

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 01-1/24 on January 16, 2024

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	Vit-B-Denk	thiamine (thiamine hydrochloride)(vitaminB1), pyridoxine (pyridoxine hydrochloride) (vitaminB6)	tablets film-coated	100mg+200mg; (20/2x10) in blister, (100/10x10) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, quality control (physicochemical), batch releaser, Swiss Caps GmbH, Grassingerstrasse 9, 83043 Bad Aibling, Germany- packager, GBA Pharma GmbH, Ernst-Abbe-Str. 40, Ulm, Baden-Wuerttemberg, 89079, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	21867 16.01.2024
2	Paracetamol	paracetamol	tablets	500mg; (20/2x10) in blister	Open joint stock company «Borisovskiy zavod medicinskih preparatov» 64A, Chapaeva str., Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinskih preparatov» 64, Chapaeva str., Borisov 222518, Minsk region	Republic of Belarus	OTC	21868 16.01.2024

LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 01-1/24 on January 16,

2024

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	Cavinton	vinpocetine	tablets	5mg; (50/2x25) in blister	Gedeon Richter-RUS JSC, Lesnaya st. 40, Shuvoe, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, quality control, batch releaser, Gedeon Richter-RUS JSC, Lesnaya st. 43/5, Shuvoe, Moscow region, Yegoriyevsky district, 140342, Russia Gedeon Richter-RUS JSC, Lesnaya st. 43/5, Shuvoe, Moscow region, Yegoriyevsky district, 140342, Russia- packager	Hungary	Gedeon Richter Plc., Gyomroi ut 19-21, Budapest, 1103	Hungary	PoM	21872 (004633) 16.01.2024
2	Cavinton	vinpocetine	tablets	5mg; (50/2x25) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	21873 (004633) 16.01.2024
3	Cavinton Forte	vinpocetine	tablets	10mg; (30/2x15) in blister, (90/6x15) in blister	Gedeon Richter-RUS JSC, Lesnaya st. 40, Shuvoe, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, quality control, batch releaser, Gedeon Richter-RUS JSC, Lesnaya st. 43/5, Shuvoe, Moscow region, Yegoriyevsky district, 140342, Russia- packager	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	21874 (004636) 16.01.2024
4	Cavinton Forte	vinpocetine	tablets	10mg; (30/2x15) in blister, (90/6x15) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	21875 (004636) 16.01.2024

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 01-1/24 on January 16, 2024

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	Sutent	sunitinib (sunitinib malate)	capsules hard	12,5mg; (30) plastic container	Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno	Italy	Pfizer Inc., 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	21876 16.01.2024
2	Sutent	sunitinib (sunitinib malate)	capsules hard	25mg; (30) plastic container	Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno	Italy	Pfizer Inc., 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	21877 16.01.2024
3	Sutent	sunitinib (sunitinib malate)	capsules hard	50mg; (30) plastic container	Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno	Italy	Pfizer Inc., 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	21878 16.01.2024
4	Levetiracetam Canon	levetiracetam	tablets film-coated	500mg; (30/3x10) in blister, (60/6x10) in blister	CJSC Canonpharma production, 105B bldg., 11, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, 141100- quality control, batch releaser, CJSC Canonpharma production, 105, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, 141100, Russia- bulk manufacturer, packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	PoM	21879 16.01.2024
5	Furaginum Adamed	furazidin	tablets	50mg; (30/1x30) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pi-enkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	PoM	21880 16.01.2024
6	Dynapar AQ	diclofenac (diclofenac sodium)	solution for injection	75mg/ml; (5) ampoules 1ml	Troikaa Pharmaceuticals Ltd., C-1, Sara Industrial Estate, Selaqui, Dehradun-248197, Uttarakhand	India	Troikaa Pharmaceuticals Ltd., Commerce House-1, Satya Marg, Bodakdev, Ahmedabad-380054	India	PoM	21881 16.01.2024

7	Methyluracil	methyluracil	ointment for external use	100mg/g; aluminum tube 15g	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, No2, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinskih preparatov» 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	OTC	21882 16.01.2024
8	Rivanol	ethacridine lactate	powder for solution for external use	100mg; glass bottle 0,1g	Esco-Pharm LLC, Nor-Norq, Mikoyan 13, Yerevan	Republic of Armenia	Esco-Pharm LLC, Nor-Norq, Mikoyan 13, Yerevan	Republic of Armenia	OTC	21883 16.01.2024
9	Prednisolone	prednisolone	ointment for external use	5mg/g; aluminium tube 10g	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, No2, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinskih preparatov» 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	PoM	21884 16.01.2024
10	Stomatidin	hexetidine	solution for topical use	1mg/ml; 200ml glass vial	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	21885 16.01.2024
11	Acupan	nefopam (nefopam hydrochloride)	solution for injection	10mg/ml; (5) ampoules 2ml	Biocodex, 1 avenue Blaise Pascal, 60000 Beauvais	France	Biocodex, 7 avenue Gallieni 94250 Gentilly	France	PoM	21886 16.01.2024
12	Triderm	betamethasone (betamethasone dipropionate), clotrimazole, gentamicin (gentamicin sulfate)	cream	0,5mg/g+10mg/g+1mg/g; aluminium tube 15g	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	21887 16.01.2024
13	Depantol	dexpanthenol, chlorhexidine (chlorhexidine bigluconate)	suppositories vaginal	100mg+16mg; (10/2x5/), (20/4x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	21888 16.01.2024
14	Formidron	formaldehyde	solution for external use	37mg/ml; glass bottle 30ml	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	OTC	21889 16.01.2024
15	Betasalic	betamethasone (betamethasone dipropionate), salicylic acid	ointment	0,64mg/g+30mg/g; aluminium tube 15g	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	PoM	21890 16.01.2024
16	Lidocaine-Liqvo with epinephrine	lidocaine (lidocaine hydrochloride), epinephrine	solution for injection	20mg/ml+0,01mg/ml; (1) glass vial 20ml, (10) glass vials 20ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	21891 16.01.2024

17	Sea Buckthorn Oil	hippopheae oil	suppositories rectal	500mg; (10/2x5)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	21892 16.01.2024
18	Trozamil	azithromycin (azithromycin dihydrate)	tablets film-coat- ed	500mg; (3/1x3) in blister	Special Products Line S.p.A., Via Fratta Rotonda Vado Largo,1-03012 Anagni (FR)	Italy	So.Se.Pharm. S.r.l., Via dei Cas- telli Romani 22, 00071 Pomezia (Rome)	Italy	PoM	21893 16.01.2024

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of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 01-1/24 on January 16,
2024

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	Panthomekol Plus	dexpantenol, chlorhexidine (chlorhexidine digluconate)	cream for external use	52,5mg/g+8,02mg/g; aluminium tube 30g	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	18493/3/1 16.01.2024
2	Enalapril	enalapril (enalapril maleate)	tablets	5mg; (20/2x10) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway-bulk manufacturer, packager, quality control (physicochemical), batch releaser, Farmoborona Test Center, Ltd., 141074, Korolyov, Moscow Region, Gagarin St., 46A, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	PoM	20842/2/1 16.01.2024

3	Enalapril	enalapril (enalapril maleate)	tablets	10mg; (20/2x10) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Farmoborona Test Center, Ltd., 141074, Korolyov, Moscow Region, Gagarin St., 46A, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	PoM	20843/2/1 16.01.2024
4	Enalapril	enalapril (enalapril maleate)	tablets	20mg; (20/2x10) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Farmoborona Test Center, Ltd., 141074, Korolyov, Moscow Region, Gagarin St., 46A, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	PoM	20844/2/1 16.01.2024
5	Sodium chloride	sodium chloride	solution for injection	9mg/ml; (10/1x10) ampoules 5ml label banderol, (10/1x10) ampoules 5ml dividella, (10/1x10) ampoules 5ml CAMA	Open joint stock company «Borisovskiy zavod medicinskikh preparatov» 64, N1 ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinskikh preparatov» 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	PoM	20465/1/1 16.01.2024
6	Mexidol	ethylmethylhydroxypyridine succinate	solution for i/v and i/m injection	50mg/ml; (10/2x5) ampoules 2ml in blister	ООО «Ellara», 601122, Vladimir reg., Petushinsky district, Pokrov, str. Franza Shtolverka, b. 20/2	Russia	LLC «RPC «PHARMASOFT», 115407, Moscow, Sudostroitel'naya str., bld. 41, floor 1, premises 12	Russia	PoM	21141/1/1 16.01.2024

7	Mexidol	ethylmethylhydroxypyridine succinate	solution for i/v and i/m injection	50mg/ml; (5/1x5) ampoules 5ml, in blister	ООО «Ellara», 601122, Vladimir reg., Petushinsky district, Pokrov, str. Franza Shtolverka, b. 20/2	Russia	LLC «RPC «PHARMASOFT», 115407, Moscow, Sudostroitel'naya str., bld. 41, floor 1, premises 12	Russia	PoM	21142/1/1 16.01.2024
8	GastroGuard	calcium carbonate, magnesium carbonate	tablets chewable	680mg+80mg; (24/3x8) 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	OTC	21416/1/1 16.01.2024
9	Nasonex	mometasone (mometasone furoate)	spray nasal (suspension)	50mcg/dose; 18g (140 dose) plastic bottle with spray pump 18g (140 dose)	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	19067/5/2 16.01.2024
10	Glucovance	glibenclamide, metformin (metformin hydrochloride)	tablets film-coated	2,5mg+500mg; (30/2x15) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400 Semoy	France	Merck Sante s.a.s., 37 rue Saint Romain- 69008 Lyon	France	PoM	19379/3/1 16.01.2024
11	Glucovance	glibenclamide, metformin (metformin hydrochloride)	tablets film-coated	5mg+500mg; (30/2x15) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400 Semoy	France	Merck Sante s.a.s., 37 rue Saint Romain- 69008 Lyon	France	PoM	19380/3/1 16.01.2024

12	Omeprazole	omeprazole	capsules	20mg; (30/3x10) in blister	Open joint stock company «Borisovskiy zavod medicinskih preparatov» 64A, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinskih preparatov» 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	PoM	20015/1/1 16.01.2024
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LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 01-1/24 on January 16,

2024

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	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, P.O. Box 4220, Nydalen, 0401 Oslo	Norway	PoM	19107/4/1 16.01.2024
2	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, P.O. Box 4220, Nydalen, 0401 Oslo	Norway	PoM	19108/4/1 16.01.2024
3	Theraflex Chondrocream Forte	chondroitin sulfate, meloxicam	cream for external use	50mg/g+10mg/g; 30g aluminium tube, 100g aluminium tube	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	JSC BAYER, 3rd Rybinskaya st., 18, build. 2, 107113 Moscow	Russia	OTC	17771/3/2 16.01.2024
4	Parlazin	cetirizine (cetirizine dihydrochloride)	tablets film-coated	10mg (10/1x10) in blister, (30/3x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	OTC	19516/4 16.01.2024
5	Isoflurane	isoflurane	liquid for inhalation	100%; 250ml glass bottle	Piramal Pharma Limited, Sy. No.7-70, 70/1 & 70/2, Digwal Village, Kohir Mandal, Sangareddy District- 502 321, Telangana	India	Piramal Pharma Limited, Piramal Ananta, Agastya Corporate Park, Opposite Fire Brigade, Kamani Junction, LBS Marg, Kurla (West), Mumbai- 400070, Maharashtra	India	PoM	21544/1 16.01.2024

6	Sevoflurane	sevoflurane	liquid for inhalation	100%; 250ml glass bottle	Piramal Pharma Limited, Sy.Nos.7-70, 70/1 & 70/2, Digwal Village, Kohir Mandal, Sangareddy District- 502 321, Telangana	India	Piramal Pharma Limited, Piramal Ananta, Agastya Corporate Park, Opposite Fire Brigade, Kamani Junction, LBS Marg, Kurla (West), Mumbai- 400070, Maharashtra	India	PoM	21366/1 16.01.2024
7	Laevomycetin	chloramphenicol	powder for solution for injection	500mg; (40) glass vials	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	20265/2 16.01.2024
8	Laevomycetin	chloramphenicol	powder for solution for injection	1000mg; (40) glass vials	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	20266/2 16.01.2024
9	Controloc	pantoprazole (pantoprazole sodium sesquihydrate)	powder for solution for injection	40mg; glass vial	Takeda GmbH, Robert-Bosch-Str. 8, 78224 Singen	Germany	Takeda GmbH, Byk-Gulden str. 2, D-78467, Konstanz	Germany	PoM	18714/4 16.01.2024
10	Seretide Accuhaler /Diskus	salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)	powder for inhalation	50mcg+100mcg; (1) plastic inhaler disk (60 doses)	Glaxo Wellcome Production, Zone Industrielle N 2, 23 Rue Lavoisier, 27000 Evreux	France	Laboratoire GlaxoSmith-Kline, 23 rue Francois Jacob, 92500 Rueil-Malmaison	France	PoM	19371/5 16.01.2024
11	Seretide Accuhaler /Diskus	salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)	powder for inhalation	50mcg+250mcg; (1) plastic inhaler disk (60 doses)	Glaxo Wellcome Production, Zone Industrielle N 2, 23 Rue Lavoisier, 27000 Evreux	France	Laboratoire GlaxoSmith-Kline, 23 rue Francois Jacob, 92500 Rueil-Malmaison	France	PoM	19372/5 16.01.2024
12	Seretide Accuhaler /Diskus	salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)	powder for inhalation	50mcg+500mcg; (1) plastic inhaler disk (60 doses)	Glaxo Wellcome Production, Zone Industrielle N 2, 23 Rue Lavoisier, 27000 Evreux	France	Laboratoire GlaxoSmith-Kline, 23 rue Francois Jacob, 92500 Rueil-Malmaison	France	PoM	19373/5 16.01.2024
13	Taflotan PF	tafluprost	drops eye	15mcg/ml; pastic bottle 3ml	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, Tubilux Pharma S.p.A., Via Costarica, 20/22, 00071 Pomezia/Rome, Italy- bulk manufacturer, packager, quality control	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	PoM	19799/2 16.01.2024

14	Levetiracetam Canon	levetiracetam	tablets film-coated	500mg; (30/3x10) in blister, (60/6x10) in blister	CJSC Canonpharma production, 105B bldg, 11, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, 141100- quality control, batch releaser, CJSC Canonpharma production, 105, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow re- gion, 141100, Russia- bulk manufacturer, primary and secondary packager	Russia	CJSC Canonpharma produc- tion, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	PoM	18288/4/1 16.01.2024
15	Lorista	losartan (losartan potassium)	tablets film-coated	25mg; (28/2x14) in blister, (28/4x7) 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	18819/1 16.01.2024
16	Lorista	losartan (losartan potassium)	tablets film-coated	50mg; (28/2x14/ blisters, (28/4x7/ blisters	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	18820/1 16.01.2024
17	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	PoM	21138/1 16.01.2024
18	Betasalic	betamethasone (beta- methasone dipropionate), salicylic acid	ointment	0,64mg/g+30mg/g; 15g aluminium tube	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	18101/2 16.01.2024
19	Rivanol	ethacridine lactate	powder for solu- tion for external use	100mg; glass bottle 0,1g	Esco-Pharm LLC, Nor-Norq, Mikoyan 13, Yerevan	Republic of Armenia	Esco-Pharm LLC, Nor-Norq, Mikoyan 13, Yerevan	Republic of Armenia	OTC	18808/1 16.01.2024
20	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	21021/1 16.01.2024
21	Dibazol-Darnitsa	bendazol (bendazol hydrochloride)	solution for injection	10mg/ml; (10/2x5/ ampoules 1ml in blister	PrJSC «Pharmaceutical firm «Darnitsa», 02093, Kyiv, Boryspilska Str.,13	Ukraine	PrJSC «Pharmaceutical firm «Darnitsa», 02093, Kyiv, Boryspilska Str.,13	Ukraine	PoM	20929/1 16.01.2024
22	Neiromidin	ipidacrine (ipidacrine hydrochloride)	solution for i/m and s/c injection	15mg/ml; (10) ampoules 1ml	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114- quality control, batch releaser, Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia, Bulgaria- bulk manufacturer, packager	Latvia	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	PoM	20020/1 16.01.2024

23	Dynapar AQ	diclofenac (diclofenac sodium)	solution for injection	75mg/ml; (5) ampoules 1ml	Troikaa Pharmaceuticals Ltd., C-1, Sara Industrial Estate, Selaqui, Dehradun-248197, Uttarakhand	India	Troikaa Pharmaceuticals Ltd., Commerce House-1, Satya Marg, Bodakdev, Ahmedabad-380054	India	PoM	17451/2 16.01.2024
24	Furaginum Adamed	furazidin	tablets	50mg; (30/1x30) in blister	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	PoM	17277/2/1 16.01.2024
25	Formidron	formaldehyde	solution for external use	37mg/ml; glass bottle 30ml	Esco-Pharm LLC, Nor-Norq, Mikoyan 13, Yerevan	Republic of Armenia	Esco-Pharm LLC, Nor-Norq, Mikoyan 13, Yerevan	Republic of Armenia	OTC	18825/1 16.01.2024
26	Clivas	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (30/3x10) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	21721/1 16.01.2024
27	Clivas	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (30/3x10) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	21722/2 16.01.2024
28	Trozamil	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3) in blister	Special Products Line S.p.A., Via Fratta Rotonda Vado Largo, 1-03012 Anagni (FR)	Italy	So.Se.Pharm. S.r.l., Via dei Castelli Romani 22, 00071 Pomezia (Rome)	Italy	PoM	17991/3 16.01.2024
29	Enalapril	enalapril (enalapril maleate)	tablets	5mg; (20/2x10) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway-bulk manufacturer, packager, quality control (physicochemical), batch releaser, Farmoborona Test Center, Ltd., 141074, Korolyov, Moscow Region, Gagarin St., 46A, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	PoM	20842/1 16.01.2024
30	Enalapril	enalapril (enalapril maleate)	tablets	10mg; (20/2x10) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway-bulk manufacturer, packager, quality control (physicochemical), batch releaser, Farmoborona Test Center, Ltd., 141074, Korolyov, Moscow Region, Gagarin St., 46A, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	PoM	20843/1 16.01.2024

31	Enalapril	enalapril (enalapril maleate)	tablets	20mg; (20/2x10) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway-bulk manufacturer, packager, quality control (physicochemical), batch releaser, Farmoborona Test Center, Ltd., 141074, Korolyov, Moscow Region, Gagarin St., 46A, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	PoM	20844/1 16.01.2024
32	Magnesium sulfate	magnesium sulfate	solution for i/v and i/m injection	250mg/ml; (10) ampoules 5ml	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, No10/1, No11/1 ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	18987/2/1 16.01.2024
33	L-Thyroxin 25 Berlin-Chemie	levothyroxine sodium	tablets	25mcg; (100/4x25) in blister	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1. Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany, 2. Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin, Germany- quality control (physicochemical)	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	PoM	21167/1 16.01.2024
34	Diclofenac	diclofenac (diclofenac sodium)	tablets film-coated prolonged-release	100mg; (20/2x10) in blister	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	PoM	18311/2 16.01.2024

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 01-1/24 on January 16, 2024

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	Cevikap	ascorbic acid	drops oral	100mg/ml; glass bottle-dropper 10ml, glass bottle-dropper 30ml	Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 10 Władysława Lokietka St. 98-200 Sieradz- batch releaser, Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 57 Polskiej Organizacji Wojskowej st. 98-200 Sieradz, Poland- bulk manufacturer, packager, quality control	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplińska Str., 83-200 Starogard Gdański	Poland	OTC	003564 16.01.2024
2	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	5mg+5mg; (29) in plastic container, (30) in plastic container, (90/3x30) 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	000575 16.01.2024
3	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	5mg+10mg; (29) in plastic container, (30) in plastic container, (90/3x30) 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	000575 16.01.2024
4	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	10mg+5mg; (29) in plastic container, (30) in plastic container, (90/3x30) 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	000575 16.01.2024
5	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	10mg+10mg; (29) in plastic container, (30) in plastic container, (90/3x30) 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	000575 16.01.2024