

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 11-2/22 on November 30, 2022

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Champix	varenicline (varenicline tartrate)	tablets film-coated	0,5mg/1mg; (11/1x11/) (0,5mg) in blister and (14/1x14/) (1mg) in blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstatte Freiburg, Mooswaldallee 1, 79090 Frieburg- packager, batch releaser, Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno, Italy- bulk manufacturer, quality control	Germany	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	20998 30.11.2022
2	Champix	varenicline (varenicline tartrate)	tablets film-coated	1mg; (28/4x7/) in blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstatte Freiburg, Mooswaldallee 1, 79090 Frieburg- packager, batch releaser, Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno, Italy- bulk manufacturer, quality control	Germany	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	20999 30.11.2022

3	Steptenbact-Aversi	piperacillin (piperacillin sodium), tazobactam (tazobactam sodium)	powder for solution for infusion	4000mg+500mg; (25) glass vials 4,5g	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi- secondary packager, quality control, batch releaser, Reyoung Pharmaceutical Co. Ltd., No1 Ruiyang Road, Yiyuan County, Shandong Province, China- bulk manufacturer, primary packager	Georgia	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi	Georgia	PoM	21000 30.11.2022
4	Visine Comfort	tetryzoline (tetryzoline hydrochloride)	drops eye	0,5mg/ml; plastic vial 15ml	Janssen Pharmaceutica N.V., Turnhoutseweg 30, B-2340 Beerse	Belgium	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	OTC	21001 30.11.2022
5	D3-CAPS	colecalfiferol	capsules	2000IU; (30/2x15/) in blister	Minskintercaps U.V., 26/3 bild. No2, Inzhenernaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Republic of Belarus	OTC	21002 30.11.2022
6	D3-CAPS	colecalfiferol	capsules	5000IU; (30/3x10/) in blister	Minskintercaps U.V., 26/3 bild. No2, Inzhenernaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Republic of Belarus	OTC	21003 30.11.2022

7	Meloxicam	meloxicam	solution for i/m injection	10mg/ml; (3) ampoules 1,5ml, (5) ampoules 1,5ml	FKP Kurskaya Biofabrika, Kurskaya district, Kursk city, st. Razina, 5	Russia	B-Pharm Ltd., 143026, Moscow district, Odincovsky area, village Novoivanskoe, st. Agrochimikov, building 2A	Russia	PoM	21004 30.11.2022
8	Valdocef	cefadroxil (cefadroxil monohydrate)	granules for oral suspension	250mg/5ml; 150ml glass bottle	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- quality control, 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	PoM	21005 30.11.2022
9	Claritine	loratadine	tablets	10mg; (10/1x10/) in blister	Bayer Bitterfeld GmbH, Ortsteil Greppin Salegaster Chaussee 1, 06803 Bitterfeld-Wolfen	Germany	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	21006 30.11.2022

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of the medicines recommended for the mutual recognition of the EAEU registration by the Center according to the meeting decision N 11-2/22 on November 30, 2022

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Noliprel arginine	perindopril arginine, indapamide	tablets film-coated	2,5mg+0,625mg; (14) in plastic container, (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21035 (000407) 30.11.2022
2	Noliprel arginine	perindopril arginine, indapamide	tablets film-coated	2,5mg+0,625mg; (14) in plastic container, (29) in plastic container, (30) in plastic container, (90) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21036 (000407) 30.11.2022

3	Noliprel arginine	perindopril arginine, indapamide	tablets film-coated	2,5mg+0,625mg; (14) in plastic container, (30) in plastic container, (90) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21037 (000407) 30.11.2022
4	Noliprel Forte arginine	perindopril arginine, indapamide	tablets film-coated	5mg+1,25mg; (14) in plastic container, (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21038 (000407) 30.11.2022
5	Noliprel Forte arginine	perindopril arginine, indapamide	tablets film-coated	5mg+1,25mg; (14) in plastic container, (29) in plastic container, (30) in plastic container, (90) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21039 (000407) 30.11.2022

6	Noliprel Forte arginine	perindopril arginine, indapamide	tablets film-coated	5mg+1,25mg; (14) in plastic container, (30) in plastic container, (90) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21040 (000407) 30.11.2022
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LIST

of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 11-2/22 on November 30, 2022

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Viropil	dolutegravir (dolutegravir sodium), lamivudine, tenofovir disoproxil fumarate	tablets film-coated	50mg+300mg+300mg; (30) in plastic container, (90) in plastic container	Emcure Pharmaceuticals Ltd., Plot No. P-1 & P-2, I.T.B.T., Park Phase-II, M.I.D.C., Hinjwadi, Pune-411057, Maharashtra State	India	Emcure Pharmaceuticals Ltd., T-184, M.I.D.C., Bhosari, Pune-411026, Maharashtra State	India	PoM	21034 30.11.2022

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of the medicines recommended for the registration (new packaging) by the Center according to the meeting decision N 11-2/22 on November 30, 2022

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Panangin	magnesium aspartate (magnesium aspartate tetrahydrate), potassium aspartate (potassium aspartate hemihydrate)	tablets film-coated	140mg+158mg; (50) in plastic container, (60/3x20/) in blister, (100/5x20/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	OTC	19515/1 30.11.2022

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of the medicines recommended for the re-registration by the Center according to the meeting decision N 11-2/22 on November 30, 2022

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Pancreatin	pancreatin (amylase, protease, lipase)	tablets gastro-resistant	125mg (not less than 2800IU, not less than 180IU, not less than 3000IU); (50/5x10/) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	21007 30.11.2022
2	Acetylsalicylic acid	acetylsalicylic acid	tablets	500mg; (10) in blister	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	OTC	21008 30.11.2022
3	Grippostad C	paracetamol, ascorbic acid, caffeine, chlorphenamine (chlorphenamine maleate)	capsules	200mg+150mg+25mg+2,5mg; (10/1x10/) in blister	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	OTC	21009 30.11.2022

4	Upsarin Ursa	acetylsalicylic acid	tablets effervescent	500mg; (16/4x4/) in strip	UPSA SAS, 979, Avenue des Pyrenees, 47520 Le Passage	France	UPSA SAS, 3, rue Joseph Monier-92500 Rueil-Malmaison	France	OTC	21010 30.11.2022
5	Oxolin	oxolin	ointment nasal	2,5mg/g; aluminium tube 10g	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	21011 30.11.2022
6	Pabi-Dexamethason	dexamethasone	tablets	500mcg; (20/1x20/) in blister	Adamed Pharma S.A., 5 Marszalka Jozefa Pilsudskiego Str., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	PoM	21012 30.11.2022
7	Kagocel	kagocel	tablets	12mg; (10/1x10/) in blister, (20/2x10/) in blister, (30/3x10/) in blister	NEARMEDIC PHARMA LLC, 120 Kiev highway, bldg. 3, 4, 5, Obninsk, Obninsk City District, Kaluga Region, 249030	Russia	NEARMEDIC PLUS LLC, Aviakonstruktora Mikoyana St., 12, room 26, premises NII, floor 2, 125252, Moscow	Russia	OTC	21013 30.11.2022

8	Nosacare	oxymetazoline (oxymetazoline hydrochloride)	spray nasal	0,5mg/ml; 15ml plastic vial with pump dispenser	Pharmacare PLC, Ramallah, Betunia, Industrial Zone	Palestine	Pharmacare Int. Co./German Palestinian Joint Venture, Jerusalem, P.O. box 51621	Palestine	OTC	21014 30.11.2022
9	Nosacare Mentho	oxymetazoline (oxymetazoline hydrochloride)	spray nasal	0,5mg/ml; 15ml plastic vial with pump dispenser	Pharmacare PLC, Ramallah, Betunia, Industrial Zone	Palestine	Pharmacare Int. Co./German Palestinian Joint Venture, Jerusalem, P.O. box 51621	Palestine	OTC	21015 30.11.2022
10	Nosacare Baby	oxymetazoline (oxymetazoline hydrochloride)	spray nasal	0,25mg/ml; 15ml plastic vial with pump dispenser	Pharmacare PLC, Ramallah, Betunia, Industrial Zone	Palestine	Pharmacare Int. Co./German Palestinian Joint Venture, Jerusalem, P.O. box 51621	Palestine	OTC	21016 30.11.2022
11	Nosacare Extra Moisturizing	oxymetazoline (oxymetazoline hydrochloride)	spray nasal	0,5mg/ml; 15ml plastic vial with pump dispenser	Pharmacare PLC, Ramallah, Betunia, Industrial Zone	Palestine	Pharmacare Int. Co./German Palestinian Joint Venture, Jerusalem, P.O. box 51621	Palestine	OTC	21017 30.11.2022

12	BoriVit	thiamine (thiamine hydrochloride), pyridoxine (pyridoxine hydrochloride), cyanocobalamin, lidocaine (lidocaine hydrochloride)	solution for i/m injection	100mg/2ml+100mg/2ml+1mg/2ml+20mg/2ml; (10) ampoules 2ml label banderol, (10) ampoules 2ml dividella, (10) ampoules 2ml CAMA	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	PoM	21018 30.11.2022
13	Dexatobrom	tobramycin, dexamethasone	drops eye (suspension)	3mg/ml+1mg/ml; plastic vial 5ml	Rompharm Company SRL, Eroilor Str., No. 1A, Otopeni city, Ilfov county, 075100, buildings Rompharm 1 and Rompharm 2	Romania	Rompharm Company SRL, Eroilor Str., No. 1A, Otopeni city, Ilfov county, 075100	Romania	PoM	21019 30.11.2022
14	Bisoprolol	bisoprolol (bisoprolol fumarate)	tablets coated	5mg; (30/3x10/) 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	PoM	21020 30.11.2022
15	Driptane	oxybutynin (oxybutynin hydrochloride)	tablets	5mg; (30/1x30/) in blister	Recipharm Fontaine, Rue des Pres Potets, 21121 Fontaine les Dijon	France	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	PoM	21021 30.11.2022
16	Rissar	risperidone	tablets film-coated	1mg; (20/2x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	21022 30.11.2022

17	Rissar	risperidone	tablets film-coated	2mg; (20/2x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	21023 30.11.2022
18	Rissar	risperidone	tablets film-coated	3mg; (20/2x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	21024 30.11.2022
19	Mirolute	misoprostol	tablets	200mcg; (4) in blister, (4) in plastic container	Obninsk Chemical Pharmaceutical Company CJSC, Kaluga reg., Kiyevskoe str., b.103, b.107, Obninsk	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	21025 30.11.2022
20	Tavin	tenofovir (tenofovir disoproxil fumarate)	tablets film-coated	300mg; (30) in plastic container	Emcure Pharmaceuticals Ltd., Lane No. 3, Phase II, SIDCO Industrial Complex, Bari-Brahmana, Jammu (J&K)-181 133	India	Emcure Pharmaceuticals Ltd., T-184, M.I.D.C., Bhosari, Pune-411026	India	PoM	21026 30.11.2022
21	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-Aventis Group, 54, rue La Boetie 75008 Paris	France	PoM	21027 30.11.2022

22	Fluconazole	fluconazole	capsules	50mg; (7) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64A, No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	21028 30.11.2022
23	Fluconazole	fluconazole	capsules	150mg; (1) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64A, No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	21029 30.11.2022
24	Nifedipin	nifedipine	tablets coated	10mg; (50/5x10/) in blister	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PoM	21030 30.11.2022

25	Amoxicillin 250mg	amoxicillin (amoxicillin trihydrate)	capsules	250mg; (100/10x10/) in blister	Medopharm Private Limited, No. 50 Kayarambedu Village, Guduvanchery, Chennai-603202	India	Troge Scientific Research I.PVT.LTD., Unit no.412, 4 th floor, Plot no.D-6 Wave Silver Tower, sector-18 Noida-201301, Gautam Buddha nagar,Uttar Pradesh	India	PoM	21031 30.11.2022
26	Amoxicillin 500mg	amoxicillin (amoxicillin trihydrate)	capsules	500mg; (100/10x10/) in blister	Medopharm Private Limited, No. 50 Kayarambedu Village, Guduvanchery, Chennai-603202	India	Troge Scientific Research I.PVT.LTD., Unit no.412, 4 th floor, Plot no.D-6 Wave Silver Tower, sector-18 Noida-201301, Gautam Buddha nagar,Uttar Pradesh	India	PoM	21032 30.11.2022
27	Nolicin	norfloxacin	tablets film-coated	400mg; (20/2x10/) 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	PoM	21033 30.11.2022

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 11-2/22 on November 30, 2022

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Ropuido	rosuvastatin (rosuvastatin calcium)	tablets film-coated	5mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	18173/1/1 30.11.2022
2	Ropuido	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	18174/1/1 30.11.2022
3	Ropuido	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	18175/1/1 30.11.2022

4	Ropuido	rosuvastatin (rosuvastatin calcium)	tablets film-coated	40mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	18176/1/1 30.11.2022
5	Angiovit-AV	folic acid, pyridoxine (pyridoxine hydrochloride), cyanocobalamin	tablets film-coated	5mg+4mg+0,006mg; (50/5x10/) in blister	Altayvitaminy JSC, 659325, Altay region, Biysk, st. Zavodskaya, 69	Russia	Altayvitaminy JSC, 659325, Altay region, Biysk, st. Zavodskaya, 69	Russia	OTC	18787/1/1 30.11.2022
6	Espumisan L	simeticone	emulsion oral	40mg/ml; glass vial-dropper 30ml	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	OTC	19102/1/1 30.11.2022
7	Mildronat	meldonium (meldonium dihydrate)	solution for injection	100mg/ml; (10/2x5/) ampoules 5ml in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga-batch releaser, Santonika UAB, 134B Veiveriu street, Kaunas, LT-46353, Lithuania- bulk manufacturer, packager, quality control	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	20304/1/1 30.11.2022
8	Fenistil New	dimetindene (dimetindene maleate)	drops oral (solution)	1mg/ml glass bottle 20ml	GlaxoSmithKline Consumer Healthcare SARM, Route de l' Etraz, 1260 Nyon	Switzerland	GlaxoSmithKline Consumer Healthcare SARM, Route de l' Etraz, 1260 Nyon	Switzerland	OTC	18328/2/2 30.11.2022

9	Ascorbic acid with glucose	ascorbic acid, glucose (glucose monohydrate)	tablets	100mg+877mg; (10) in strip, (20/2x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 24, Stroiteley str., Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	OTC	17547/1/1 30.11.2022
10	Oxycodone Hydrochloride	oxycodone (oxycodone hydrochloride)	solution for injection/infusion	10mg/ml; (5/1x5/) ampoules 1ml in plastic liner, (10/2x5/) ampoules 1ml in plastic liner	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057-batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia-bulk manufacturer, packager, quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	19796/1/1 30.11.2022
11	Oxycodone Hydrochloride	oxycodone (oxycodone hydrochloride)	solution for injection infusion	10mg/ml; (5/1x5/) ampoules 2ml in plastic liner, (10/2x5/) ampoules 2ml in plastic liner	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057-batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia-bulk manufacturer, packager, quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	19797/1/1 30.11.2022
12	Oxycodone Hydrochloride	oxycodone (oxycodone hydrochloride)	solution for injection infusion	50mg/ml; (5/1x5/) ampoules 1ml in plastic liner, (10/2x5/) ampoules 1ml in plastic liner	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057-batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia-bulk manufacturer, packager, quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	19798/1/1 30.11.2022

13	Doxycycline	doxycycline (doxycycline hyclate)	capsules	100mg; (10/1x10/) in blister, (1500/150x/1x10/) in blister	Belmedpreparaty RUE, Grodinsky region, Skidzyel, Kizevich str., 50-4	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	17710/2/1 30.11.2022
14	Vibrocil	dimethindene (dimethindene maleate), phenylephrine	drops nasal	0,25mg/ml+2,5mg/ml; 15ml glass vial	GlaxoSmithKline Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon	Switzerland	GlaxoSmithKline Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon	Switzerland	OTC	18087/2/2 30.11.2022
15	Calgel	lidocaine (lidocaine hydrochloride), cetylpyridinium (cetylpyridinium chloride)	gel	3,3mg/g+1mg/g; 10g aluminium tube	Delpharm Poznan S.A., 189 Grunwaldzka street, 60-322 Poznan	Poland	Glaxo Wellcome UK Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	PoM	17787/2/2 30.11.2022
16	Furosemide	furosemide	tablets	40mg; (50/5x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64A, No4, str. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, str. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	18847/1/1 30.11.2022
17	Co-Amlessa	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate), indapamide	tablets	2mg+5mg+0,625mg; (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	PoM	19775/1/1 30.11.2022

18	Co-Amlessa	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate), indapamide	tablets	4mg+5mg+1,25mg; (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	PoM	19776/1/1 30.11.2022
19	Co-Amlessa	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate), indapamide	tablets	4mg+10mg+1,25mg; (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	PoM	19777/1/1 30.11.2022
20	Co-Amlessa	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate), indapamide	tablets	8mg+5mg+2,5mg; (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	PoM	19778/1/1 30.11.2022
21	Co-Amlessa	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate), indapamide	tablets	8mg+10mg+2,5mg; (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	PoM	19779/1/1 30.11.2022
22	Aevit-AV	retinol palmitate (vitamin A), alfa-tocopherol acetate (vitamin E)	capsules	55mg(100000IU)+100mg; (50/5x10/) in blister	Altayvitaminy JSC, 659325, Altay region, Biysk, st. Zavodskaya, 69	Russia	Altayvitaminy JSC, 659325, Altay region, Biysk, st. Zavodskaya, 69	Russia	OTC	18694/1/1 30.11.2022

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 11-2/22 on November 30, 2022

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Sirturo	bedaquiline (bedaquiline fumarate)	tablets	100mg; (188) in plastic container	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	PoM	18267/1 30.11.2022
2	Amlo-Denk 5	amlodipine (amlodipine mesilate monohydrate)	tablets	5mg; (50/5x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, packager, batch releaser, GBA Pharma GmbH, Ernst-Abbe-Str. 40, Ulm, Baden-Wuerttemberg, 89079, Germany- quality control	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20535/1 30.11.2022

3	Fluditec	carbocisteine	syrup	20mg/ml; 125ml glass bottle and 20ml measuring cup	Innothera Chouzy, Rue Rene Chantereau, Chouzy-sur-Cisse, Valloire-sur-Cisse, 41150-batch releaser, Unither Liquid Manufacturing, 1-3 Allee de la Neste, Z.I. d` En Sigal, 31770, Colomiers, France-bulk manufacturer, packager, quality control	France	Laboratoire Innotech International, 22, Avenue Aristide Briand, 94110 Arcueil	France	OTC	18707/1 30.11.2022
4	Fluditec	carbocisteine	syrup	50mg/ml; 125ml glass bottle and 20ml measuring cup	Innothera Chouzy, Rue Rene Chantereau, Chouzy-sur-Cisse, Valloire-sur-Cisse, 41150-batch releaser, Unither Liquid Manufacturing, 1-3 Allee de la Neste, Z.I. d` En Sigal, 31770, Colomiers, France-bulk manufacturer, packager, quality control	France	Laboratoire Innotech International, 22, Avenue Aristide Briand, 94110 Arcueil	France	OTC	18708/1 30.11.2022
5	Bisoprolol	bisoprolol (bisoprolol fumarate)	tablets coated	5mg; (30/3x10/) 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	PoM	17480/1 30.11.2022
6	Rissar	risperidone	tablets film-coated	1mg; (20/2x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	17405/3/1 30.11.2022

7	Rissar	risperidone	tablets film-coated	2mg; (20/2x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	17406/3/1 30.11.2022
8	Rissar	risperidone	tablets film-coated	3mg; (20/2x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	17407/3/1 30.11.2022
9	Lopraxer	citalopram (citalopram hydrochloride)	drops oral (solution)	40mg/ml; 15ml glass bottle	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorphosis, Attica	Greece	PoM	17049/2 30.11.2022
10	Devit 50000	colecalfiferol	tablets film-coated	1,25mg (50 000IU); (15/1x15/) and (8/1x8/) in blister	Quest Vitamins Middle East Fze, Jebel- Ali Free Zone, P.O. Box 17836, Dubai	United Arab Emirates	Quest Vitamins Middle East Fze, Jebel- Ali Free Zone, P.O. Box 17836, Dubai	United Arab Emirates	PoM	16794/1 30.11.2022
11	Pollezin	levocetirizine (levocetirizine dihydrochloride)	drops oral	5mg/ml; glass vial 20ml	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	18276/2 30.11.2022

12	Magnefar B6	magnesium hydroaspartate(magnesium hydroasparaginate tetrahydrate), pyridoxine (pyridoxine hydrochloride)	tablets	500mg+5mg; (60/6x10/) in blister	Biofarm Sp. z o.o., 13, Walbrzyska Str., 60-198, Poznan- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Phytopharm Kleka S.A., Kleka 1, Nowe Miasto nad Wartq, 63-040, Poland- quality control (microbiological)	Poland	Biofarm Sp. z o.o., 13, Walbrzyska Str., 60-198, Poznan	Poland	OTC	19985/1 30.11.2022
13	Paracetamol Sopharma 120mg/5ml syrup	paracetamol	syrup	120mg/5ml; 125ml glass or plastic bottle and measuring cup	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia-batch releaser, Sopharma JSC, Vrabevo vlg. 5660, district of Lovetch, Bulgaria-bulk manufacturer, packager	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	18237/2 30.11.2022
14	Exoderil	naftifine hydrochloride	cream for external use	10mg/g; aluminium tube 15g	Salutas Pharma GmbH, Betriebsstaette Osterweddingen, Lange Goehren 3,Suelzetal, OT Osterweddingen,Sachsen-Anhalt, 39171- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Salutas Pharma GmbH, Otto-von-Guericke- Alle-1, 39179 Barleben, Sachsen-Anhalt, Germany- quality control (microbiological)	Germany	Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl	Austria	OTC	20970/1 30.11.2022

15	Grippostad C	paracetamol, ascorbic acid, caffeine, chlorphenamine (chlorphenamine maleate)	capsules	200mg+150mg+25mg +2,5mg; (10/1x10/) in blister	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel	Germany	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel	Germany	OTC	16972/2 30.11.2022
16	Acetylsalicylic acid	acetylsalicylic acid	tablets	500mg; (10) in blister	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	OTC	17342/2 30.11.2022
17	Doxycycline	doxycycline (doxycycline hyclate)	capsules	100mg; (10/1x10/) in blister, (20/2x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, No3/3, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	PoM	19032/1 30.11.2022
18	Ascorutin	rutoside, ascorbic acid	tablets	50mg+50mg; (50) in plastic container	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	PoM	18993/1 30.11.2022

19	Driptane	oxybutynin (oxybutynin hydrochloride)	tablets	5mg; (30/1x30/) in blister	Recipharm Fontaine, Rue des Pres Potets, 21121 Fontaine les Dijon	France	Abbot Laboratories GmbH, Germany Freundallee 9A, 30173 Hannover	Germany	PoM	17385/4/1 30.11.2022
20	Kagocel	kagocel	tablets	12mg; (10/1x10/) in blister, (20/2x10/) in blister, (30/3x10/) in blister	NEARMEDIC PHARMA LLC, 120 Kiev highway, bldg. 3, 4, 5, Obninsk, Obninsk City District, Kaluga Region, 249030	Russia	NEARMEDIC PLUS LLC, Aviakonstruktora Mikoyana St., 12, room 26, premises NII, floor 2, 125252, Moscow	Russia	OTC	17166/3/2 30.11.2022
21	Fluconazole	fluconazole	capsules	50mg; (7) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64a, No4, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	PoM	17414/2 30.11.2022

22	Fluconazole	fluconazole	capsules	150mg; (1) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64a, No4, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	PoM	17413/2 30.11.2022
23	BoriVit	thiamine (thiamine hydrochloride), pyridoxine (pyridoxine hydrochloride), cyanocobalamin, lidocaine (lidocaine hydrochloride)	solution for i/m injection	100mg/2ml+100mg/2ml+1mg/2ml+20mg/2ml; (10) ampoules 2ml	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	PoM	16978/3/1 30.11.2022
24	NovoMix 30 Penfill	insulin aspart (recombinant)	suspension for injection	100U/ml; (5) cartridges 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	17661/1 30.11.2022
25	NovoMix 30 FlexPen	insulin aspart (recombinant)	suspension for injection	100U/ml; (5) pre-filled pen 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	17660/2 30.11.2022

26	Omniscan	gadodiamide	solution for i/v injection	287mg/ml (0,5mmol/ml); (10) glass vials 20ml	GE Healthcare Ireland Limited, IDA Business Park, Carrigtwohill, Cork, T45 AV60	Ireland	GE Healthcare AS, P.O. Box 4220, Nydalen, 0401 Oslo	Norway	PoM	19140/2/1 30.11.2022
27	CITOLEPT	citicoline (citicoline sodium)	solution for i/v and i/m injection	125mg/ml; (5/1x5/) ampoules 4ml in blister	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region- quality control, batch releaser, "Sotex"PharmFirm" CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, Russia- bulk manufacturer, packager	Russia	"Sotex"PharmFirm " CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	PoM	20255/1 30.11.2022
28	CITOLEPT	citicoline (citicoline sodium)	solution for i/v and i/m injection	250mg/ml; (5/1x5/) ampoules 4ml in blister	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region- quality control, batch releaser, "Sotex"PharmFirm" CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, Russia- bulk manufacturer, packager	Russia	"Sotex"PharmFirm " CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	PoM	20256/1 30.11.2022

29	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	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	16963/5/1 30.11.2022
30	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	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	16962/5/1 30.11.2022
31	Furamag	furazidin (furazidin potassium)	capsules	25mg; (30/3x10/) in blister	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	PoM	20510/1 30.11.2022
32	Paracetamol	paracetamol	tablets	500mg; (10/1x10/) in blister, (20/2x10/) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	18975/2/1 30.11.2022

33	Nolicin	norfloxacin	tablets film-coated	400mg; (20/2x10/) 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	PoM	17063/3 30.11.2022
34	Arifam 1.5mg/5mg	indapamide, amlodipine (amlodipine besilate)	tablets modified-release	1,5mg+5mg; (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	PoM	18548/3 30.11.2022
35	Arifam 1.5mg/10mg	indapamide, amlodipine (amlodipine besilate)	tablets modified-release	1,5mg+10mg; (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	PoM	18549/3 30.11.2022
36	Levoyaps	levofloxacin (levofloxacin hemihydrate)	drops eye	5 mg/ml; plastic vial-dropper 5ml	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd., Razgrad 7200	Bulgaria	Belinda Laboratories LLP, Unit 18, 53 Norman road, London	United Kingdom	PoM	20525/1 30.11.2022
37	Nifedipin	nifedipine	tablets coated	10mg; (50/5x10/) in blister	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PoM	17228/3 30.11.2022

38	Convulex	valproic acid	tablets prolonged-release film-coated	300mg; (50) glass container, (50) plastic container	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach- batch releaser, G.L. Pharma GmbH, Industriestrasse 1, 8502 Lannach, Austria- bulk manufacturer, packager, quality control (physicochemical), G.L. Pharma GmbH, Arnethgasse 3, 1160 Vienna, Austria- quality control (microbiological)	Austria	Bausch Health LLC., Shabolovka st. 31, building 5, 115162, Moscow	Russia	PoM	19710/1 30.11.2022
39	Convulex	valproic acid	tablets prolonged-release film-coated	500mg; (50) glass container, (50) plastic container	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach- batch releaser, G.L. Pharma GmbH, Industriestrasse 1, 8502 Lannach, Austria- bulk manufacturer, packager, quality control (physicochemical), G.L. Pharma GmbH, Arnethgasse 3, 1160 Vienna, Austria- quality control (microbiological)	Austria	Bausch Health LLC., Shabolovka st. 31, building 5, 115162, Moscow	Russia	PoM	19711/1 30.11.2022
40	Humalog	insulin lispro	solution for injection	100IU/ml (3,5mg/ml); (5) cartridges 3ml	Lilly France S.A.S., Zone Industrielle, 2 rue du Colonel Lilly, 67640 Fegersheim	France	Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht	the Netherlands	PoM	20018/2 30.11.2022

41	Humalog	insulin lispro	solution for injection	100IU/ml (3,5mg/ml); (5) cartridges 3ml	Lilly France S.A.S., Zone Industrielle, 2 rue du Colonel Lilly, 67640 Fegersheim	France	Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht	the Netherlands	PoM	20819/1 30.11.2022
42	Humalog Mix 25	insulin lispro solution and insulin lispro protamine suspension	suspension for injection	100IU/ml (3,5mg/ml); (5) cartridges 3ml	Lilly France S.A.S., Zone Industrielle, 2 rue du Colonel Lilly, 67640 Fegersheim	France	Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht	the Netherlands	PoM	20820/1 30.11.2022
43	Humalog Mix 50	insulin lispro solution and insulin lispro protamine suspension	suspension for injection	100U/ml (3,5mg/ml); (5) cartridges 3ml	Lilly France S.A.S., Zone Industrielle, 2 rue du Colonel Lilly, 67640 Fegersheim	France	Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht	the Netherlands	PoM	20821/1 30.11.2022

44	Rowatinex	a-pinene, b-pinene, camphene, borneol, anethol, fenchone, cineole	capsules gastro-resistant, soft	24,8mg+6,2mg+15mg+10mg+4mg+4mg+3mg (100/10x10/) in blister	Rowa Pharmaceuticals Ltd., Newtown, Bantry, Cork- quality control (physicochemical), batch releaser, SwissCaps Romania SRL, No. 20 Carol I Street, Comuna Cornu, Jud. Prahova 107180, Romania- bulk manufacturer, Sharp Clinical Services (UK) Limited, Unit 28, Heads of the Valley Industrial Estate, Rhymney, Tredegar, NP22 5RL, UK- primary packager, Norfachema UAB, Vytauto g. 6, LT-55175 Jonava, Lithuania- secondary packager, Eurofins Biopharma Product Testing Ireland Limited, Clogherane, Dungarvan, Co. Waterford, Ireland- quality control (microbiological)	Ireland	Rowa Pharmaceuticals Ltd., Newtown, Bantry, Cork	Ireland	PoM	19479/2 30.11.2022
45	Hexaxim	diphtheria toxoid, tetanus toxoid, pertussis toxoid/filamentous haemagglutinin, poliovirus types 1/2/3, hepatitis B surface antigen, haemophilus influenzae type b polysaccharide, haemophilus influenzae type b polysaccharide conjugated to tetanus protein	suspension for injection	20IU/0,5ml+40IU/0,5ml+25/25mcg/0,5ml+40/8/32 DU/0,5ml+10mcg/0,5ml+12mcg/0,5ml+22-36mcg/0,5ml; (10) glass vials 0,5ml	Sanofi Pasteur, Parc Industriel d`Incarville, 27100 Val de Reuil	France	Sanofi Pasteur, 14 Espace Henry Vallee, 69007 Lyon	France	PoM	20298/4 30.11.2022

46	Hexaxim	diphtheria toxoid, tetanus toxoid, pertussis toxoid/filamentous haemagglutinin, poliovirus types 1/2/3, hepatitis B surface antigen, haemophilus influenzae type b polysaccharide, haemophilus influenzae type b polysaccharide conjugated to tetanus protein	suspension for injection	20IU/0,5ml+40IU/0,5ml+25/25mcg/0,5ml+40/8/32 DU/0,5ml+10mcg/0,5ml+12mcg/0,5ml+22-36mcg/0,5ml; pre-filled syringe 0,5ml and (2) needles	Sanofi Pasteur, Parc Industriel d` Incarville, 27100 Val de Reuil	France	Sanofi Pasteur, 14 Espace Henry Vallee, 69007 Lyon	France	PoM	20299/4 30.11.2022
47	Spazmaton	metamizole (metamizole sodium), pitofenone (pitofenone hydrochloride), fenpiverinium bromide	solution for i/m injection	2500mg/5ml+10mg/5ml+0,1mg/5ml; (10) ampoules 5ml label banderol, (10) ampoules 5ml dividella, (10) ampoules 5ml CAMA	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	PoM	20221/1 30.11.2022
48	Duspatalin	mebeverine (mebeverine hydrochloride)	capsules hard prolonged-release	200mg (30/2x15/) in blister	Mylan Laboratories SAS, Route de Belleville, Lieudit Maillard, 01400 Chatillon sur Chalaronne	France	Abbott Healthcare Products B.V., C.J. van Houtenlaan 36, 1381 CP Weesp	the Netherlands	PoM	19581/1 30.11.2022
49	Voltaren	diclofenac (diclofenac sodium)	solution for injection	25mg/ml; (5) ampoules 3ml	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18640/8 30.11.2022

50	Voltaren Retard	diclofenac (diclofenac sodium)	tablets prolonged-release	75mg; (20/2x10/) in blister	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20294/1 30.11.2022
51	Glimepiride Denk 2	glimepiride	tablets	2mg; (30/3x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	PoM	17345/4 30.11.2022
52	Metformin Denk 850	metformin (metformin hydrochloride)	tablets film-coated	850mg; (30/2x15/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany - quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20333/1 30.11.2022

53	Deslora-Denk 5mg	desloratadine	tablets film-coated	5mg; (10/1x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, packager, quality control (physico-chemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany-quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	19269/1 30.11.2022
54	Elocom	mometasone (mometasone furoate)	lotion	1mg/g; 30ml plastic vial-dropper	Delpharm Montreal Inc., 3535 Route Trans Canada Highway, Pointe-Claire, QC H9R 1B4	Canada	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	17857/5/1 30.11.2022
55	Elocom	mometasone (mometasone furoate)	ointment	1mg/g; aluminum tube 15g	Schering-Plough Labo N.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	18795/4/1 30.11.2022
56	Termicon	terbinafine (terbinafine hydrochloride)	cream for external use	10mg/g; 10g and 15g aluminium tube	Pharmaceutical Firm "LEKKO" CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement	Russia	OTCPharm PJSC, 123317, Moscow, Testovskaya str., 10	Russia	OTC	17329/2/1 30.11.2022

57	Myfortic	mycophenolic acid (mycophenolate sodium)	tablets gastro- resistant	180mg; (120/12x10/ in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr, Germany-bulk manufacturer, quality control (physicochemical), Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland- quality control (microbiological)	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	19445/5 30.11.2022
58	Myfortic	mycophenolic acid (mycophenolate sodium)	tablets gastro- resistant	180mg; (120/12x10/ in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	18043/6 30.11.2022

59	Rowachol	a-pinene, b-pinene, menthol, menthone, borneol, camphene, cineole	capsules gastro-resistant, soft	13,6mg+3,4mg+32mg+6mg+5mg+5mg+2mg (100/10x10/) in blister	Rowa Pharmaceuticals Ltd., Newtown, Bantry, Cork- quality control (physicochemical), batch releaser, SwissCaps Romania SRL, No. 20 Carol I Street, Comuna Cornu, Jud. Prahova 107180, Romania- bulk manufacturer, Sharp Clinical Services (UK) Limited, Unit 28, Heads of the Valley Industrial Estate, Rhymney, Tredegar, NP22 5RL, UK- primary packager, Norfachema UAB, Vytauto g. 6, LT-55175 Jonava, Lithuania- secondary packager, Eurofins Biopharma Product Testing Ireland Limited, Clogherane, Dungarvan, Co. Waterford, Ireland- quality control (microbiological)	Ireland	Rowa Pharmaceuticals Ltd., Newtown, Bantry, Cork	Ireland	PoM	19478/2 30.11.2022
60	Phezam	piracetam, cinnarizine	capsules hard	400mg+25mg; (60/6x10/) in blister	Balkanpharma-Dupnitsa AD, str."Samokovsko Shosse" N3, Dupnitsa 2600	Bulgaria	Balkanpharma-Dupnitsa AD, (ACTAVIS GROUP), str."Samokovsko Shosse" N3, Dupnitsa 2600	Bulgaria	PoM	17106/1 30.11.2022
61	Calcium D3 Nycomed	calcium (calcium carbonate), colecalciferol	tablets chewable with orange flavour	500mg+5mcg(200IU); (20) in plastic container, (50) in plastic container, (100) in plastic container	Takeda AS, Drammensveien 852 No-1383 Asker	Norway	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	20034/2/1 30.11.2022

62	Calcium D3 Nycomed Forte	calcium (calcium carbonate), colecalfiferol	tablets chewable with lemon flavour	500mg+10mcg(400IU) ; (30) in plastic container, (60) in plastic container, (120) in plastic container	Takeda AS, Drammensveien 852 No- 1383 Asker	Norway	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	20035/2/1 30.11.2022
63	Voltaren Emulgel	diclofenac (diclofenac diethylamine)	gel for external use	10mg/g; 20g, 50g and 100g laminated tube	GlaxoSmithKline Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon	Switzerland	GlaxoSmithKline Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon	Switzerland	OTC	17180/3/1 30.11.2022

LIST

of the variations not requiring reformulation of certificate for the mutual recognition of the EAEU registration approved by the Center according to the meeting decision N 11-2/22 on November 30, 2022

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Metadon Alkaloid	methadone (methadone hydrochloride)	solution oral	10mg/ml; 100ml glass bottle and graduated pipette, 1000ml glass bottle	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	000653 30.11.2022