, selen, iodine	tablets chewable raspberry-strawberry	400mcg+10mcg+5mg+0.7mg+0.8mg+0.9mg+1mcg+9mg+3mg+20mcg+40mg+10mg+5mg+1mg+1mg+20mcg+25mcg+70mcg; (30/3x10/) and (60/6x10/) in blister	Pfizer Consumer Manufacturing Italy S.R.L., Via Nettunense, 90, Aprilia, 04011	Italy	Pfizer Innovations LLC, Presnenskaya nab., building 10, Moscow, 123112	Russia	OTC	17376/1/2 31.01.2020
2	Multi-tabs Junior	vitamin A, vitamin D3, vitamin E, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin PP, vitamin B5, folic acid hydrate, vitamin C, iron, zinc, copper, manganese, chromium, selen, iodine	tablets chewable raspberry-strawberry	800mcg+5mcg+10mg+1.4mg+1.6mg+2mg+1mcg+18mg+6mg+100mcg+60mg+14mg+15mg+2mg+2.5mg+50mcg+50mcg+150mcg; (30/3x10/) and (60/6x10/) in blister	Pfizer Consumer Manufacturing Italy S.R.L., Via Nettunense, 90, Aprilia, 04011	Italy	Pfizer Innovations LLC, Presnenskaya nab., building 10, Moscow, 123112	Russia	OTC	17378/1/2 31.01.2020

3	Multi-tabs Junior	vitamin A, vitamin D3, vitamin E, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin PP, vitamin B5, folic acid hydrate, vitamin C, iron, zinc, copper, manganese, chromium, selen, iodine	tablets chewable fruit	800mcg+5mcg+10mg+1.4mg+1.6mg+2mg+1mcg+18mg+6mg+100mcg+60mg+14mg+15mg+2mg+2.5mg+50mcg+50mcg+150mcg; (30/3x10/) and (60/6x10/) in blister	Pfizer Consumer Manufacturing Italy S.R.L., Via Nettunense, 90, Aprilia, 04011	Italy	Pfizer Innovations LLC, Presnenskaya nab., building 10, Moscow, 123112	Russia	OTC	17377/1/2 31.01.2020
4	Polcortolon	triamcinolone	tablets	4mg; (50/2x25/) blisters	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	R	14255/1/1 31.01.2020
5	Otrivin	xylometazoline (xylometazoline hydrochloride)	drops nasal	0,5mg/ml; plastic bottle-dropper 10ml	GlaxoSmithKline Consumer Healthcare S.A., Route de l' Etraz, 1260 Nyon	Switzerland	GlaxoSmithKline Consumer Healthcare S.A., Route de l' Etraz, 1260 Nyon	Switzerland	OTC	18307/1/1 31.01.2020
6	Visipaque	iodixanol	solution for injection	320mg iodine/ml; (10) plastic vials 50ml	GE Healthcare Ireland Limited, IDA Business Park, Carrigtohill Co. Cork	Ireland	GE Healthcare AS, Nycoveien 1-2, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	R	14309/2/2 31.01.2020
7	Xarelto	rivaroxaban	tablets film-coated	15mg; (28/2x14), in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	R	17615/1/1 31.01.2020

8	Xarelto	rivaroxaban	tablets film-coated	20mg; (28/2x14/), in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	R	17614/1/1 31.01.2020
9	Stronger Neo-Minophagen C	monoammonium glycyrrhizinate (glycyrrhizic acid), glycine, L-cysteine hydrochloride hydrate (L-cysteine hydrochloride)	solution for injection	53mg/20ml(40mg/20ml)+400mg/20ml+22,29mg/20ml (20mg/20ml); (30) ampoules 20ml	Minophagen Pharmaceutical Co., Ltd., 2-2-3, Komatsubara, Zama-shi, Kanagawa	Japan	Minophagen Pharmaceutical Co., Ltd., 2-2-3, Komatsubara, Zama-shi, Kanagawa	Japan	R	14419/1/1 31.01.2020
10	Folic Acid	folic acid	tablets	1mg; (50/5x10/) blisters	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, No3/2, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	R	14283/1/1 31.01.2020
11	Lamal	lamotrigine	tablets	25mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	R	17149/1/1 31.01.2020
12	Lamal	lamotrigine	tablets	50mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	R	17150/1/1 31.01.2020

13	Lamal	lamotrigine	tablets	100mg; (30/2x15/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	R	17151/1/1 31.01.2020
14	Lamal	lamotrigine	tablets	200mg; (30/2x15/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	R	17152/1/1 31.01.2020
15	Skopryl	lisinopril (lisinopril dihydrate)	tablets	10mg; (30/3x10/) and (90/9x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	R	17355/1/1 31.01.2020
16	Skopryl	lisinopril (lisinopril dihydrate)	tablets	20mg; (30/3x10/) and (90/9x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	R	17356/1/1 31.01.2020

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 1-1/20 on January 31, 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	Movalis	meloxicam	tablets	7,5mg; (20/2x10/) in blister	Boehringer Ingelheim Ellas A.E., 5th km, Paiania-Markopoulo, 194 00 Koropi	Greece	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein	Germany	R	16506/1 31.01.2020
2	Movalis	meloxicam	tablets	15mg; (20/2x10/) in blister	Boehringer Ingelheim Ellas A.E., 5th km, Paiania-Markopoulo, 194 00 Koropi	Greece	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein	Germany	R	16507/1 31.01.2020
3	Beriate 500	human blood coagulation factor VIII	powder and solvent for solution for injection/infusion	500IU; (1) glass vial, 5ml glass vial with solvent, (1) transfer/filter set	CSL Behring GmbH, Emil-von-Behring-Strasse 76, 35041 Marburg	Germany	CSL Behring GmbH, Emil-von-Behring-Strasse 76, 35041 Marburg	Germany	R	14830/1 31.01.2020

4	Beriate 1000	human blood coagulation factor VIII	powder and solvent for solution for injection/infusion	1000IU; (1) glass vial, 10ml glass vial with solvent, (1) transfer/filter set	CSL Behring GmbH, Emil-von-Behring-Strasse 76, 35041 Marburg	Germany	CSL Behring GmbH, Emil-von-Behring-Strasse 76, 35041 Marburg	Germany	R	14831/1 31.01.2020
5	Ergoferon	affinity purified antibodies to human interferon gamma, affinity purified antibodies to histamine, affinity purified antibodies to CD4	tablets to be sucked	6mg+6mg+6mg; (20/1x20/), (40/2x20/) and (100/5x20/) in blister	NPF Materia Medica Holding LLC, 54, Buguruslanskaya st., Chelyabinsk 454139	Russia	NPF Materia Medica Holding LLC, 9 bld., 3rd Samotyochny per., Moscow 127473	Russia	OTC	17550/1 31.01.2020
6	Levofloxacin-Asteria	levofloxacin	tablets film-coated	500mg; (10/1x10/) in blister and(100/10x10/) in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-si, Chungcheongbuk-do	Korea South	GL Corporation, Woori Venture Tower #201, 70, Seonyu-ro, Yeongdeungpo-ku, Seoul	South Korea	R	15254/1 31.01.2020
7	Lorista	losartan (losartan potassium)	tablets film-coated	100mg; (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	16942/1 31.01.2020
8	Nuvaring	etonogestrel, ethinylestradiol	vaginal delivery system (vaginal ring)	11,7mg+2,7mg; (1) sachet	N.V. Organon, Kloosterstraat 6, 5349 AB Oss	the Netherlands	Schering-Plough Central East AG, Weystrasse 20, 6000 Lucerne 6	Switzerland	R	18919/2 31.01.2020

9	Elonva	corifollitropin alfa	solution for injection	100mcg/0,5ml; (1) pre-filled syringe 0,5ml and needle	N.V. Organon, Kloosterstraat 6, 5349 AB Oss- batch releaser, secondary packager, Vetter Pharma-Fertigung GmbH & Co. KG, Schutzenstrasse 87 and 99/101, D-88212 Ravensburg, Germany- bulk manufacturer, primary packager	the Netherlands	Schering-Plough Central East AG, Weyrstrasse 20, CH 6000 Lucerne 6	Switzerland	R	16963/1 31.01.2020
10	Elonva	corifollitropin alfa	solution for injection	150mcg/0,5ml; (1) pre-filled syringe 0,5ml and needle	N.V. Organon, Kloosterstraat 6, 5349 AB Oss- batch releaser, secondary packager, Vetter Pharma-Fertigung GmbH & Co. KG, Schutzenstrasse 87 and 99/101, D-88212 Ravensburg, Germany- bulk manufacturer, primary packager	the Netherlands	Schering-Plough Central East AG, Weyrstrasse 20, CH 6000 Lucerne 6	Switzerland	R	16962/1 31.01.2020
11	Divigel	estradiol (estradiol hemihydrate)	gel	1mg/g; (28) sachets 0,5g	Orion Corporation, Orionintie 1, 02200 Espoo- batch releaser, Orion Corporation, Tengstrominkatu 8, 20360 Turku, Finland- bulk manufacturer, packager	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	R	15412/2 31.01.2020
12	Divigel	estradiol (estradiol hemihydrate)	gel	1mg/g; (28) sachets 1g	Orion Corporation, Orionintie 1, 02200 Espoo- batch releaser, Orion Corporation, Tengstrominkatu 8, 20360 Turku, Finland- bulk manufacturer, packager	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	R	15066/2 31.01.2020



13	Strepsils Intensive	flurbiprofen	lozenges with honey and lemon flavour	8,75mg; (24/3x8/) 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	15037/1 31.01.2020
14	Methotrexate Orion	methotrexate	tablets	2,5mg; (30) plastic container, (100) plastic container	Orion Corporation, Orionintie 1, 02200 Espoo- batch releaser (Orion Corporation, Tengstrominkatu 8, 20360 Turku, Finland-bulk manufacturer, packager)	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	R	14485/1 31.01.2020
15	Methotrexate Orion	methotrexate	tablets	10mg; (30) plastic container, (100) plastic container	Orion Corporation, Orionintie 1, 02200 Espoo- batch releaser (Orion Corporation, Tengstrominkatu 8, 20360 Turku, Finland-bulk manufacturer, packager)	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	R	14486/1 31.01.2020
16	Cerotex	choline alfoscerate polyhydrate	solution for i/m and i/v injection	250mg/ml; (3) ampoules 4ml, (5) ampoules 4ml	SotexPharmFirm" CJSC, Bld. 10, 11, 12, village Belikovo, rural settlement Bereznjakovskoe, Sergiev-Posad municipal district, Moscow Region, 141345	Russia	"Sotex"PharmFirm " CJSC, Bld. 11, village Belikovo, rural settlement Bereznjakovskoe, Sergiev-Posad municipal district, Moscow Region, 141345	Russia	R	16480/1 31.01.2020

17	Strepsils	dichlorobenzyl alcohol, amylmetacresol	lozenges sugar free, with strawberry flavour	1,2mg+0,6mg; (16/2x8/) 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	14817/2 31.01.2020
18	Strepsils Express	dichlorobenzyl alcohol, amylmetacresol, lidocaine	lozenges	1,2mg+0.6mg+10mg; (24/2x12/), (24/3x8), 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	15040/4 31.01.2020
19	Tyzine	xylometazoline (xylometazoline hydrochloride)	spray nasal	0,5mg/ml; glass bottle 10ml (140 dose) with dosator	Famar Orleans, 5 avenue de Concyr, 45071 Orleans, Cedex 2	France	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	OTC	18357/2 31.01.2020
20	Tyzine	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; glass bottle 10ml (70 dose) with dosator	Famar Orleans, 5 avenue de Concyr, 45071 Orleans, Cedex 2	France	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	OTC	18358/2 31.01.2020

21	Coripren	lercanidipine (lercanidipine hydrochloride), enalapril (enalapril maleate)	tablets film-coated	10mg+10mg; (28/2x14/) blisters	Recordati Industria Chimica e Farmaceutica S.p.A., Via Civitali, 1-20148 Milano	Italy	Recordati Ireland Ltd., Raheens East, Ringaskiddy, Co Cork	Ireland	R	15780/1 31.01.2020
22	Coripren	lercanidipine (lercanidipine hydrochloride), enalapril (enalapril maleate)	tablets film-coated	10mg+20mg; (28/2x14/) blisters	Recordati Industria Chimica e Farmaceutica S.p.A., Via Civitali, 1-20148 Milano	Italy	Recordati Ireland Ltd., Raheens East, Ringaskiddy, Co Cork	Ireland	R	15781/1 31.01.2020
23	Pancef	cefixime (cefixime trihydrate)	powder for oral suspension	100mg/5ml; powder 32g in glass bottle 60ml and measuring spoon 5ml	Alkaloid AD-Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje-batch releaser, Alkaloid AD-Skopje, Blvd. Partizanski odredi 98A,1000 Skopje, Republic of North Macedonia -bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD-Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	R	14714/2/1 31.01.2020
24	Pancef	cefixime (cefixime trihydrate)	powder for oral suspension	100mg/5ml; 53g powder in 100ml glass bottle and 5ml measuring spoon	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje-batch releaser, Alkaloid AD-Skopje, Blvd. Partizanski odredi 98A,1000 Skopje, Macedonia- bulk manufacturer, packager	Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Macedonia	R	17082/2 31.01.2020

25	Visanne	dienogest (micronised)	tablets	2mg; (28/2x14/) blisters	Bayer Weimar GmbH & Co. KG, Dobereinerstrasse 20, 99427 Weimar	Germany	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	R	17987/2 31.01.2020
26	Rispolept	risperidone	tablets film-coated	2mg; (20/2x10/) in blister	Janssen-Cilag S.p.A., Via C. Janssen, 04100 Borgo S. Michele, Latina	Italy	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	R	18655/1 31.01.2020
27	Tyverb	lapatinib (lapatinib ditosylate monohydrate)	tablets film-coated	250mg; (70) in plastic bottle	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos-batch releaser, packager, Glaxo Wellcome Operations, Priory Street, Ware, Hertfordshire, SG12 0DJ, UK- bulk manufacturer	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	17200/1 31.01.2020
28	Panangin	magnesium aspartate (magnesium aspartate tetrahydrate), potassium aspartate (potassium aspartate hemihydrate)	concentrate for solution for infusion	40mg/ml+45,2mg/ml; (5/1x5/) ampoules 10ml, blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	14562/1 31.01.2020

29	Gangleron	ganglefene	solution for injection	15mg/ml; (10) ampoules 2ml	the Scientific Technological Center of Organic and Pharmaceutical Chemistry,A.L. Mndjoyan Institute of Fine Organic Chemistry NAS RA , Yerevan, Azatutyun avenue 26 - batch releaser (Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building, Republic of Armenia- bulk manufacturer, packager)	Republic of Armenia	the Scientific Technological Center of Organic and Pharmaceutical Chemistry,A.L. Mndjoyan Institute of Fine Organic Chemistry NAS RA , Yerevan, Azatutyun avenue 26	Republic of Armenia	R	13684/1 31.01.2020
30	Lindynette 20	gestodene, ethinylestradiol	tablets coated	0,02mg+0,075mg; (21/1x21/) and (63/3x21/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	17723/1 31.01.2020
31	Fervex	paracetamol, ascorbic acid, pheniramine (pheniramine maleate)	powder for oral solution with raspberry flavour and sugar	500mg+200mg+25mg; (8) sachets 12,75g	UPSA SAS, 979, Avenue des Pyrenees, 47520 Le Passage	France	UPSA SAS, 3, rue Joseph Monier-92500 Rueil-Malmaison	France	OTC	17479/1 31.01.2020
32	Analgin	metamizole (metamizole sodium)	tablets	500mg; (10) blister, (10) strip	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	OTC	13971/1 31.01.2020

33	Paracetamol	paracetamol	tablets	500mg; (10) 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	OTC	14081/1 31.01.2020
34	Viagra	sildenafil (sildenafil citrate)	tablets orodispersible	50mg; (2/1x2/) in blister, (4/1x4/) in blister, (8/2x4/) 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	18828/1 31.01.2020
35	Viagra	sildenafil (sildenafil citrate)	tablets film-coated	25mg; (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	18317/2 31.01.2020
36	Viagra	sildenafil (sildenafil citrate)	tablets film-coated	50mg; (1) in blister, (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	18831/1 31.01.2020
37	Viagra	sildenafil (sildenafil citrate)	tablets film-coated	100mg; (1) in blister, (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	18832/1 31.01.2020
38	Prestance 5mg/5mg	perindopril (perindopril arginine), amlodipine (amlodipine besilate)	tablets	5mg+5mg; (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co Wicklow	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	17894/1 3101.2020

39	Prestance 5mg/10mg	perindopril (perindopril arginine), amlodipine (amlodipine besilate)	tablets	5mg+10mg; (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co Wicklow	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	17895/1 31.01.2020
40	Prestance 10mg/5mg	perindopril (perindopril arginine), amlodipine (amlodipine besilate)	tablets	10mg+5mg; (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co Wicklow	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	17897/1 31.01.2020
41	Prestance 10mg/10mg	perindopril (perindopril arginine), amlodipine (amlodipine besilate)	tablets	10mg+10mg; (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co Wicklow	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	17896/1 31.01.2020
42	Bactrim	sulfamethoxazole, trimethoprim	suspension oral	200mg/5ml+40mg/5ml; 100ml glass bottle	F. Hoffmann-La Roche AG, Viadukstrasse 33, CH-4051 Basel - batch releaser, Cenexi SAS, Rue Marcel et Jacques Gaucher, 52, Fontenay sous Bois, 94120, France- bulk manufacturer, packager	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	R	17724/1 31.01.2020

43	Bactrim forte	sulfamethoxazole, trimethoprim	tablets	800mg+160mg; (10/1x10/), in blister	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel - batch releaser, Productos Roche S.A. de C.V., Via Isidro Fabela Norte N 1536-B, Parque Industrial Toluca (Estado de Mexico) 50030, Mexico, Mexico-bulk manufacturer, F. Hoffmann La Roche Ltd, Betriebsstandort Kaiseraugst, 4303 Kaiseraugst, Switzerland- primary and secondary packager	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	R	15388/1 31.01.2020
44	Bactrim forte	sulfamethoxazole, trimethoprim	tablets film-coated	800mg+160mg; (10/1x10/) in blister	F. Hoffmann-La Roche Ltd, 4303 Kaiseraugst- packager, batch releaser, Produtos Roche Quimicos e Farmaceuticos S/A, Estrada dos Bandeirantes 2020 Taquara, RJ, 22775-109, Brazil-bulk manufacturer, DELPHARM MILANO S.R.L. VIA CARNEVALE, 1 - 20090 SEGRATE (MI), Italy- quality control	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070	Switzerland	R	18954/1 31.01.2020
45	Ekvator	lisinopril (lisinopril dihydrate), amlodipine (amlodipine besilate)	tablets	10mg+5mg; (10), (30/3x10/), (60/6x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	14888/1 31.01.2020



46	Ekvator	lisinopril (lisinopril dihydrate), amlodipine (amlodipine besilate)	tablets	20mg+10mg; (10), (30/3x10/), (60/6x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	14887/1 31.01.2020
47	Cycloferon	acridonacetic acid, N-methyl glucamin (meglumin)	solution for i/m and i/v injection	125mg/ml+96,3mg/ml ; (5) ampoules 2ml, in blister	Scientific Technological Pharmaceutical Firm "POLISAN" Ltd, 192102, Saint Petersburg, Salova st. 72, building 2, lit. A	Russia	Scientific Technological Pharmaceutical Firm "POLISAN" Ltd, 192102, Saint Petersburg, Salova st. 72, building 2, lit. A	Russia	R	16641/1 31.01.2020
48	Clomentin	escitalopram (escitalopram oxalate)	tablets film-coated	20mg; (28/2x14/) in blister	Delorbis Pharmaceuticals Ltd., 17 Athinon Street, Ergates Industrial Area, 2643 Ergates, Lefkosia-secondary packager, batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia-bulk manufacturer, primary packager, quality control	Cyprus	Delorbis Pharmaceuticals Ltd., 17 Athinon Street, Ergates Industrial Area, 2643 Ergates, P.O. Box 28629, 2081 Lefkosia	Cyprus	R	18723/3 31.01.2020
49	Puroxan	doxofylline	syrup	20mg/ml; glass bottle 100ml and measuring spoon	M & H Manufacturing Co. Ltd., 41 Sukhumvit Road, Paknam, Muang, Samutprakarn 10270	Thailand	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	R	18427/1 31.01.2020
50	Alka-Seltzer	acetylsalicylic acid, citric acid, sodium bicarbonate	tablets effervescent	324mg+965mg+1625 mg; (10/5x2/) in strip	Bayer Bitterfeld GmbH, Ortsteil Greppin, Salegaster Chaussee 1, 06803 Bitterfeld-Wolfen	Germany	JSC BAYER, 3rd Rybinskaya st., 18, build. 2, 107113 Moscow	Russia	OTC	18020/2 31.01.2020

51	Zindolin	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	500mg; (10/1x10/) in blister	Remedica Ltd, Aharnon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	Remedica Ltd, Aharnon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	R	18476/1 31.01.2020
52	Unidox Solutab	doxycycline (doxycycline monohydrate)	tablets dispersible	100mg; (10/1x10) in blister	ZiO-Zdorovie JSC, 142103, Moskovskaya oblast, Podolsk, str. Zheleznodorozhnaya, 2	Russia	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	R	17328/2 31.01.2020