

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 06-1/24 on June 11, 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	Nanotropil novo	fonturacetam	tablets	100mg; (10/1x10) in blister, (30/3x10) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Centemo LTD, Moscow Region, Shchelkovo, Fabrichnaya St., 2, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	PoM	22106 11.06.2024
2	Senadexin	calcium sennosides A and B	tablets	70mg; (10) in blister	Lubnypharm JSC, 37500, Poltava region, Lubny, Barvinkova str. 16	Ukraine	Lubnypharm JSC, 37500, Poltava region, Lubny, Barvinkova str. 16	Ukraine	OTC	22107 11.06.2024
3	Medical Alcohol 96%	ethanol	concentrate for solution for external use	96%; plastic container 100ml, plastic container 250ml, plastic container 500ml, plastic container 1000ml	Natali Pharm LLC, Arshakunyac 127/12, Shengavit, Yerevan- bulk manufacturer, packager, batch releaser, Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9, Republic of Armenia- quality control	Republic of Armenia	Natali Pharm LLC, Abovyan St. 42, Apt. 2, Yerevan	Republic of Armenia	OTC	22108 11.06.2024
4	Rehydron	sodium chloride, potassium chloride, sodium citrate, glucose anhydrous	powder dose	3,5g+2,5g+2,9g+10g; (20) sachets 18,9g	Pharmakor Production LLC, Int. Ter. g. Knyazhevo Municipal District, Leninsky Prospekt, 140, lit. F, room 1H/2H/5H, Saint Peterburg- secondary packager, quality control (physicochemical), batch releaser, Recipharm Parets S.L.U, C/ Ramon and Cajal 2 , 08150 Parets del Valles (Barcelona), Spain- bulk manufacturer, primary packager, Expert Bio LLC, Institutsky Prospekt, 21, build. 2, Saint Petersburg, 194021, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	22109 11.06.2024

LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 06-1/24 on June 11,
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	Propafenon Alkaloid	propafenone (propafenone hydrochloride)	tablets film-coated	150mg; (40/4x10) in blister, (50/5x10) 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	22111 (001393) 11.06.2024
2	Anaferon	affinity purified antibodies to human interferon gamma	tablets to be sucked	10000IU; (20/1x20) 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	22112 (185223) 11.06.2024
3	Neyrotex	ethylmethylhydroxypyridine succinate	solution for i/m and i/v injection	50mg/ml; (10/2x5) ampoules 2ml in blister with film, (10/2x5) ampoules 2ml in blister without film, (50/10x5) ampoules 2ml in blister with film, (50/10x5) ampoules 2ml in blister without film	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 urban district, Moscow Region	Russia	PoM	22113 (000316) 11.06.2024
4	Neyrotex	ethylmethylhydroxypyridine succinate	solution for i/m and i/v injection	50mg/ml; (5/1x5) ampoules 5ml in blister with film, (5/1x5) ampoules 5ml in blister without film	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 urban district, Moscow Region	Russia	PoM	22114 (000316) 11.06.2024

5	Decaris	levamisole (levamisole hydrochloride)	tablets	50mg; (2/1x2) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Romania S.A., 99-105 Guza Voda str., Targu-Mures, Jud. Mures, 540306, Romania- bulk manufacturer, packager, quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22115 (005920) 11.06.2024
6	Decaris	levamisole (levamisole hydrochloride)	tablets	50mg; (2/1x2) in blister	Gedeon Richter Romania S.A., 99-105 Guza Voda str., Targu-Mures, Jud. Mures, 540306	Romania	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22116 (005920) 11.06.2024
7	Decaris	levamisole (levamisole hydrochloride)	tablets	150mg; (1/1x1) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Romania S.A., 99-105 Guza Voda str., Targu-Mures, Jud. Mures, 540306, Romania- bulk manufacturer, packager, quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22117 (005920) 11.06.2024
8	Decaris	levamisole (levamisole hydrochloride)	tablets	150mg; (1/1x1) in blister	Gedeon Richter Romania S.A., 99-105 Guza Voda str., Targu-Mures, Jud. Mures, 540306	Romania	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22118 (005920) 11.06.2024
9	Snup	xylometazoline (xylometazoline hydrochloride)	spray nasal	0,5mg/ml; plastic vial 15ml (150 dose)	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel- batch releaser, Ursapharm Arzneimittel GmbH, Industriestrasse 66129 Saarbrucken, Germany- bulk manufacturer, packager, quality control	Germany	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel	Germany	OTC	22119 (006014) 11.06.2024
10	Snup	xylometazoline (xylometazoline hydrochloride)	spray nasal	0,5mg/ml; plastic vial 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	22120 (006014) 11.06.2024
11	Snup	xylometazoline (xylometazoline hydrochloride)	spray nasal	0,5mg/ml; plastic vial 15ml (150 dose)	Hemomont d.o.o., 81000, Podgorica, Ilije Plamenca bb	Montenegro	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel	Germany	OTC	22121 (006014) 11.06.2024

12	Snup	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; plastic vial 15ml (150 dose)	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel- batch releaser, Ursapharm Arzneimittel GmbH, Industriestrasse 66129 Saarbrucken, Germany- bulk manufacturer, packager, quality control	Germany	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel	Germany	OTC	22122 (006014) 11.06.2024
13	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	22123 (006014) 11.06.2024
14	Snup	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; plastic bottle 15ml (150 dose) with metering pump	Hemomont d.o.o., 81000, Podgorica, Ilije Plamenca bb	Montenegro	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel	Germany	OTC	22124 (006014) 11.06.2024
15	Grandaxin	tofisopam	tablets	50mg; (20/2x10) in blister, (60/6x10) in blister, (90/9x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22125 (000172) 11.06.2024
16	Grandaxin	tofisopam	tablets	50mg; (20/2x10) in blister, (60/6x10) in blister, (90/9x10) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly u. 65- packager, batch releaser, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22126 (000172) 11.06.2024
17	Bromocriptin-Richter	bromocriptine (bromocriptine mesilate)	tablets	2,5mg; (30) glass bottle	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22127 (005103) 11.06.2024
18	Oxytocin-Richter	oxytocin	solution for i/m and i/v injection	5IU/ml; (5/1x5) ampoules 1ml in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22128 (005622) 11.06.2024

19	Ibuprofen Medana	ibuprofen	suspension oral with strawberry flavour	20mg/ml; 100ml plastic container and measuring syringe, 120ml plastic container and measuring syringe	Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 10 Wladyslawa 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 Pelp-linska Str., 83-200 Starogard Gdanski	Poland	OTC	22110 (005837) 11.06.2024
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LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 06-1/24 on June 11, 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	Klimadynon	extract of Cimicifuga rhizome with roots	tablets film-coated	2,8mg; (60/4x15) in blister	Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt- packager, batch releaser, Rottendorf Pharma GmbH, Ostenfelder Strasse 51-61, Ennigerloh, North Rhine, Westphalia, 59320, Germany- bulk manufacturer, 1. Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt, Germany, 2. Labor L+S AG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control	Germany	Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt	Germany	OTC	22129 11.06.2024
2	Amlodipine	amlodipine (amlodipine besilate)	tablets	5mg; (10/1x10) in blister, (30/3x10) in blister	Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo St., 1- quality control, batch releaser, Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st. 1/5, No6, Republic of Belarus- bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	22130 11.06.2024
3	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	22131 11.06.2024
4	Polyoxidonium	azoximer bromide	powder lyophilized for solution for injection and local use	6mg; (5) glass vials 3ml	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	PoM	22132 11.06.2024

5	Prednisolone	prednisolone	ointment for external use	5mg/g; 10g aluminium tube	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30- quality control, batch releaser, Belmedpreparaty RUE, 220007, Minsk, Fabritsius lane 3/11, Republic of Belarus- bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	22133 11.06.2024
6	Atorvastatin	atorvastatin (atorvastatin calcium trihydrate)	tablets film-coated	10mg; (10/1x10) in blister, (30/3x10) in blister	Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo St., 1- quality control, batch releaser, Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st. 1/5 No6, Republic of Belarus- bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	22134 11.06.2024
7	Atorvastatin	atorvastatin (atorvastatin calcium trihydrate)	tablets film-coated	20mg; (10/1x10) in blister, (30/3x10) in blister	Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo St., 1- quality control, batch releaser, Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st. 1/5 No6, Republic of Belarus- bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius st., 30	Republic of Belarus	PoM	22135 11.06.2024
8	Fluconazole	fluconazole	tablets	50mg; (12/1x12) in blister	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	22136 11.06.2024
9	Ketonal	ketoprofen	solution for injection	50mg/ml; (10) ampoules 2ml	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	22137 11.06.2024
10	Ketonal Extra Plus 50mg granules for oral solution	ketoprofen (ketoprofen lysine)	granules for oral solution	50mg; (12) bipartite sachets	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- batch releaser, Fine Foods & Pharmaceuticals N.T.M. S.p.A., Via Grignano, 43, 24041, Brembate (BG), Italy- bulk manufacturer, packager, quality control	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	22138 11.06.2024
11	Tinctura Crataegi	fructus crataegi	tincture	100mg/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	22139 11.06.2024

12	Decapeptyl	triptorelin (triptorelin acetate)	solution for injection	0,1mg/ml; (7) pre-filled syringes 1ml	Ferring GmbH, Wittland 11, 24109 Kiel- bulk manufacturer, primary packager, quality control, batch releaser, Ferring-Leciva, a.s.(areal spol. ECP, a.s.), Ke Skale 455, Vestec u Prahy, 25242, Czech Republic- secondary packager	Germany	Ferring GmbH, Wittland 11, 24109 Kiel	Germany	PoM	22140 11.06.2024
13	Co-Sentor	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	50mg+12,5mg; (30/3x10) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35,Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager, Gedeon Richter Polska Sp. z o.o. ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825, Poland- quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22141 11.06.2024
14	Co-Sentor	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+25mg; (30/3x10) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest - batch releaser, Gedeon Richter Poland Spz o.o., ul.Graniczna 35,Grodzisk Mazowiecki, 05-825, Poland - bulk manufacturer, packager	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22142 11.06.2024
15	Benzonal Tatpharm	benzobarbital	tablets	100mg; (50/5x10) in blister	Tatchempharmpreparaty JSC, 420091, Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091, Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	PoM	22143 11.06.2024
16	Diovan	valsartan	tablets film-coated	80mg; (14/1x14) in blister, (28/2x14) in blister	Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22144 11.06.2024
17	Diovan	valsartan	tablets film-coated	160mg; (14/1x14) in blister, (28/2x14) in blister	Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22145 11.06.2024
18	Clindabiox	clindamycin (clindamycin phosphate)	suppositories vaginal	100mg; (3/1x3)	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	PoM	22146 11.06.2024
19	Artrozan	meloxicam	solution for injection	6mg/ml; (3/1x3) ampoules 2,5ml in blister, (10/2x5) ampoules 2,5ml in blister	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	PoM	22147 11.06.2024

20	Celestoderm-V with Garamycin	betamethasone (betamethasone valerate), gentamicin (gentamicin sulfate)	ointment	1mg/g+1mg/g; aluminium tube 30g	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	22148 11.06.2024
21	Celestoderm-V cream with Garamycin	betamethasone (betamethasone 17-valerate), gentamicin (gentamicin sulfate)	cream	1mg/g+1mg/g; aluminium tube 30g	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	22149 11.06.2024
22	Piracetam	piracetam	capsules	400mg; (10) in blister, (60/6x10/) in blister	Open joint stock company «Borisovskiy zavod medicinskikh preparatov», 64A, No4, ul. Chapaveva, Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinskikh preparatov», 64, ul. Chapaveva, Borisov 222518, Minsk region	Republic of Belarus	PoM	22150 11.06.2024
23	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	PoM	22151 11.06.2024
24	Puroxan	doxofylline	tablets	400mg; (10/1x10/) in blister, (20/2x10/) in blister	M & H Manufacturing Co. Ltd., 41 Sukhumvit Road, Paknam, Muang, Samutprakarn 10270	Thailand	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	22152 11.06.2024
25	Tinctura Leonuri	herba leonuri	tincture	200mg/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	22153 11.06.2024
26	Dexalgin inject	dexketoprofen (dexketoprofen trometamol)	solution for injection/infusion	25mg/ml; (1) ampoul 2ml, (5) ampoules 2ml, (10) ampoules 2ml	A. Menarini Manufacturing Logistics and Services S.r.l., Via Sette Santi, 3-50131 Florence	Italy	Menarini International Operations Luxembourg S.A., 1, avenue de la Gare, 1611	Luxembourg	PoM	22154 11.06.2024

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 06-1/24 on June 11, 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	Diflukonazol	fluconazole	capsules	150mg; (1/1x1) in blister	REPLEK FARM Ltd. Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	Esculap Ltd., 17/2, 1 block, Davidashen, 0054, Yerevan	Republic of Armenia	PoM	22155 11.06.2024
2	Klopidogrel AKTIV	clopidogrel (clopidogrel bisulfate)	tablets film-coated	75mg; (30/3x10) in blister	Replek Farm Ltd. Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	Replek Farm Ltd. Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	PoM	22156 11.06.2024

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of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 06-1/24 on June 11, 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	Septanazal for children	xylometazoline (xylometazoline hydrochloride), dexpanthenol	spray nasal	0,5mg/ml+50mg/ml; 10ml (90 doses) plastic container with pump dispenser	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	19573/1/1 11.06.2024
2	Septanazal for adults	xylometazoline (xylometazoline hydrochloride), dexpanthenol	spray nasal	1mg/ml+50mg/ml; 10ml (90 doses) plastic container with pump dispenser	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	19574/1/1 11.06.2024

3	Dalacin	clindamycin (clindamycin hydrochloride)	capsules	150mg; (16/2x8) in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	Pfizer H.C.P. Corporation, 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	21780/1/1 11.06.2024
4	Dalacin	clindamycin (clindamycin hydrochloride)	capsules	300mg; (16/2x8) in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	Pfizer H.C.P. Corporation, 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	21781/1/1 11.06.2024
5	CoPlavix	clopidogrel, acetylsalicylic acid	tablets film-coated	75mg+100mg; (30/3x10) in blister	Sanofi Winthrop Industrie, 1, rue de la Vi-erge, Ambares et Lagrave, 33565 Carbon Blanc cedex	France	Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly	France	PoM	21027/2/1 11.06.2024
6	Kagoceel	kagoceel	tablets	12mg; (10/1x10) in blister, (20/2x10) in blister, (20/1x20) in blister, (30/3x10) in blister, (30/2x15) in blister	NEARMEDIC PHARMA LLC, 120 Kiev highway, bldg. 7, Obninsk, Obninsk City District, Kaluga Region- quality control, batch releaser, NEARMEDIC PHARMA LLC, 120 Kiev highway, bldg. 4, Obninsk, Obninsk City District, Kaluga Region, Russia- bulk manufacturer, packager	Russia	NEARMEDIC PLUS LLC, KOZHEVNICHESKAYA St., 14, bldg. 5, floor 3, room 17	Russia	OTC	21013/1/1 11.06.2024

7	Mexidol	ethylmethylhydroxypyridine succinate	solution for i/v and i/m injection	50mg/ml; (10/2x5) ampoules 2ml in blister	LLC «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	21141/2/2 11.06.2024
8	Mexidol	ethylmethylhydroxypyridine succinate	solution for i/v and i/m injection	50mg/ml; (5/1x5) ampoules 5ml, in blister	LLC «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	21142/2/2 11.06.2024
9	Orlobin-NEO	amikacin (amikacin sulfate)	solution for injection/ infusion	500mg/2ml; glass vial	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Medicus S.A., 10 Valaoritou str., GR 144 52, Metamorfofi, Attiki	Greece	PoM	21414/1/1 11.06.2024
10	Lisinopril	lisinopril (lisinopril dihydrate)	tablets	5mg; (24/1x24) in blister	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	19618/1/1 11.06.2024
11	Lisinopril	lisinopril (lisinopril dihydrate)	tablets	10mg; (24/1x24) in blister	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	22018/1/1 11.06.2024

12	Dexmedetomidine Kalceks	dexmedetomidine (dexmedetomidine hydrochloride)	concentrate for solution for infusion	100mcg/ml; (5) ampoules 2ml, (25) ampoules 2ml	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	19002/2/2 11.06.2024
13	Cinnabsin	cinnabaris trit. D3, hydrastis trit. D3, kalium bichromicum trit. D3, echinacea trit.D1	tablets	25mg+25mg+25mg+25mg; (60/3x20) in blister	Dr. Gustav Klein GmbH & Co. KG, Stein- enfeld 3, 77736 Zell am Harmersbach- bulk manufacturer, packager, quality control (physicochemical), batch releaser, GBA Pharma GmbH, Ernst-Abbe-Str. 40, Ulm, Baden-Wuerttemberg, 89079, Ger- many- quality control (microbiological)	Germany	Alpen Pharma GmbH, Steinenfeld 3 Zell am Harmersbach, 77736	Germany	OTC	20052/1/1 11.06.2024

LIST

of variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting decision N
06-1/24 on June 11, 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	Zafilla	dienogest	tablets	2mg; 28(2x14) in blister, 84(6x14) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	000003 11.06.2024

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 06-1/24 on June 11, 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	Artrozán	meloxicam	solution for injection	6mg/ml; (10/2x5) ampoules 2,5ml in blister, (3/1x3) ampoules 2,5ml in blister	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	PoM	18722/1 11.06.2024
2	Andipal	metamizole (metamizole sodium), phenobarbital, bendazol (bendazol hydrochloride), papaverine (papaverine hydrochloride)	tablets	250mg+20mg+20mg+20mg; (10/1x10) in blister	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	18892/1 11.06.2024
3	Klimadynon	cimicifuga rhizome dry extract	tablets film-coated	2.8mg; (60/4x15) in blister	Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt-packager, batch releaser, Rottendorf Pharma GmbH, Ostfelder Strasse 51-61, 59320 Ennigerloh, Nordrhein-Westfalen, Germany-bulk manufacturer	Germany	Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt	Germany	PoM	18188/1 11.06.2024
4	Nucleo CMP Forte	cytidine-5-disodium monophosphate + (uridine-5-trisodium triphosphate, uridine-5-disodium diphosphate, uridine-5-disodium monophosphate)	powder lyophilized for solution for injection	10mg+6mg; (3) ampoules, (3) solvent in ampoules 2ml	Ferrer International, S.A., Joan Buscalla, 1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer International, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	PoM	21393/1 11.06.2024
5	Polyoxidonium	azoximer bromide	powder lyophilized for solution for injection and local use	6mg; (5) glass vials 3ml	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	PoM	18601/2 11.06.2024

6	IMMUNOMAX BIO	peptidoglycan	powder lyophilized for solution for i/m injection	200IU; (3) glass vial	IMMAPHARMA LLC, 18/11, st. Gamaleya, Moscow, 123098- batch releaser, bulk manufacturer, packager, quality control (physicochemical), Avexima Sibir LLC, 7, st. Hercen, Kemerovskaya region, Kuzbass, Anjero-Sudjensk, 652473, Russia- quality control (microbiological)	Russia	Avexima OJSC, 31A/1, Leningradsky pr., Moscow, 125284	Russia	PoM	20679/1 11.06.2024
7	Snup	xylometazoline (xylometazoline hydrochloride)	spray nasal	0,5mg/ml; plastic vial 15ml (150 dose)	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel- batch releaser, Ursapharm Arzneimittel GmbH, Industriestrasse 66129 Saarbrucken, Germany- bulk manufacturer, packager, quality control	Germany	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel	Germany	OTC	21106/1 11.06.2024
8	Snup	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; plastic vial 15ml (150 dose)	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel- batch releaser, Ursapharm Arzneimittel GmbH, Industriestrasse 66129 Saarbrucken, Germany- bulk manufacturer, packager, quality control	Germany	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel	Germany	OTC	21107/1 11.06.2024
9	Snup	xylometazoline (xylometazoline hydrochloride)	spray nasal	0,5mg/ml; plastic bottle 15ml (150 dose) with metering pump	Hemomont d.o.o., 81000, Podgorica, Ilije Plamenca bb	Montenegro	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel	Germany	OTC	18377/5/1 11.06.2024
10	Snup	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; plastic bottle 15ml (150 dose) with metering pump	Hemomont d.o.o., 81000, Podgorica, Ilije Plamenca bb	Montenegro	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel	Germany	OTC	18378/5/1 11.06.2024

11	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	19103/4 11.06.2024
12	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	19104/4 11.06.2024
13	Decapeptil	triptorelin (triptorelin acetate)	solution for s/c injection	0,1mg/ml; (7) pre-filled syringe 1ml	Ferring GmbH, Wittland 11, 24109 Kiel - bulk manufacturer, primary packager, batch releaser, Ferring-Leciva, a.s.(areal spol. ECP, a.s.), Ke Skale 455, Vestec u Prahy, 25242, Czech Republic- secondary packager	Germany	Ferring GmbH, Wittland 11, 24109 Kiel	Germany	PoM	17949/3/1 11.06.2024
14	Ferrum Lek	iron (III)-hydroxide dextran complex	solution for i/m injection	50mg/ml; (5) ampoules 2ml, (50) ampoules 2ml	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19069/6 11.06.2024
15	Puregon	follitropin beta (recombinant)	solution for s/c injection	300IU/0,36ml; cartridge 0,42ml, (6/2x3) needles	N.V. Organon, Molenstraat 110, 5342 CC OSS- secondary packager, quality control, batch releaser (legal address- N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands), Vetter Pharma-Fertigung GmbH & Co. KG, Mooswiesen 2, Ravensburg, Baden-Wuerttemberg, 88214, Germany- bulk manufacturer, primary packager	the Netherlands	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	19260/5/1 11.06.2024

16	Puregon	follitropin beta (recombinant)	solution for s/c injection	600IU/0,72ml; cartridge 0,78ml, (6/2x3/) needles	N.V. Organon, Molenstraat 110, 5342 CC OSS- secondary packager, quality control, batch releaser (legal address- N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands), Vetter Pharma-Fertigung GmbH & Co. KG, Mooswiesen 2, Ravensburg, Baden-Wuerttemberg, 88214, Germany- bulk manufacturer, primary packager	the Netherlands	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	19261/5/1 11.06.2024
17	Ariprazol	aripiprazole	tablets	10mg; (30/3x10) in blister, (60/6x10) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	21916/1 11.06.2024
18	Ariprazol	aripiprazole	tablets	15mg; (30/3x10) in blister, (60/6x10) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	21917/1 11.06.2024
19	Letiram	levetiracetam	tablets coated	250mg (30/3x10) in blister, (60/6x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa, Greece- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19469/1 11.06.2024
20	Letiram	levetiracetam	tablets coated	500mg (30/3x10) in blister, (60/6x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa, Greece- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19470/1 11.06.2024

21	Letiram	levetiracetam	tablets coated	750mg (30/3x10) in blister, (60/6x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa, Greece- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19471/1 11.06.2024
22	Letiram	levetiracetam	tablets coated	1000mg (30/3x10) in blister, (60/6x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa, Greece- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19472/1 11.06.2024
23	Oftaquix	levofloxacin (levofloxacin hemihydrate)	drops eye	5mg/ml; 5ml plastic bottle-dropper	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, NextPharma Oy, Niittyhaankatu 20, 33720 Tampere, Finland- bulk manufacturer, primary packager, quality control, Manufacturing Packaging Farmaca (MPF) B.V., Neptunus 12, HEERENVEEN, 8448 CN, the Netherlands- secondary packager	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	PoM	19335/1 11.06.2024
24	PARACETAMOL 500mg tablets	paracetamol	tablets	500mg; (1000/100x10) in blister	M/s Medopharm, No. 34-B, Industrial Area, Kolar district, Malur, 563 160, Karnataka	India	Troge Scientific Research I. PVT.LTD., Tower C, Unit No- A-12-A, 2nd floor, Al-phathum, sector-90, Noida 201305, Gautam Buddha nagar, Uttar Pradesh	India	OTC	21998/1 11.06.2024
25	Deavit Neo	colecalfiferol	drops oral (solution)	0,5mg/ml; 10ml glass bottle	Sopharma JSC, Industrial zone Sandanski 2800	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	20607/2 11.06.2024
26	Heparin ointment	heparin (heparin sodium), benzocaine, benzyl nicotinate	ointment for external use	100IU/g+40mg/g+0.8mg/g; 25g aluminium or plastic tube	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	20784/1/2 11.06.2024

27	Orabloc	articaine (articaine hydrochloride), adrenaline (adrenaline tartrate)	solution for injection	40mg/ml+10mcg/ml; (100/10x10/) cartridges 1,8ml in blister	Pierrel S.p.A., S.S. Appia, 7 Bis, 46/48 Capua (CE) 81043	Italy	Pierrel S.p.A., S.S. Appia, 7 Bis, 46/48 Capua (CE) 81043	Italy	PoM	22006/1 11.06.2024
28	Cosopt PF	timolol (timolol maleate), dorzolamide (dorzolamide hydrochloride)	drops eye (solution)	5mg/ml+20mg/ml; plastic vial 10ml	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch re- leaser, 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	19865/2 11.06.2024
29	Duressa	dexamethasone (dexamethasone sodium phosphate), levofloxacin (levofloxacin hemihydrate)	drops eye	1mg/ml+5mg/ml; 5ml plastic vial-droper	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch re- leaser, 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	20402/4/1 11.06.2024
30	Lecrolyn	cromoglicic acid (sodium cromoglicate)	drops eye	40mg/ml; 5ml plastic vial-dropper	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releas- er, NextPharma Oy, Niitty- haankatu 20, Tampere, 33720, Finland- bulk manufacturer, primary packager, quality con- trol, Manufacturing Packaging Farmaca (MPF) B.V., Neptunus 12, HEERENVEEN, 8448 CN, the Netherlands- secondary packager	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	OTC	19529/1 11.06.2024
31	Oftagel	carbomer 974P	gel eye	2,5mg/g; plastic vial-dropper 10g	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releas- er, Ursapharm Arzneimittel GmbH, Industriestrasse 35, 66129 Saarbrücken, Germany- bulk manufacturer, packager, quality control	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	OTC	19860/3 11.06.2024

32	Oftan Catachrom	cytochrome C, adenosine, nicotinamide	drops eye	0,675mg/ml+2mg/ml+20mg/ml; plastic bottle-dropper 10ml	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, NextPharma Oy, Niittyhaankatu 20, Tampere, 33720, Finland- bulk manufacturer, primary packager, quality control, Manufacturing Packaging Farmaca (MPF) B.V., Neptunus 12, HEERENVEEN, 8448 CN, the Netherlands- secondary packager	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	PoM	19804/1 11.06.2024
33	Oftan Dexamethason	dexamethasone (dexamethasone sodium phosphate)	drops eye	1mg/ml; 5ml plastic bottle-dropper	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, NextPharma Oy, Niittyhaankatu 20, 33720 Tampere, Finland- bulk manufacturer, primary packager, quality control, Manufacturing Packaging Farmaca (MPF) B.V., Neptunus 12, HEERENVEEN, 8448 CN, the Netherlands- secondary packager	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	PoM	19337/2 11.06.2024
34	Oftan Timolol	timolol (timolol maleate)	drops eye	5mg/ml; plastic vial-dropper 5ml	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, NextPharma Oy, Niittyhaankatu 20, Tampere, 33720, Finland- bulk manufacturer, primary packager, quality control, Manufacturing Packaging Farmaca (MPF) B.V. Neptunus 12, HEERENVEEN, 8448CN, the Netherlands- secondary packager	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	PoM	20106/1 11.06.2024

35	Oftaquix	levofloxacin (levofloxacin hemihydrate)	drops eye	5mg/ml; 5ml plastic bottle-dropper	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, NextPharma Oy, Niittyhaankatu 20, 33720 Tampere, Finland- bulk manufacturer, primary packager, quality control, Manufacturing Packaging Farmaca (MPF) B.V., Neptunus 12, HEERENVEEN, 8448 CN, the Netherlands- secondary packager	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	PoM	19335/2 11.06.2024
36	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	19799/3 11.06.2024
37	Taflotan	tafluprost	drops eye	15mcg/ml; plastic bottle-dropper 2,5ml	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, Santen Pharmaceutical Co. Ltd., Shiga Plant 348-3, Aza-suwa, Oaza-shide, Taga-cho, Inukami-gun, Shiga 522-0314, Japan- bulk manufacturer, primary packager, quality control, Manufacturing Packaging Farmaca (MPF) B.V., Neptunus 12, HEERENVEEN, 8448 CN, the Netherlands- secondary packager	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	PoM	19806/1 11.06.2024
38	Phescetam	piracetam, cinnarizine	capsules	400mg+25mg; (60/4x15) in blister	ADIPHARM EAD, 130 Simeonovsko shose Blvd., Sofia 1700	Bulgaria	ADIPHARMEAD, 130 Simeonovsko shose Blvd., Sofia 1700	Bulgaria	PoM	18840/1 11.06.2024
39	Befeton	diclofenac (diclofenac sodium)	solution for injection	25mg/ml; (10) ampoules 3ml	Divine Laboratories Pvt. Ltd. Block N471, Dabhasa, Tal-Padara, Dist. Vadodara-391440	India	Giga Farm LLC, Gogunca str.3/5, Gyumri	Republic of Armenia	PoM	20641/1 11.06.2024

40	Furacilin Tatpharm	nitrofurazone	tablets for solution for local and external use	20mg; (10) in blister, (10) in strip	Tatchempharmpreparaty JSC, 420091, Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091, Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	OTC	21987/1 11.06.2024
41	Gonadotropin chorionic	gonadotrophin chorionic	powder lyophilized for solution for i/m injection	500IU; (5) glass vials and (5) solvent in ampoules 1ml	Moscow Endocrine Plant FSUE, 25, bld. 1, Novokhokhlovskaya st., Moscow, 109052-quality control (physicochemical and microbiological), batch releaser, «Moscow Endocrine Plant FSUE», 25, bld. 2, Novokhokhlovskaya st., Moscow, 109052, Russia-bulk manufacturer, packager (powder and solvent)	Russia	«Moscow Endocrine Plant FSUE», 25, Novokhokhlovskaya st., Moscow 109052	Russia	PoM	19521/2/1 11.06.2024
42	Gonadotropin chorionic	gonadotrophin chorionic	powder lyophilized for solution for i/m injection	1000IU; (5) glass vials and (5) solvent in ampoules 1ml	Moscow Endocrine Plant FSUE, 25, bld. 1, Novokhokhlovskaya st., Moscow, 109052-quality control (physicochemical and microbiological), batch releaser, «Moscow Endocrine Plant FSUE», 25, bld. 2, Novokhokhlovskaya st., Moscow, 109052, Russia-bulk manufacturer, packager (powder and solvent)	Russia	«Moscow Endocrine Plant FSUE», 25, Novokhokhlovskaya st., Moscow 109052	Russia	PoM	19522/2/1 11.06.2024
43	Fevarin	fluvoxamine (fluvoxamine maleate)	tablets film-coated	50mg; (15/1x15) in blister	Mylan Laboratories SAS, Route de Belleville, Lieu-dit Maillard, 01400 Chatillon sur Chalaronne	France	Abbott Healthcare Products B.V., C.J. van Houtenlaan 36, 1381 CP Weesp	the Netherlands	PoM	18477/4 11.06.2024
44	Fevarin	fluvoxamine (fluvoxamine maleate)	tablets film-coated	100mg; (15/1x15) in blister	Mylan Laboratories SAS, Route de Belleville, Lieu-dit Maillard, 01400 Chatillon sur Chalaronne	France	Abbott Healthcare Products B.V., C.J. van Houtenlaan 36, 1381 CP Weesp	the Netherlands	PoM	18478/4 11.06.2024

45	Rexocef	cefepodoxime (cefepodoxime proxetil)	powder for oral suspension	40mg/5ml; 64,8g powder in 100ml plastic vial with measuring cup and dosing syringe	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- quality control, batch releaser, Lupin Limited, 198-202, New Industrial Estate Area No.2 Mandideep-462046 district-Raisen M.P, India- bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	21692/2 11.06.2024
46	Fluconazole	fluconazole	tablets	50mg; (12/1x12) 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	18109/1 11.06.2024
47	Cosopt PF	timolol (timolol maleate), dorzolamide (dorzolamide hydrochloride)	drops eye (solution)	5mg/ml+20mg/ml; plastic vial 10ml	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	19865/3 11.06.2024
48	Bupi Heavy	bupivacaine (bupivacaine hydrochloride)	solution for injection	5mg/ml; (10) ampoules 4ml	Swiss Parenterals Pvt. Ltd., 809 Kerala Industrial Estate , G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220,Gujarat	India	Swiss Parenterals Pvt. Ltd., 809 Kerala Industrial Estate , G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220,Gujarat	India	PoM	18156/1 11.06.2024
49	Suprostilin	chloropyramine (chloropyramine hydrochloride)	tablets	25mg; (10/1x10) in blister, (20/2x10) in blister	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	OTC	21782/1 11.06.2024
50	Alteyka Arterium	althaea radix dry extract	syrup	7,5mg/5ml; 100ml plastic or glass bottle and measuring spoon, 100ml plastic or glass container and measuring spoon, 200ml plastic or glass bottle and measuring spoon	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	OTC	21299/1 11.06.2024
51	Azimac	azithromycin (azithromycin dihydrate)	powder for oral suspension	200mg/5ml; glass bottle 37.5ml and measuring syringe	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	GM Pharmaceuticals Ltd, Rustavi Highway 52,Tbilisi	Georgia	PoM	18415/2/1 11.06.2024

52	Fentanyl Kalceks	fentanyl (fentanyl citrate)	solution for injection	0,05mg/ml; (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	19795/2/1 11.06.2024
53	Dexdor	dexmedetomidine (dexmedetomidine hydrochloride)	concentrate for solution for infusion	100mcg/ml (5) ampoules 2ml, (25) ampoules 2ml	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	PoM	19463/4 11.06.2024
54	Tinctura Leonuri	herba leonuri	tincture	200mg/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	18725/1 11.06.2024
55	Clindabiox	clindamycin (clindamycin phosphate)	suppositories vaginal	100mg; (3/1x3/)	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	PoM	18712/1 11.06.2024
56	Doxycycline	doxycycline (doxycycline hyclate)	capsules	100mg; (10/1x10) in blister, (20/2x10) in blister	Open joint stock company «Borisovskiy zavod medicinski-kh preparatov», 64, No3/3, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinski-kh preparatov», 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	19032/3/1 11.06.2024
57	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	PoM	18427/4 11.06.2024
58	Puroxan	doxofylline	tablets	400mg; (10/1x10) in blister, (20/2x10) in blister	M & H Manufacturing Co. Ltd., 41 Sukhumvit Road, Paknam, Muang, Samutprakarn 10270	Thailand	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	18366/4 11.06.2024
59	Ondansetron	ondansetron	solution for injection	2mg/ml; (5/1x5/) ampoules 4ml in blister	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	21929/1 11.06.2024
60	Klopidogrel AKTIV	clopidogrel (clopidogrel bisulfate)	tablets film-coated	75mg; (30/3x10) in blister	REPLEK FARM Ltd. Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	REPLEK FARM Ltd. Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	PoM	18931/2 11.06.2024

61	Diflufukonazol	fluconazole	capsules	150mg; (1) in blister	REPLEK FARM Ltd. Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	Esculap Ltd., 17/2, 1 block, Davidashen, 0054, Yerevan	Republic of Armenia	PoM	18930/2 11.06.2024
62	Tinctura Crataegi	fructus crataegi	tincture	100mg/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	18862/1 11.06.2024
63	Numeta G13%E Preterm	alanine, arginine, aspartic acid, cysteine, glutamic acid, glycine, histidine, Isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenyl- alanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, potassium acetate, calcium chloride dehydrate, magnesium acetate tetrahydrate, sodium glyc- erophosphate hydrated, glucose monohydrate, refined olive oil + refined soya bean oil	emulsion for infusion	0,75g+0,78g+0,56g+0,18g+0,93g+0,37g+ 0,35g+0,62g+0,93g+1,15g+0,22g+0,30g+ 0,39g+0,28g+0,37g+0,06g+0,35g+0,19g+ 0,07g+0,71g+0,61g+0,55g+0,10g+0,98g+ 44g+7,5g; (10) bags 300ml	Baxter SA., Boulevard Rene Branquart 80, Lessines, 7860	Belgium	Baxter Healthcare Ltd, Caxton Way, Thretford, Norfolk, IP24 3SE	UK	PoM	19411/3 11.06.2024
64	Numeta G16%E	alanine, arginine, aspartic acid, cysteine, glutamic acid, glycine, histidine, Isoleucine, leucine, lysine monohydrate, methi- onine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, sodium chloride, potassium acetate, calcium chloride dehydrate, magnesium acetate tetrahydrate, sodium glyc- erophosphate hydrated, glucose monohydrate, refined olive oil + refined soya bean oil	emulsion for infusion	1,03g+1,08g+0,77g+0,24g+1,29g+0,51g+ 0,49g+0,86g+1,29g+1,59g+0,31g+0,41g+ 0,54g+0,39g+0,51g+0,08g+0,48g+0,26g+ 0,10g+0,98g+0,30g+1,12g+0,46g+0,33g+ 0,98g+85,25+15,5g (6) bags 500ml	Baxter SA., Boulevard Rene Branquart 80, Lessines, 7860	Belgium	Baxter Healthcare Ltd, Caxton Way, Thretford, Norfolk, IP24 3SE	UK	PoM	19412/3 11.06.2024

65	Numeta G19%E	alanine, arginine, aspartic acid, cysteine, glutamic acid, glycine, histidine, Isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, sodium chloride, potassium acetate, calcium chloride dehydrate, magnesium acetate tetrahydrate, sodium glycerophosphate hydrated, glucose monohydrate, refined olive oil + refined soya bean oil	emulsion for infusion	1,83g+1,9g+1,37g+0,43g+2,29g+0,91g+0,87g+1,53g+2,29g+2,82g+0,55g+0,73g+0,96g+0,69g+0,91g+0,14g+0,85g+0,46g+0,18g+1,74g+1,79g+3,14g+0,56g+0,55g+2,21g+210,65+28,1g; (6) bags 1000ml	Baxter SA., Boulevard Rene Branquart 80, Lessines, 7860	Belgium	Baxter Healthcare Ltd, Caxton Way, Thretford, Norfolk, IP24 3SE	UK	PoM	19413/3 11.06.2024
66	Kapsikam	dimethyl sulfoxide, camphor racemic, turpentine oil, benzyl nicotinate, nonivamide	ointment for external use	50mg/g+30mg/g+30mg/g+20mg/g+2mg/g; aluminium tube 30g and applicator, aluminium tube 50g and applicator	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	OTC	18480/4/1 11.06.2024
67	Remycin	doxycycline (doxycycline hyclate)	tablets film-coated	100mg; (10/1x10) in blister	Remedica Ltd, Aharon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	Remedica Ltd, Aharon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	PoM	21626/1 11.06.2024
68	Thiotriazolin	thiotriazoline	tablets	200mg; (90/9x10) in blister, (90/6x15) in blister	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	22028/1 11.06.2024
69	Distem	paracetamol, methocarbamol	tablets	300mg+ 380mg; (50/5x10) in blister	FAES FARMA S.A., C/Maximo Aguirre, 14, Lejona-Leioa, 48940 Vizcaya/Bizkaia	Spain	FAES FARMA S.A., C/Maximo Aguirre, 14, Lejona-Leioa, 48940 Vizcaya/Bizkaia	Spain	PoM	18868/3/1 11.06.2024

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 06-1/24 on June 11, 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	Preductal OD	trimetazidine (trimetazidine dihydrochloride)	capsules prolonged-release	80mg; (30/3x10) in blister, (60/6x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, quality control, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65, Hungary- bulk manufacturer	Hungary	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000215 11.06.2024
2	Preductal OD	trimetazidine (trimetazidine dihydrochloride)	capsules prolonged-release	80mg; (30/3x10) in blister, (60/6x10) in blister	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	000215 11.06.2024
3	VizuSol	loteprednol etabonate	drops eye	5mg/ml; (1) plastic vial-dropper 5ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	003947 11.06.2024
4	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 Wladyslawa 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 Pelplinska Str., 83-200 Starogard Gdanski	Poland	OTC	003564 11.06.2024

5	Oncaspar	Pegaspargase	lyophilizate for solution for i/m injection and infusion	750IU/ml; glass vial 5ml	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy- quality control, batch releaser, Lyophilization Services of New England, Inc (LSNE),25 Commerce Drive, Bedford, New Hampshire (NH) 03110, USA- bulk manufacturer, primary packager, Exelead Inc., 6925 Guion Road, Indianapolis, Indiana (IN) 46268, USA- secondary packager	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000545 11.06.2024
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