

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 06-2/25 on June 25, 2025

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	Tadalafil Canon	tadalafil	tablets film-coated	5mg; (28/4x7) in blister	CJSC Canonpharma production, 105B bldg, 11, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region- quality control, batch releaser, CJSC Canonpharma production, 105B bldg, 16, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, Russia- bulk manufacturer, primary and secondary packager	Russia	CJSC Canonpharma production, 105 Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, 141100	Russia	PoM	23136 25.06.2025
2	Tadalafil Canon	tadalafil	tablets film-coated	20mg; (1/1x1) in blister	CJSC Canonpharma production, 105B bldg, 11, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region- quality control, batch releaser, CJSC Canonpharma production, 105B bldg, 16, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, Russia- bulk manufacturer, primary and secondary packager	Russia	CJSC Canonpharma production, 105 Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, 141100	Russia	PoM	23137 25.06.2025
3	Metrofungyn Biforte	miconazole (miconazole nitrate), metronidazole	capsules vaginal	200mg+750mg; (10/2x5/)	Minskintercaps U.V., 26/3, Inzhenemaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhenemaya str., 220075, Minsk	Republic of Belarus	PoM	23138 25.06.2025
4	Vegapenem	meropenem (meropenem trihydrate)	powder for solution injection/ infusion	1g; (10) glass vials	ACS DOBFAR S.p.A., Nucleo Industriale S. Atto, 64100 TERAMO (TE)	Italy	Vegapharm LLP, Unit 18, Norman road 53, Greenwich Centre Business park, SE10 9QF, London	United Kingdom	PoM	23139 25.06.2025

5	Lonsurf	tipiracil (tipiracil hydrochloride), trifluridine	tablets film-coated	6,14mg+15mg; (60/6x10/) in blister	Taiho Pharmaceutical Co. Ltd., Kitajima Plant, 1-1, Iuchi, Takabo, Kitajima-cho, Itano-gun, 771-0206, Tokushima, Japan- bulk manufacturer, Les Laboratoires Servier Industrie, 905, route de Saran, 45520 Gidy- packager, quality control, batch releaser	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes Cedex	France	PoM	23140 25.06.2025
6	Lonsurf	tipiracil (tipiracil hydrochloride), trifluridine	tablets film-coated	8,19mg+20mg; (60/6x10/) in blister	Taiho Pharmaceutical Co. Ltd., Kitajima Plant, 1-1, Iuchi, Takabo, Kitajima-cho, Itano-gun, 771-0206, Tokushima, Japan- bulk manufacturer, Les Laboratoires Servier Industrie, 905, route de Saran, 45520 Gidy- packager, quality control, batch releaser	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes Cedex	France	PoM	23141 25.06.2025
7	Lonsurf	tipiracil (tipiracil hydrochloride), trifluridine	tablets film-coated	6,14mg+15mg; (60/6x10/) in blister	Taiho Pharmaceutical Co. Ltd., Kitajima Plant, 1-1, Iuchi, Takabo, Kitajima-cho, Itano-gun, 771-0206 Tokushima, Japan- bulk manufacturer, Servier (Ireland) Industries Limited, Gorey Road, Arklow, Y14 E284- packager, quality control, batch releaser	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes Cedex	France	PoM	23142 25.06.2025
8	Lonsurf	tipiracil (tipiracil hydrochloride), trifluridine	tablets film-coated	8,19mg+20mg; (60/6x10/) in blister	Taiho Pharmaceutical Co. Ltd., Kitajima Plant, 1-1, Iuchi, Takabo, Kitajima-cho, Itano-gun, 771-0206 Tokushima, Japan- bulk manufacturer, Servier (Ireland) Industries Limited, Gorey Road, Arklow, Y14 E284- packager, quality control, batch releaser	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes Cedex	France	PoM	23143 25.06.2025
9	Tacrolimus STADA 0,5mg	tacrolimus	capsules hard	0,5mg; (30(3x10/1x10/)) blister in aluminium sachet	Laboratories Cinfa S.A., Poligono Industrial Areta Carretera Olaz-Chipi 10, Huarte, 31620- quality control (microbiological), batch releaser, Laboratories Cinfa S.A., Travesia De Roncesvalles 1, Olloki, Esterbiar 31699, Spain, bulk manufacturer, packager, quality control (physicocemical)	Spain	Laboratorio STADA, S.L, Frederic Mompou 5, 08960 Sant Just Desvern, Barcelona	Spain	PoM	23144 25.06.2025

10	Tacrolimus STADA 1mg	tacrolimus	capsules hard	1mg; (60(6x10/1x10)) blister in aluminium sachet	Laboratories Cinfa S.A., Poligono Industrial Areta Carretera Olaz-Chipi 10, Huarte, 31620- quality control (microbiological), batch releaser, Laboratories Cinfa S.A., Travesia De Roncesvalles 1, Olloki, Esterbiar 31699, Spain, bulk manufacturer, packager, quality control (physicocemical)	Spain	Laboratorio STADA, S.L, Frederic Mompou 5, 08960 Sant Just Desvern, Barcelona	Spain	PoM	23145 25.06.2025
11	Baclofen-Usolye	baclofen	tablets	10mg; (50/5x10/) in blister	JSC "Usolye-Sibirsky Chemical and Pharmaceutical Plant", 665462, Irkutsk region, Usolye-Sibirskoye	Russia	JSC "Usolye-Sibirsky Chemical and Pharmaceutical Plant", 665462, Irkutsk region, Usolye- Sibirskoye	Russia	PoM	23146 25.06.2025
12	Baclofen-Usolye	baclofen	tablets	25mg; (50/5x10/) in blister	JSC "Usolye-Sibirsky Chemical and Pharmaceutical Plant", 665462, Irkutsk region, Usolye-Sibirskoye	Russia	JSC "Usolye-Sibirsky Chemical and Pharmaceutical Plant", 665462, Irkutsk region, Usolye- Sibirskoye	Russia	PoM	23147 25.06.2025
13	GENFERON LIGHT	interferon alfa-2b, taurine	suppositories vaginal and rectal	125000IU+5mg; (10/2x5/)	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460	Russia	BIOCAD JSC, d. 38, str.1, pomesch. 89, Intracity Municipality the Settlement of Strelna, ul. Svyazi, Saint Petersburg, 198515	Russia	PoM	23148 25.06.2025
14	GENFERON LIGHT	interferon alfa-2b, taurine	suppositories vaginal and rectal	250000IU+5mg; (10/2x5/)	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460	Russia	BIOCAD JSC, d. 38, str.1, pomesch. 89, Intracity Municipality the Settlement of Strelna, ul. Svyazi, Saint Petersburg, 198515	Russia	PoM	23149 25.06.2025

LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 06-2/25 on June 25, 2025

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	Carsil Forte	silymarin	capsules hard	90mg; (30/5x6') in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	23153 (009346) 25.06.2025
2	Siofor 850	metformin (metformin hydrochloride)	tablets film-coated	850mg; 30(2x15) in blister, 60(4x15) in blister, 120(8x15) in blister	Berlin-Chemie AG, 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 AG, Glienicker Weg 125, 12489 Berlin, Germany- quality control (physicochemical)	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	23154 (008603) 25.06.2025
3	Siofor 850	metformin (metformin hydrochloride)	tablets film-coated	850mg; 30(2x15) in blister, 60(4x15) in blister, 120(8x15) in blister	ZAO Berlin-Pharma, 248926, Kaluga 2nd, Avtomobilniy proezd, bld. 5	Russia	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	23155 (008603) 25.06.2025
4	Siofor 850	metformin (metformin hydrochloride)	tablets film-coated	850mg; 30(2x15) in blister, 60(4x15) in blister, 120(8x15) in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- batch releaser, Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden, Germany- bulk manufacturer, packager, quality control	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	23156 (008603) 25.06.2025
5	Clivas	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (30/3x10') in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kyiv	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kyiv	Ukraine	PoM	23157 (006308) 25.06.2025

6	Clivas	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (30/3x10') in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kyiv	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kyiv	Ukraine	PoM	23158 (006308) 25.06.2025
7	Xarelto	rivaroxaban	tablets film-coated	2,5mg; (56/4x14') in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	23160 (008557) 25.06.2025
8	Xarelto	rivaroxaban	tablets film-coated	2,5mg; (56/4x14') in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen- bulk manufacturer, primary packager, quality control, batch releaser, Stegemann GmbH & Co. KG Up' n Nien Esch 14, 48268 Greven, Germany-secondary packager	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	23160 (008557) 25.06.2025
9	Xarelto	rivaroxaban	tablets film-coated	10mg; (30/3x10') in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	23161 (007767) 25.06.2025
10	Xarelto	rivaroxaban	tablets film-coated	10mg; (30/3x10') in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen- bulk manufacturer, primary packager, quality control, batch releaser, Stegemann GmbH & Co. KG Up' n Nien Esch 14, 48268 Greven, Germany-secondary packager	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	23162 (007767) 25.06.2025
11	Xarelto	rivaroxaban	tablets film-coated	15mg; (28/2x14') in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	23163 (010578) 25.06.2025
12	Xarelto	rivaroxaban	tablets film-coated	15mg; (28/2x14') in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen- bulk manufacturer, primary packager, quality control, batch releaser, Stegemann GmbH & Co. KG Up' n Nien Esch 14, 48268 Greven, Germany-secondary packager	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	23164 (010578) 25.06.2025
13	Xarelto	rivaroxaban	tablets film-coated	20mg; (28/2x14') in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	23165 (010578) 25.06.2025
14	Xarelto	rivaroxaban	tablets film-coated	20mg; (28/2x14') in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen- bulk manufacturer, primary packager, quality control, batch releaser, Stegemann GmbH & Co. KG Up' n Nien Esch 14, 48268 Greven, Germany-secondary packager	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	23166 (010578) 25.06.2025

15	RHINO-TON	xylometazoline (xylometazoline hydrochloride)	spray nasal	0,5mg/ml; 10ml plastic bottle with pump dispenser	Pharmtechnology LLC, Korzhenevskogo str., 22, 220024, Minsk	Republic of Belarus	Giga Farm LLC, Gogunts str.3/5, Gyumri	Republic of Armenia	OTC	23150 (018472) 25.06.2025
16	RHINO-TON	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; 10ml plastic bottle with pump dispenser	Pharmtechnology LLC, Korzhenevskogo str., 22, 220024, Minsk	Republic of Belarus	Giga Farm LLC, Gogunts str.3/5, Gyumri	Republic of Armenia	OTC	23151 (018472) 25.06.2025
17	L-Thyroxin 25 Berlin-Chemie	levothyroxine sodium	tablets	25mcg; (28/1x28/) in blister, (50/2x25/) in blister, (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	23152 (025148) 25.06.2025

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 06-2/25 on June 25, 2025

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	Kaptopril	captopril	tablets	50mg; (20/2x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, quality control, batch releaser, KRKA d.d., Novo mesto, Ulica Rada Pusenjaka 10, Ljutomer, 9240, Slovenia- packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	23167 25.06.2025
2	Fucorcin	resorcin	solution for external use	78mg/ml; 10ml glass bottle, 15ml glass bottle, 25ml glass bottle, 30ml glass bottle	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	OTC	23168 25.06.2025

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 06-2/25 on June 25, 2025

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	Codelac Broncho	ambroxol (ambroxol hydrochloride), sodium glycyrrhizinate (glycyrrhizinic acid trisodium), thermopsis extract, sodium hydrocarbonate	tablets	20mg+30mg+10mg+200mg; (10/1x10/) in blister, (20/2x10/) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	"OTCPharm" JSC, Testovskaya street, 10, flr. 12, apartment II, room. 29, Moscow 123112	Russia	OTC	23169 25.06.2025
2	Pedeks	permethrin	solution for external use	5mg/g; 60ml glass bottle	LMP Ltd., 1, Vietalvas street, Riga, LV-1009- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Grindeks JSC, Krustpils street 53, Riga, LV- 1057, Latvia- quality control (microbiological)	Latvia	LMP Ltd., 1, Vietalvas street, Riga, LV-1009	Latvia	OTC	23170 25.06.2025
3	Kreon 10000	pancreatin (lipase 10000PhEU, amylase 8000 PhEU, protease 600 PhEU)	capsules gastro-resistant	150mg; (20/2x10/) in blister, (20) in plastic container	Abbott Laboratories GmbH, Justus-von-Liebig-Strasse 33, 31535 Neustadt	Germany	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	OTC	23171 25.06.2025
4	Kreon 25000	pancreatin (lipase 25000PhEU, amylase 18000 PhEU, protease 1000 PhEU)	capsules gastro-resistant	300mg; (20/2x10/) in blister, (20) in plastic container	Abbott Laboratories GmbH, Justus-von-Liebig-Strasse 33, 31535 Neustadt	Germany	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	OTC	23172 25.06.2025

5	Kreon 40000	pancreatin (lipase 40000PhEU, amylase 25000 PhEU, protease 1600 PhEU)	capsules gastro-resistant	400mg; (20/2x10/) in blister, (20) in plastic container	Abbott Laboratories GmbH, Justus-von-Liebig-Strasse 33, 31535 Neustadt	Germany	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	OTC	23173 25.06.2025
---	-------------	---	---------------------------	---	--	---------	--	---------	-----	------------------

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 06-2/25 on June 25, 2025

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	MELON-RATIONAL	ambroxol (ambroxol hydrochloride), salbutamol (salbutamol sulfate), guaifenesin	tablets	15mg+2mg+100mg; (30/3x10/) in blister	Aversi-Rational Ltd, Chirakhuli Str. 14, 0198 Tbilisi- secondary packager, quality control, batch releaser, Geno Pharmaceuticals Pvt. Ltd, Tivim Industrial Estate, Karaswada Mapusa, Goa 403526, India- bulk manufacturer, primary packager	Georgia	Aversi-Rational Ltd, Chirakhuli Str. 14, 0198 Tbilisi	Georgia	PoM	21746/1/1 25.06.2025
2	Metronidazole	metronidazole	tablets	250mg; (10) in blister, (20/2x10/) blisters	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, 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	20949/2/2 25.06.2025

LIST

of the variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 06-1/25 on June 12, 2025

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	Lactodepantol	lactic acid	suppositories vaginal	100mg; (10/2x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, s.1- quality control, batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia-bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	ЖПТ-N°000078-ІТІ-AM 25.06.2025
2	Azopt	brinzolamide	drops eye	10mg/ml; plastic vial 5ml	Novartis Manufacturing N.V., Rijksweg 14, Puurs-Sint- Amands, 2870	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	ЖПТ-N°002603-ІТІ-AM 25.06.2025
3	Telmista AM	amlodipine (amlodipine besilate), telmisartan	tablets	5mg+40mg; (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	ЖПТ-N°000412-ІТІ-AM 25.06.2025
4	Telmista AM	amlodipine (amlodipine besilate), telmisartan	tablets	5mg+80mg; (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	ЖПТ-N°000412-ІТІ-AM 25.06.2025
5	Telmista AM	amlodipine (amlodipine besilate), telmisartan	tablets	10mg+40mg; (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	ЖПТ-N°000412-ІТІ-AM 25.06.2025
6	Telmista AM	amlodipine (amlodipine besilate), telmisartan	tablets	10mg+80mg; (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	ЖПТ-N°000412-ІТІ-AM 25.06.2025

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 06-2/25 on June 25, 2025

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	Berlipril plus	enalapril (enalapril maleate), hydrochlorothiazide	tablets	10mg+25mg (30/3x10/) in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, quality control, batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	19588/3 25.06.2025
2	Vsiqq	brolocizumab	solution for intraocular injection	120mg/ml; glass vial and filter needle	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- secondary packager, batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, 4332, Switzerland- bulk manufacturer, primary packager, quality control	Slovenia	Novartis Overseas Investments AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22251/1 25.06.2025
3	Vsiqq	Brolocizumab	solution for intraocular injection	120mg/ml; glass vial and filter needle	Novartis Pharma Stein AG Technical Operations Schweiz, Stein Steriles, Schaffhauserstrasse, Stein AG, 4332	Switzerland	Novartis Overseas Investments AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19953/4/2 25.06.2025
4	Artraxicam	meloxicam, peper siliculose fruits tincture	cream	30mg/g+100mg/g; aluminium or plastic tube 30g	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, build. 1 - quality control, batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia - bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st. 7	Russia	OTC	22363/1 25.06.2025

5	Nevrolek	thiamine (thiamine hydrochloride), pyridoxine (pyridoxine hydrochloride), cyanocobalamin, lidocaine (lidocaine hydrochloride monohydrate)	solution for i/m injection	50mg/ml+50mg/ml+0,5mg/ml+10mg/ml; (5) ampoules 2ml, (5/1x5/) ampoules 2ml 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	PoM	19732/4 25.06.2025
6	Victoza	liraglutide	solution for s/c injection	6mg/ml; (2) pre-filled pen 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd- bulk manufacturer, packager, quality control, batch releaser, Novo Nordisk A/S, Hallas Alle, DK-4400 Kalundborg, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	20181/6 25.06.2025
7	TaiCold with raspberry flavour	paracetamol, chlorpheniramine (chlorpheniramine maleate), ascorbic acid	powder for oral solution with raspberry flavour	500mg+2mg+30mg; (10) sachet	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	OTC	21659/1 25.06.2025
8	TaiCold with lemon flavour	paracetamol, chlorpheniramine (chlorpheniramine maleate), ascorbic acid	powder for oral solution with lemon flavour	500mg+2mg+30mg; (10) sachets	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	OTC	21658/1 25.06.2025

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 06-2/25 on June 25, 2025

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	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	ЖП №000575-ITI-AM 25.06.2025
2	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	ЖП №000575-ITI-AM 25.06.2025
3	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	ЖП №000575-ITI-AM 25.06.2025
4	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	ЖП №000575-ITI-AM 25.06.2025
5	Noliprel A Forte	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	ЖП-№000175-ITI-AM 25.06.2025

6	Noliprel A Forte	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	ЛПТ-№000175-ITI-AM 25.06.2025
7	Noliprel A Forte	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	ЛПТ-№000175-ITI-AM 25.06.2025
8	Noliprel A Forte	perindopril arginine, indapamide	tablets film-coated	5mg+1,25mg; (14) in plastic container, (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284- batch releaser, packager, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№000175-ITI-AM 25.06.2025
9	Verapamil Alkaloid	verapamil (verapamil hydrochloride)	tablets coated	40mg; (30/2x15) 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	ЛПТ-№000280-ITI-AM 25.06.2025
10	Verapamil Alkaloid	verapamil (verapamil hydrochloride)	tablets coated	80mg; (30/2x15) 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	ЛПТ-№000280-ITI-AM 25.06.2025
11	Besponsa	inotuzumab ozogamicin	lyophilizate for concentrate for solution for infusion	1mg; glass vial 20ml	Pharmacia and Upjohn Company, 7000 Portage road, Kalamazoo, Michigan, 49001- secondary packager, batch releaser, Wyeth pharmaceutical Division of Wyeth Holdings LLC, 401 North Middletown Road, Pearl River, New York 10965, USA- bulk manufacturer, primary packager, quality control	USA	Pfizer Inc. 235, East 42nd street, New York 10017	USA	PoM	ЛПТ-№000413-ITI-AM 25.06.2025
12	Tamsol	tamsulosin (tamsulosin hydrochloride)	capsules modified-release	0,4mg; (10/1x10) in blister, (30/3x10) in blister	Gedeon Richter Romania S.A., Guza Voda str. 99-105, Targu-Mures, 540306	Romania	Gedeon Richter Plc., Gyomroi ut 19-21, Budapest, 1103	Hungary	PoM	ЛПТ-№000753-ITI-AM 25.06.2025

13	Tamsol	tamsulosin (tamsulosin hydrochloride)	capsules modified-release	0,4mg; (10/1x10/) in blister, (30/3x10/) in blister	Gedeon Richter-RUS JSC, Lesnaya st. 40, Bld. 2, Shuvoye, Moscow region, Yegoriyevsky district, 140342- quality control, batch releaser, Gedeon Richter-RUS JSC, Lesnaya st. 40, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- bulk manufacturer, Gedeon Richter-RUS JSC, Lesnaya st. 43/5, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager	Russia	Gedeon Richter Plc., Gyomroi ut 19-21, Budapest, 1103	Hungary	PoM	ЛПТ-№000753-ITI-AM 25.06.2025
----	--------	---------------------------------------	---------------------------	---	---	--------	---	---------	-----	----------------------------------