

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 05-2/25 on May 30, 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	Oxytocin Grindeks	oxytocin	solution for injection	5IU/ml; (10/2x5) ampoules 1ml in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, quality control	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	23055 30.05.2025
2	Ambroxol	ambroxol (ambroxol hydrochloride)	tablets	30mg; (20/2x10/) in blister, (40/4x10/) in blister	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	OTC	23056 30.05.2025
3	HUONS ARTICAINE HCl with Epinephrine Inj. 4% 1:100000	articaine (articaine hydrochloride), epinephrine (epinephrine bitartrate)	solution for injection	40mg/ml+0,01mg/ml; (50/5x10/) cartridges 1,7ml in a plastic tray	Huons Co., Ltd., 100, Biovalley-ro, Jecheon-si, Chungcheongbuk-do	Republic of Korea	Huons Co., Ltd., 8th Floor Huonglobal Bldg., A-dong Pangyo I-Square, 17 Changeop-ro, 13449 Sujeong-gu, Seongnam-si, Gyeonggi-do	Republic of Korea	PoM	23057 30.05.2025

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of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 05-2/25 on May 30,
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	Afrin extro	oxymetazoline (oxymetazoline hydrochloride)	spray nasal	0,5mg/ml; 15ml plastic vial with pump dispenser	Delpharm Montreal Inc., 3535, Route Transcanadienne, Pointe-Claire, Quebec H9R 1B4	Canada	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	23058 (001399) 30.05.2025
2	Lusefi	luseogliflozin	tablets film-coated	2,5mg; (30/2x15/) in blister, (60/4x15/) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Servier JSC, 125196, 7/8/9, Lesnaya str., 7, Moscow	Russia	PoM	23059 (005543) 30.05.2025
3	Lusefi	luseogliflozin	tablets film-coated	5mg; (30/2x15/) in blister, (60/4x15/) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Servier JSC, 125196, 7/8/9, Lesnaya str., 7, Moscow	Russia	PoM	23060 (005543) 30.05.2025
4	Vitamin E	alfa-tocopheril acetate	capsules	200mg; (30/3x10/) in blister, (60/6x10/) in blister	Minskintercaps U.V., 26/3, Inzhenemaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhenemaya str., 220075, Minsk	Republic of Belarus	PoM	23061 (008007) 30.05.2025
5	Vitamin E	alfa-tocopheril acetate	capsules	400mg; (30/3x10/) in blister, (60/6x10/) in blister	Minskintercaps U.V., 26/3, Inzhenemaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhenemaya str., 220075, Minsk	Republic of Belarus	OTC	23062 (008007) 30.05.2025
6	Ciprinol	ciprofloxacin (ciprofloxacin hydrochloride monohydrate)	tablets film-coated	250mg; (10/1x10/) 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	OTC	23063 (000412) 30.05.2025
7	Ciprinol	ciprofloxacin (ciprofloxacin hydrochloride monohydrate)	tablets film-coated	500mg; (10/1x10/) 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	23064 (000412) 30.05.2025

8	Singlon	montelukast (montelukast sodium)	tablets chewable	4mg; (28/4x7/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Poland 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	23065 (011611) 30.05.2025
9	Singlon	montelukast (montelukast sodium)	tablets chewable	5mg; (28/4x7/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Poland 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	23066 (011611) 30.05.2025
10	Warfarin STADA	warfarin (warfarin sodium)	tablets	2,5mg; (50) in plastic container, (100) in plastic container, (50/1x50/) in plastic container, (100/1x100/) in plastic container	Orifarm Manufacturing Poland Sp.z o.o., 12 Ksiestwa Lowickiego st., 99-420 Lyszkowice	Poland	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	PoM	23067 (012782) 30.05.2025
11	Acellbia	rituximab	concentrate for solution for infusion	10mg/ml; (2/1x2/) glass vial 10ml in blister, (1/1x1/) glass vial 30ml in blister, (1/1x1/) glass vial 50ml in blister	BIOCAD JSC, Intracity Municipality the Settlement of Strelina, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelina, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	23068 (015576) 30.05.2025
12	Acellbia	rituximab	concentrate for solution for infusion	10mg/ml; (2/1x2/) glass vial 10ml in blister, (1/1x1/) glass vial 30ml in blister, (1/1x1/) glass vial 50ml in blister	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalneye, Krasnogorsk Urban District, Moscow Region, 143422- quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalneye, Krasnogorsk Urban District, Moscow Region, 143422, Russia- bulk manufacturer, packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelina, the Settlement of Strelina, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	23069 (015576) 30.05.2025
13	Acellbia	rituximab	concentrate for solution for infusion	10mg/ml; (2/1x2/) glass vial 10ml in blister, (1/1x1/) glass vial 30ml in blister, (1/1x1/) glass vial 50ml in blister	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460	Russia	BIOCAD JSC, d. 38, str.1, pomeshch. 89, Intracity Municipality the Settlement of Strelina, ul. Svyazi, Saint Petersburg, 198515	Russia	PoM	23070 (015576) 30.05.2025

14	Acellbia	rituximab	concentrate for solution for infusion	10mg/ml; (2/1x2/) glass vial 10ml in blister, (1/1x1/) glass vial 30ml in blister, (1/1x1/) glass vial 50ml in blister	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460- secondary packager, quality control, batch releaser, BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515, Russia	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515	Russia	PoM	23071 (015576) 30.05.2025
15	Acellbia	rituximab	concentrate for solution for infusion	10mg/ml; (2/1x2/) glass vial 10ml in blister, (1/1x1/) glass vial 30ml in blister, (1/1x1/) glass vial 50ml in blister	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460- secondary packager, quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalneye, Krasnogorsk Urban District, Moscow Region, 143422, Russia- bulk manufacturer, primary packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515	Russia	PoM	23072 (015576) 30.05.2025

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of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 05-2/25 on May
30, 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	Semglee	insulin glargine	solution for s/c injection	100U/ml; (1) pre-filled pen 3ml	Biosmiller Collaborations Ireland Limited, Block B, The Crescent Building, Santry Demense Dublin, D09 C6X8- batch releaser, Biocon Snd. Bhd., No.1, Jalan Bioteknologi 1, Kawasan Perindustrian SiLC, 79200, Iskandar Puteri, Johor, Malaysia- bulk manufacturer, packager, quality control	Ireland	Biosimilar Collaborations Ireland Limited, Block B, The Crescent Building, Santry Demesne	Ireland	PoM	23073 30.05.2025
2	Rivaroxaban/ Pharmazac	rivaroxaban	tablets film-coated	10mg; (28/2x14) in blister	Remedica Ltd., Ahamon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	Pharmazac S.A., 31 Naousis street, 10447 Athens	Greece	PoM	23074 30.05.2025
3	Rivaroxaban/ Pharmazac	rivaroxaban	tablets film-coated	15mg; (28/2x14) in blister	Remedica Ltd., Ahamon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	Pharmazac S.A., 31 Naousis street, 10447 Athens	Greece	PoM	23075 30.05.2025
4	Rivaroxaban/ Pharmazac	rivaroxaban	tablets film-coated	20mg; (28/2x14) in blister	Remedica Ltd., Ahamon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	Pharmazac S.A., 31 Naousis street, 10447 Athens	Greece	PoM	23076 30.05.2025

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of the medicines recommended for the re-registration by the Center according to the meeting decision N 05-2/25 on May 30, 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	Acetylsalicylic acid	acetylsalicylic acid	tablets	500mg; (10) in blister, (10) in strip	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	23077 30.05.2025
2	Oftraquix	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	23078 30.05.2025
3	Intellan	ginkgo biloba, centella asiatica, herpestis monniera, coriandrum sativum, amomum subulatum, emblica officinalis	capsules	50mg+500mg+125mg+200mg+200mg+400mg; (20) plastic container, (60) plastic container	Herbion Pakistan Pvt. Ltd., Plot No. 30, Sector 28, Korangi Industrial Area, Karachi	Pakistan	Herbion Pakistan Pvt. Ltd., Plot No. 30, Sector 28, Korangi Industrial Area, Karachi	Pakistan	OTC	23079 30.05.2025

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of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 05-2/25 on May 30, 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	Metronidazole Denta	metronidazole (metronidazole benzoate), chlorhexidine (chlorhexidine gluconate 20% solution)	gel for gums	10mg/g+0,5mg/g; aluminium tube 20g	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	OTC	23080 30.05.2025
2	Lidocaine 5% ointment	lidocaine	ointment	50mg/g; aluminium tube 15g	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	23081 30.05.2025
3	Tiregis D	telmisartan, hydrochlorothiazide	tablets	40mg+12,5mg; (28/2x14) in blister, (56/4x14) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120-batch releaser, Actavis Ltd., BLB015, BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23082 30.05.2025
4	Tiregis D	telmisartan, hydrochlorothiazide	tablets	80mg+12,5mg; (28/2x14) in blister, (56/4x14) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120-batch releaser, Actavis Ltd., BLB015, BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23083 30.05.2025

5	Tiregis D	telmisartan, hydrochlorothiazide	tablets	80mg+25mg; (28/2x14/) in blister, (56/4x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Actavis Ltd., BLB015, BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23084 30.05.2025
6	Nurofen	ibuprofen	tablets coated	200mg (8/1x8/) in blister, (10/1x10/) in blister, (20/2x10/) in blister	Reckitt Benckiser Healthcare International LTD, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	Reckitt Benckiser Healthcare International LTD, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	OTC	23085 30.05.2025

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of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 05-2/25 on May 30, 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	SPEEDA Rabies Vaccine for Human Use (Vero cell), Freeze-Dried	Inactivated Rabies Virus	powder for suspension for i/m and i/d injection and solvent	2,5IU/ml; glass vial and solvent in ampoule 0,5ml and syringe, (5) glass vials and (5) solvents in ampoules 0,5ml	Liaoning Cheng Da Biotechnology Co., Ltd., No.1 Xinfang Street, Hunnan New District, Shenyang City- powder manufacturer, batch releaser, Jiangsu Desano Pharmaceuticals Co., Ltd., No.3 Kangan road, Economic & Technology Development District, Liyang City, Jiangsu Province- bulk manufacturer and primary packager of solvent	China	Liaoning Cheng Da Biotechnology Co., Ltd., No.1 Xinfang Street, Hunnan New District, Shenyang City	China	PoM	21684/1/1 30.05.2025
2	Cosentyx	secukinumab	solution for subcutaneous injection	150mg/ml; (1) pre-filled pen, (2) pre-filled pens	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20893/3/2 30.05.2025
3	Cosentyx	secukinumab	solution for subcutaneous injection	150mg/ml; (1) pre-filled syringe, (2) pre-filled syringes	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20894/3/2 30.05.2025
4	Atenolol	atenolol	tablets	50mg; (30/3x10) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64a, Chapayev str., Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapayev str., Borisov 222518, Minsk region	Republic of Belarus	PoM	20011/1/1 30.05.2025
5	Atenolol	atenolol	tablets	100mg; (30/3x10) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapayev str., Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapayev str., Borisov 222518, Minsk region	Republic of Belarus	PoM	20012/1/1 30.05.2025

6	Amlodipin	amlodipine (amlodipine besilate)	tablets	5mg; (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	20398/1/1 30.05.2025
7	Amlodipin	amlodipine (amlodipine besilate)	tablets	10mg; (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	20012/1/1 30.05.2025
8	Acetylsalicylic acid	acetylsalicylic acid	tablets	500mg; (10/1x1) tablets in paper/carton strip, (10/1x10') tablets in paper/ polimer strip, (50/5x10') in strip, (20/2x10') and (50/5x10') in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 24, Stroiteley str., 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	20509/2/2 30.05.2025
9	Phosphogliv-Pharmstandard	phospholipids, sodium glycyrrhizinate	powder lyophilized for solution for i/v injection	500mg+200mg; (5) glass vials 2,5g and (5) solvent in ampoules 10ml	Pharmstandard-Ufa VITA OJSC, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	Pharmstandard-Ufa VITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	PoM	21962/1/1 30.05.2025
10	Trimebat forte	trimebutine (trimebutine maleate)	tablets prolonged-release film-coated	300mg; (20/2x10) in blister, (60/6x10) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St, 2- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Centemo LLC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2, Russia-quality control (microbiological)	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2.	Russia	PoM	19333/5/3 30.05.2025
11	Noofen	gamma-amino-beta-phenylbutyric acid hydrochloride	capsules	250mg; (20/2x10') in blister	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	PoM	20379/4/1 30.05.2025
12	Noofen	gamma-amino-beta-phenylbutyric acid hydrochloride	capsules	500mg; (24/4x6) in blister	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	PoM	20380/4/1 30.05.2025
13	Pregabalin Canon	pregabalin	capsules	75mg; (14/2x7), in blister, (14/1x14), in blister, (56/8x7), in blister, (56/4x14), in blister	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100	Russia	PoM	19835/2/2 30.05.2025

14	Pregabalin Canon	pregabalin	capsules	150mg; (14/2x7/), in blister, (14/1x14/), in blister, (56/8x7/), in blister, (56/4x14/), in blister	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100	Russia	PoM	19836/2/2 30.05.2025
15	Pregabalin Canon	pregabalin	capsules	300mg; (14/2x7/), in blister, (14/1x14/), in blister, (56/8x7/), in blister, (56/4x14/), in blister	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100	Russia	PoM	19837/2/2 30.05.2025

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of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 05-2/25 on May 30, 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	Ingavirin	pentanedioic acid (pentanedioic acid imidazolyl ethanamide)	capsules	90mg; (7/1x7/) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	20120/3/1 30.05.2025
2	Tiregis D	telmisartan, hydrochlorothiazide	tablets	40mg+12,5mg; (28/2x14) in blister, (56/4x14) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Actavis Ltd., BLB015, BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19272/5 30.05.2025
3	Tiregis D	telmisartan, hydrochlorothiazide	tablets	80mg+12,5mg; (28/2x14) in blister, (56/4x14) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Actavis Ltd., BLB015, BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19273/5 30.05.2025
4	Tiregis D	telmisartan, hydrochlorothiazide	tablets	80mg+25mg; (28/2x14) in blister, (56/4x14) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Actavis Ltd., BLB015, BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19274/5 30.05.2025
5	Glaveral	omeprazole	capsules gastro-resistant hard	20mg; (14) in plastic container, (28) in plastic container	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorfofi, Attici	Greece	PoM	21300/2 30.05.2025

6	Lidocaine 5% ointment	lidocaine	ointment	50mg/g; aluminium tube 15g	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	19148/1 30.05.2025
7	Trinomia	acetylsalicylic acid, atorvastatin, ramipril	capsules	100mg+20mg+2,5mg; (28/4x7/) in blister	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	21485/1 30.05.2025
8	Trinomia	acetylsalicylic acid, atorvastatin, ramipril	capsules	100mg+20mg+5mg; (28/4x7/) in blister	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	21486/1 30.05.2025
9	Trinomia	acetylsalicylic acid, atorvastatin, ramipril	capsules	100mg+20mg+10mg; (28/4x7/) in blister	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	21487/1 30.05.2025
10	Cosentyx	secukinumab	lyophilisate for solution for subcutaneous injection	150mg; glass vial	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20892/3/1 30.05.2025
11	MOMETASONE-ASTERIA	mometasone (mometasone furoate)	spray nasal	0,5mg/ml; plastic bottle with metering pump 18ml (140 dose)	ILDONG PHARMACEUTICAL CO., LTD, 25, Gongdan 1-ro, Anseong-si, Gyeonggi-do- batch releaser, SAMCHUNDANG PHARM. CO., LTD, 71, Jeyakgongdan 2-gil, Hyangnam-eup, Hwaseong-si, Gyeonggi-do- bulk manufacturer, packager, quality control	Republic of Korea	ASTERIA LLC, 72/3 Nairi Zaryan street, 0051 Yerevan	Republic of Armenia	PoM	22993/1 30.05.2025
12	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	22149/1 30.05.2025
13	Intellan	ginkgo biloba, centella asiatica, herpestis monniera, coriandrum sativum, amomum subulatum, emblica officinalis	capsules	50mg+500mg+125mg+200mg+200mg+400mg; (20) plastic container, (60) plastic container	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	OTC	18982/1 30.05.2025

14	Grammidin for kids	gramicidin S (gramicidin S dihydrochloride), cetylpyridinium chloride (cetylpyridinium chloride monohydrate)	tablets to be sucked	1,5mg+1mg; (18/2x9) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	19855/5/1 30.05.2025
15	Grammidin with anesthetic neo	gramicidin S (gramicidin S dihydrochloride), oxybuprocaine (oxybuprocaine hydrochloride), cetylpyridinium chloride (cetylpyridinium chloride monohydrate)	tablets to be sucked	3mg+0,2mg+1mg; (18/2x9) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Centemo LTD, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	21237/2 30.05.2025
16	Meloxicam	meloxicam	solution for i/m injection	10mg/ml; (5) ampoules 1.5ml	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	20765/4/1 30.05.2025
17	Wobenzym	pancreatin, trypsin, chymotrypsin, bromelain, papain, amylase, lipase, rutoside trihydrate	tablets gastro- resistant	300 prot.UA+360FIP-U+300FIP- U+225FIP-U+90FIP-U+50FIP- U+34FIP-U+50mg (40/2x20) and (200/10x20) in blister, (800) in plastic container	Mucos Emulsionsgesellschaft mbH, Mirastrasse 17, D-13509 Berlin	Germany	Mucos Pharma GmbH & Co. KG, Mirastrasse 17, D-13509 Berlin	Germany	OTC	21258/4 30.05.2025
18	Intellan	ginkgo biloba, centella asiatica, herpestis monniera, coriandrum sativum, amomum subulatum, emblica officinalis	syrup	50mg/10ml+500mg/10ml+50mg/10m l+150mg/10ml+150mg/10ml+200mg /10ml; 90ml glass bottle, 120ml glass bottle, 150ml glass bottle	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	OTC	18981/1 30.05.2025

19	Rexocef	cefpodoxime (cefpodoxime 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	21692/3 30.05.2025
20	Rexocef	cefpodoxime (cefpodoxime proxetil)	tablets film-coated	100mg; (10/1x10) in blister, (20/2x10) in blister	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	21690/2 30.05.2025
21	Rexocef	cefpodoxime (cefpodoxime proxetil)	tablets film-coated	200mg; (10/1x10) in blister, (20/2x10) in blister	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	21691/2 30.05.2025
22	Methyluracil	methyluracil	ointment for external use	100mg/g; aluminum tube 15g	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, No2, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	OTC	21882/1 30.05.2025
23	Piracetam	piracetam	capsules	400mg; (10) in blister, (60/6x10) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64A, No4, 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	22150/1 30.05.2025

24	Bactrim	sulfamethoxazole, trimethoprim	suspension oral	200mg/5ml+40mg/5ml; 100ml glass bottle	Eumedica Pharmaceuticals AG, Arnold Bocklin-Strasse 1, 4051 Basel- batch releaser, Cenexi SAS, Rue Marcel et Jacques Gaucher, 52, Fontenay sous Bois, 94120, France- bulk manufacturer, packager, quality control	Switzerland	Eumedica Pharmaceuticals AG, Arnold Bocklin-Strasse 1, 4051 Basel	Switzerland	PoM	20232/430.05.2025
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LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 05-2/25 on May 30, 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	Coraxan 5mg	ivabradine	tablets film-coated	5mg; (14/1x14) in blister, (28/2x14) in blister, (52/2x26) in blister, (56/4x14) in blister, (1000-300000) 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	ЛПТ-№000306-ITI-AM 30.05.2025
2	Coraxan 5mg	ivabradine	tablets film-coated	5mg; (14/1x14) in blister, (28/2x14) in blister, (52/2x26) in blister, (56/4x14) in blister, (1000-300000) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, quality control, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№000306-ITI-AM 30.05.2025
3	Coraxan 5mg	ivabradine	tablets film-coated	5mg; (14/1x14) in blister, (28/2x14) in blister, (52/2x26) in blister, (56/4x14) in blister, (1000-300000) 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-№000306-ITI-AM 30.05.2025
4	Coraxan 7,5mg	ivabradine	tablets film-coated	7,5mg; (14/1x14) in blister, (28/2x14) in blister, (52/2x26) in blister, (56/4x14) in blister, (1000-300000) 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	ЛПТ-№000306-ITI-AM 30.05.2025

5	Coraxan 7,5mg	ivabradine	tablets film-coated	7,5mg; (14/1x14') in blister, (28/2x14') in blister, (52/2x26') in blister, (56/4x14') in blister, (1000-300000) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, quality control, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№000306-ITI-AM 30.05.2025
6	Coraxan 7,5mg	ivabradine	tablets film-coated	7,5mg; (14/1x14') in blister, (28/2x14') in blister, (52/2x26') in blister, (56/4x14') in blister, (1000-300000) 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-№000306-ITI-AM 30.05.2025
7	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	ЛПТ-№000545-ITI-AM 30.05.2025