

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 10-2/25 on November 03, 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	Gensulin M30 (30/70)	insulin human (recombinant DNA)	suspension for injection	100IU/ml; glass vial 10ml	Bioton S.A., Macierzysz, 12 Poznanska Street, 05-850, Ozarow Mazowiecki	Poland	Bioton S.A., 5 Strascinska Street, 02-516, Warsaw	Poland	PoM	23597 03.11.2025
2	Gensulin N	insulin human (recombinant DNA)	suspension for injection	100IU/ml; glass vial 10ml	Bioton S.A., Macierzysz, 12 Poznanska Street, 05-850, Ozarow Mazowiecki	Poland	Bioton S.A., 5 Strascinska Street, 02-516, Warsaw	Poland	PoM	23598 03.11.2025
3	Gensulin R	insulin human (recombinant DNA)	suspension for injection	100IU/ml; glass vial 10ml	Bioton S.A., Macierzysz, 12 Poznanska Street, 05-850, Ozarow Mazowiecki	Poland	Bioton S.A., 5 Strascinska Street, 02-516, Warsaw	Poland	PoM	23599 03.11.2025
4	Sirtodine	moxonidine	tablets film-coated	0,2mg; (30/3x10) in blister	Lekpharm JLLC, 223141, Minsk region, Logoysk, Minskaya str. 2A/4	Republic of Belarus	"Lekpharm" JLLC, 223141, Logoysk, Minskaya str. 2A, room 301	Republic of Belarus	PoM	23600 03.11.2025
5	Sirtodine	moxonidine	tablets film-coated	0,4mg; (30/3x10) in blister	Lekpharm JLLC, 223141, Minsk region, Logoysk, Minskaya str. 2A/4	Republic of Belarus	"Lekpharm" JLLC, 223141, Logoysk, Minskaya str. 2A, room 301	Republic of Belarus	PoM	23601 03.11.2025
6	Daplyza Tablets 5mg	dapagliflozin	tablets film-coated	5mg; (28/4x7) in blister	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	PoM	23602 03.11.2025
7	Daplyza Tablets 10mg	dapagliflozin	tablets film-coated	10mg; (28/4x7) in blister	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	PoM	23603 03.11.2025
8	Ipratrol-Pharmstandard	ipratropium bromide monohydrate (ipratropium bromide), fenoterol (fenoterol hydrobromid)	solution for inhalation	0,25mg+0,5mg; 20ml glass vial-dropper	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	PoM	23604 03.11.2025

9	Rabeprazole- Pharmstandard	rabeprazole (rabeprazole sodium)	tablets gastro-resistant	10mg; (28/4x7/) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	23605 03.11.2025
10	Rabeprazole- Pharmstandard	rabeprazole (rabeprazole sodium)	tablets gastro-resistant	20mg; (28/4x7/) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	PoM	23606 03.11.2025
11	Soliget	solifenacin (solifenacin succinate)	tablets film-coated	5mg; (10/1x10) in blister	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	PoM	23607 03.11.2025
12	Soliget	solifenacin (solifenacin succinate)	tablets film-coated	10mg; (10/1x10) in blister	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	PoM	23608 03.11.2025
13	SNUP Extra	xylometazoline (xylometazoline hydrochloride), ipratropium bromide (ipratropium bromide monohydrate)	spray nasal	70mcg/dose+84mcg/dose; plastic bottle 10ml (60 dose)	Curida AS, Solbaervegen 5, Elverum, NO-2409	Norway	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	23609 03.11.2025
14	Vonab	vonoprazan	tablets film-coated	10mg; (28/4x7/) in blister	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	PoM	23610 03.11.2025
15	Vonab	vonoprazan	tablets film-coated	20mg; (28/4x7/) in blister	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	PoM	23611 03.11.2025
16	Sitaget	sitagliptin	tablets film-coated	50mg; (35/5x7/) in blister	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	PoM	23612 03.11.2025
17	Sitaget	sitagliptin	tablets film-coated	100mg; (35/5x7/) in blister	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	PoM	23613 03.11.2025
18	Dipoveg	betamethasone (betamethasone valerate)	ointment for external use	1mg/g; aluminum tube 15g	BALKANPHARMA-RAZGRAD AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	VEGAPHARM LLP, Unit 18, Normon road 53, Greenwich Centre Business park, SE10 9QF, London	United Kingdom	PoM	23614 03.11.2025

19	Convalis-Pharmstandard	gabapentin	capsules	300mg; (50/5x10') in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmaceutical Firm "LEKKO" CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s, b. 278	Russia	PoM	23615 03.11.2025
20	Lorsept-Intensive	benzylamine hydrochloride, cetylpyridinium chloride	spray oromucosal	1,5mg/ml+5mg/ml; 30ml plastic vial with pump dispenser	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	PoM	23616 03.11.2025
21	Anaprilin	propranolol (propranolol hydrochloride)	tablets	10mg; (50/5x10') in blister, (50/2x25') in blister, (100/4x25') 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	23617 03.11.2025
22	Coldrex MaxGrip	paracetamol, phenylephrine (phenylephrine hydrochloride), ascorbic acid	powder for oral solution with lemon flavour	1000mg+10mg+40mg; (10) sachets 6,427g	Hemofarm d.o.o., Novakovici bb, Banja Luka 78000	Bosnia And Herzegovina	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	OTC	23618 03.11.2025
23	Articaine-Binergy with adrenaline	articaine (articaine hydrochloride), epinephrine (epinephrine hydrotartrate)	solution for injection	40mg/ml+0,05mg/ml; (10/1x10') glass cartridges 1,7ml in plastic tray, (50/5x10') glass cartridges 1,7ml in plastic tray, (100/10x10') glass cartridges 1,7ml in plastic tray	FKP "Armavirskaya biofabrika", 352212, Krasnodar reg, Novokubanskiy district, Progress settlement, str. Mechnikova, b. 11	Russia	"Binergia" CJSC, 143910, Moscow region, Balashikha, Krupeshina str., b. 1	Russia	PoM	23619 03.11.2025
24	Articaine-Binergy with adrenaline	articaine (articaine hydrochloride), epinephrine (epinephrine hydrotartrate)	solution for injection	40mg/ml+0,05mg/ml; (10/1x10') glass cartridges 1,8ml in plastic tray, (50/5x10') glass cartridges 1,8ml in plastic tray, (100/10x10') glass cartridges 1,8ml in plastic tray	FKP "Armavirskaya biofabrika", 352212, Krasnodar reg, Novokubanskiy district, Progress settlement, str. Mechnikova, b. 11	Russia	"Binergia" CJSC, 143910, Moscow region, Balashikha, Krupeshina str., b. 1	Russia	PoM	23620 03.11.2025
25	Articaine-Binergia with adrenaline	articaine (articaine hydrochloride), epinephrine (epinephrine hydrotartrate)	solution for injection	40mg/ml+0,05mg/ml; (5/1x5') ampoules 2ml in plastic tray, (10/2x5') ampoules 2ml in plastic tray	FKP "Armavirskaya biofabrika", 352212, Krasnodar reg, Novokubanskiy district, Progress settlement, str. Mechnikova, b. 11	Russia	"Binergia" CJSC, 143910, Moscow region, Balashikha, Krupeshina str., b. 1	Russia	PoM	23621 03.11.2025

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of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 10-2/25 on November 03, 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	Albendazole	albendazole	tablets-film coated	400mg; (1/1x1) in blister, (3/3x1) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64A, ul. Chapayeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapayeva, Borisov, 222518, Minsk region	Republic of Belarus	PoM	23534 (018958) 03.11.2025
2	Zinacoren	rivaroxaban	tablet film-coated	2,5mg; (56/4x14) in blister, (56/2x28) in blister, (60/6x10) in blister	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 St., 83-200 Starogard Gdanski	Poland	PoM	23535 (003210) 03.11.2025
3	Zinacoren	rivaroxaban	tablet film-coated	10mg; (28/1x28) in blister, (28/2x14) in blister, (30/3x10) in blister	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 St., 83-200 Starogard Gdanski	Poland	PoM	23536 (003210) 03.11.2025

4	Zinacoren	rivaroxaban	tablet film-coated	15mg; (28/1x28/) in blister, (28/2x14/) in blister, (30/3x10/) in blister	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 Pelpinska St., 83-200 Starogard Gdanski	Poland	PoM	23537 (003210) 03.11.2025
5	Zinacoren	rivaroxaban	tablet film-coated	20mg; (28/1x28/) in blister, (28/2x14/) in blister, (30/3x10/) in blister	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 Pelpinska St., 83-200 Starogard Gdanski	Poland	PoM	23538 (003210) 03.11.2025
6	Revolade	eltrombopag (eltrombopag olamine)	tablets film- coated	25mg; (28/4x7/) in blister	Novartis Pharma GmbH, Roonstrasse 25 und Obere Turnstrasse 8-10, 90429 Nurnberg- batch releaser, Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona, Spain- bulk manufacturer, packager, quality control	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	23539 (009413) 03.11.2025
7	Revolade	eltrombopag (eltrombopag olamine)	tablets film- coated	25mg; (28/4x7/) in blister	Novartis Pharmaceutical Manufacturing LLC, Verovskova Ulica 57, Ljubljana, 1000	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	23540 (009413) 03.11.2025
8	Revolade	eltrombopag (eltrombopag olamine)	tablets film- coated	25mg; (28/4x7/) in blister	Zdanie 1, Promyshlennaya Zona No 1, Skopinsky Rayon, Ryazan Oblast, 391800- secondary packager, batch releaser, Novartis Pharmaceutical Manufacturing LLC, Verovskova Ulica 57, Ljubljana, 1000, Slovenia- bulk manufacturer, primary packager, quality control	Russia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	23541 (009413) 03.11.2025

9	Revolade	eltrombopag (eltrombopag olamine)	tablets film-coated	50mg; (28/4x7/) in blister	Novartis Pharma GmbH, Roonstrasse 25 und Obere Turnstrasse 8-10, 90429 Nurnberg- batch releaser, Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona, Spain- bulk manufacturer, packager, quality control	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	23542 (009413) 03.11.2025
10	Revolade	eltrombopag (eltrombopag olamine)	tablets film-coated	50mg; (28/4x7/) in blister	Novartis Pharmaceutical Manufacturing LLC, Verovskova Ulica 57, Ljubljana, 1000	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	23543 (009413) 03.11.2025
11	Revolade	eltrombopag (eltrombopag olamine)	tablets film-coated	50mg; (28/4x7/) in blister	Zdanie 1, Promyshlennaya Zona No 1, Skopinsky Rayon, Ryazan Oblast, 391800- secondary packager, batch releaser, Novartis Pharmaceutical Manufacturing LLC, Verovskova Ulica 57, Ljubljana, 1000, Slovenia- bulk manufacturer, primary packager, quality control	Russia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	23544 (009413) 03.11.2025
12	Aerius	desloratadine	tablets film-coated	5mg; (10/1x10/) in blister, (20/2x10/) in blister, (30/3x10/) in blister	Bayer Bitterfeld GmbH, Ortsteil Greppin Salegaster Chaussee 1, 06803 Bitterfeld-Wolfen	Germany	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	PoM	23545 (002251) 03.11.2025
13	Roxera	rosuvastatin (rosuvastatin calcium)	tablets film-coated	5mg; (28/2x14/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	23546 (002249) 03.11.2025
14	Roxera	rosuvastatin (rosuvastatin calcium)	tablets film-coated	5mg; (28/2x14/) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	23547 (002249) 03.11.2025
15	Roxera	rosuvastatin (rosuvastatin calcium)	tablets film-coated	5mg; (28/2x14/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Labena, d.o.o, Teslova 30, 1000 Lyublyana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	23548 (002249) 03.11.2025

16	Roxera	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (28/2x14) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	23549 (002249) 03.11.2025
17	Roxera	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (28/2x14) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	23550 (002249) 03.11.2025
18	Roxera	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (28/2x14) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Labena, d.o.o, Teslova 30, 1000 Lyublyana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	23551 (002249) 03.11.2025
19	Roxera	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (28/2x14) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	23552 (002249) 03.11.2025
20	Roxera	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (28/2x14) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	23553 (002249) 03.11.2025
21	Roxera	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (28/2x14) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Labena, d.o.o, Teslova 30, 1000 Lyublyana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	23554 (002249) 03.11.2025
22	Roxera	rosuvastatin (rosuvastatin calcium)	tablets film-coated	40mg; (28/4x7) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	23555 (002249) 03.11.2025
23	Roxera	rosuvastatin (rosuvastatin calcium)	tablets film-coated	40mg; (28/4x7) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Labena, d.o.o, Teslova 30, 1000 Lyublyana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	23556 (002249) 03.11.2025

24	Moxodin	moxonidine	tablets film-coated	0,2mg; (20/2x10) in blister, (30/3x10) in blister	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	PoM	23557 (006853) 03.11.2025
25	Moxodin	moxonidine	tablets film-coated	0,4mg; (20/2x10) in blister, (30/3x10) in blister	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	PoM	23558 (006853) 03.11.2025
26	Broncholytin	glaucine (glaucine hydrobromide), ephedrine (ephedrine hydrochloride)	syrup	5,75mg/5ml+4,6mg/5ml; 125g glass or plastic bottle and measuring cup	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia- batch releaser, Sopharma JSC, Vrabovo vlg. 5660, district of Lovetch, Bulgaria- bulk manufacturer, packager, quality control	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	23559 (002249) 03.11.2025
27	Hartil Amlo	ramipril, amlodipine (amlodipine besilate)	capsules	5mg+5mg; (28/4x7) in blister, (30/3x10) in blister, (56/8x7) 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	23560 (009520) 03.11.2025
28	Hartil Amlo	ramipril, amlodipine (amlodipine besilate)	capsules	5mg+10mg; (28/4x7) in blister, (30/3x10) in blister, (56/8x7) 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	23561 (009520) 03.11.2025
29	Hartil Amlo	ramipril, amlodipine (amlodipine besilate)	capsules	10mg+5mg; (28/4x7) in blister, (30/3x10) in blister, (56/8x7) 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	23562 (009520) 03.11.2025
30	Hartil Amlo	ramipril, amlodipine (amlodipine besilate)	capsules	10mg+10mg; (28/4x7) in blister, (30/3x10) in blister, (56/8x7) 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	23563 (009520) 03.11.2025
31	Amlessa	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate)	tablets	4mg+5mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	23564 (008598) 03.11.2025
32	Amlessa	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate)	tablets	4mg+10mg; (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	23565 (008598) 03.11.2025
33	Amlessa	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate)	tablets	8mg+5mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	23566 (008598) 03.11.2025

34	Amlessa	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate)	tablets	8mg+10mg; (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	23567 (008598) 03.11.2025
35	Racobactam	piperacillin (piperacillin sodium), tazobactam (tazobactam sodium)	powder for concentrate for solution for infusion	2g+0,25g; glass vial 20ml, glass vial 30ml	Ruzpharma LLC, 143132, Moscow Region, Ruzskiy district, Tuchkovo Village, Komsomolskaya str., bld. 12-1	Russia	Alpharma LLC, 127247, ext. ter. city municipal district Vostochnoe Degunino, Dmitrovskoe Ave., bld.100-2 office 4541R4, Moscow	Russia	PoM	23568 (003041) 03.11.2025
36	Racobactam	piperacillin (piperacillin sodium), tazobactam (tazobactam sodium)	powder for concentrate for solution for infusion	3g+0,375g; glass vial 20ml, glass vial 30ml	Ruzpharma LLC, 143132, Moscow Region, Ruzskiy district, Tuchkovo Village, Komsomolskaya str., bld. 12-1	Russia	Alpharma LLC, 127247, ext. ter. city municipal district Vostochnoe Degunino, Dmitrovskoe Ave., bld.100-2 office 4541R4, Moscow	Russia	PoM	23569 (003041) 03.11.2025
37	Racobactam	piperacillin (piperacillin sodium), tazobactam (tazobactam sodium)	powder for concentrate for solution for infusion	4,0g+0,5g; glass vial 20ml, glass vial 30ml	Ruzpharma LLC, 143132, Moscow Region, Ruzskiy district, Tuchkovo Village, Komsomolskaya str., bld. 12-1	Russia	Alpharma LLC, 127247, ext. ter. city municipal district Vostochnoe Degunino, Dmitrovskoe Ave., bld.100-2 office 4541R4, Moscow	Russia	PoM	23570 (003041) 03.11.2025
38	Racobactam	piperacillin (piperacillin sodium), tazobactam (tazobactam sodium)	powder for concentrate for solution for infusion	2g+0,25g; glass vial 20ml, glass vial 30ml	ALTEGRA JSC, Moscow region, Dubna district, Dubna, Science Avenue, building 33- secondary packager, quality control (physicochemical), batch releaser, "Ruzpharma" LLC, 143132, Moscow Region, Ruzskiy district, Tuchkovo Village, Komsomolskaya str., bld. 12-1, Russia- bulk manufacturer, primary packager, Farmoborona LLC, 46a Gagarina street, Korolev, Moscow Region, Russia- quality control (microbiological)	Russia	Alpharma LLC, 127247, ext. ter. city municipal district Vostochnoe Degunino, Dmitrovskoe Ave., bld.100-2 office 4541R4, Moscow	Russia	PoM	23571 (003041) 03.11.2025

39	Racobactam	piperacillin (piperacillin sodium), tazobactam (tazobactam sodium)	powder for concentrate for solution for infusion	3g+0,375g; glass vial 20ml, glass vial 30ml	ALTEGRA JSC, Moscow region, Dubna district, Dubna, Science Avenue, building 33- secondary packager, quality control (physicochemical), batch releaser, "Ruzpharma" LLC, 143132, Moscow Region, Ruzskiy district, Tuchkovo Village, Komsomolskaya str., bld. 12-1, Russia- bulk manufacturer, primary packager, Farmoborona LLC, 46a Gagarina street, Korolev, Moscow Region, Russia- quality control (microbiological)	Russia	Alpharma LLC, 127247, ext. ter. city municipal district Vostochnoe Degunino, Dmitrovskoe Ave., bld.100-2 office 4541R4, Moscow	Russia	PoM	23572 (003041) 03.11.2025
40	Racobactam	piperacillin (piperacillin sodium), tazobactam (tazobactam sodium)	powder for concentrate for solution for infusion	4,0g+0,5g; glass vial 20ml, glass vial 30ml	ALTEGRA JSC, Moscow region, Dubna district, Dubna, Science Avenue, building 33- secondary packager, quality control (physicochemical), batch releaser, "Ruzpharma" LLC, 143132, Moscow Region, Ruzskiy district, Tuchkovo Village, Komsomolskaya str., bld. 12-1, Russia- bulk manufacturer, primary packager, Farmoborona LLC, 46a Gagarina street, Korolev, Moscow Region, Russia- quality control (microbiological)	Russia	Alpharma LLC, 127247, ext. ter. city municipal district Vostochnoe Degunino, Dmitrovskoe Ave., bld.100-2 office 4541R4, Moscow	Russia	PoM	23573 (003041) 03.11.2025
41	Aquadetrim Vitamin D3 Medana	colecalfiferol	drops oral	15000IU/ml; 10ml glass bottle, 15ml glass bottle, 30ml glass bottle	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	PoM	23574 (009506) 03.11.2025
42	Aquadetrim Vitamin D3 Medana	colecalfiferol	drops oral	15000IU/ml; (1) glass bottle 10ml, (2) glass bottles 10ml	Joint Stock Company "Himpharm" (JSC "Himpharm"), 160019, Shymkent city, Al-Farabi district, Sharaf Rashidov Street, No. 81	Kazakhstan	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	PoM	23575 (009506) 03.11.2025

43	Septanest with adrenaline	articaine (articaine hydrochloride), adrenaline (adrenaline tartrate)	solution for injection	40mg/ml+5mcg/ml; (50/5x10/) cartridges 1,7ml in blister	Septodont, 58 rue du Pont de Creteil, Saint-Maur-des-Fosses, 94100	France	Septodont, 58 rue du Pont de Creteil, Saint-Maur-des-Fosses, 94100	France	PoM	23576 (019081) 03.11.2025
44	Septanest with adrenaline	articaine (articaine hydrochloride), adrenaline (adrenaline tartrate)	solution for injection	40mg/ml+10mcg/ml; (50/5x10/) cartridges 1,7ml in blister	Septodont, 58 rue du Pont de Creteil, Saint-Maur-des-Fosses, 94100	France	Septodont, 58 rue du Pont de Creteil, Saint-Maur-des-Fosses, 94100	France	PoM	23577 (019081) 03.11.2025
45	Sinupret extract	gentiane radix, primulae flos, rumicis herba, sambuci flos, verbenae herba	tablets coated	160mg; (20/2x10/) in blister, (40/4x10/) in blister	Bionorica SE, Kerschensteinerstrasse 11-15, 92318 Neumarkt in der Oberpfalz- packager, quality control, batch releaser, Rottendorf Pharma GmbH, Ostenfelder Strasse 51-61, 59320 Ennigerloh, Germany- bulk manufacturer	Germany	Bionorica SE, Kerschensteinerstrasse 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	23578 (000253) 03.11.2025
46	Sinupret extract	gentiane radix, primulae flos, rumicis herba, sambuci flos, verbenae herba	tablets coated	160mg; (20/2x10/) in blister, (40/4x10/) in blister	Bionorica SE, Kerschensteinerstrasse 11-15, 92318 Neumarkt in der Oberpfalz- packager, quality control, batch releaser, Wiewelhofe GmbH, Dornebrink 19, 49479 Ibbenburen, Germany- bulk manufacturer	Germany	Bionorica SE, Kerschensteinerstrasse 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	23579 (000253) 03.11.2025
47	Sinupret extract	gentiane radix, primulae flos, rumicis herba, sambuci flos, verbenae herba	tablets coated	160mg; (20/2x10/) in blister, (40/4x10/) in blister	Bionorica Pharmaceuticals LLC, 396333, Voronezh Region, Novousmanskoy Municipal District, Nikolskoye Rural Settlement, Maslovsky Industrial Park territory, 1st Parkovaya Street, Building 2, Russia- packager, quality control(physicochemical), batch releaser, "ICLS Biotechnology" LLC10A, 8th Liniya Street, Vidnoye, 142700, Leninsky Urban District, Moscow Region, Russia- quality control (microbiological), Wiewelhofe GmbH, Dornebrink 19, 49479 Ibbenburen, Germany- bulk manufacturer	Russia	Bionorica SE, Kerschensteinerstrasse 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	23580 (000253) 03.11.2025

48	Sinupret extract	gentiane radix, primulae flos, rumicis herba, sambuci flos, verbenae herba	tablets coated	160mg; (20/2x10/) in blister, (40/4x10/) in blister	Bionorica Pharmaceuticals LLC, Voronezh Region, Novousmanskoy Municipal District, Nikolskoye Rural Settlement, Maslovsky Industrial Park territory, 1st Parkovaya Street, Building 2, Russia- packager, quality control (physicochemical), batch releaser, "ICLS Biotechnology" LLC10A, 8th Liniya Street, Vidnoye, Leninsky Urban District, Moscow Region, Russia- quality control (microbiological), Rottendorf Pharma GmbH, Ostenfelder Strasse 51-61, 59320 Ennigerloh, Germany- bulk manufacturer	Russia	Bionorica SE, Kerschensteinerstrasse 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	23581 (000253) 03.11.2025
49	Utrogestan	progesterone	capsules soft	100mg; (28/2x14/) in blister	Cyndeia Pharma S.L., Poligono Industrial Emiliano Revilla Sanz, Avenida de Agreda, 31, Olvega 42110, (Soria)	Spain	Besins Healthcare SA, Rue Washington 80, Ixelles 1050	Belgium	PoM	23582 (012686) 03.11.2025
50	Utrogestan	progesterone	capsules soft	100mg; (28/2x14/) in blister	Besins Manufacturing Rus LLC, 1-st Technologicheskaya st., 14, Yaroslavl, Yaroslavl region, 150066- bulk manufacturer, packager, quality control (physicochemical), batch releaser, FSBI "IMCEAACMP" of Roszdravnadzor, 1-st Technologicheskaya st., 4, Yaroslavl, Yaroslavl city district, Yaroslavl region, Russia- quality control (microbiological)	Russia	Besins Healthcare SA, Rue Washington 80, Ixelles 1050	Belgium	PoM	23583 (012686) 03.11.2025
51	Utrogestan	progesterone	capsules soft	100mg; (28/2x14/) in blister	Besins Manufacturing Rus LLC, 1-st Technologicheskaya st., 14, Yaroslavl, Yaroslavl region, 150066- bulk manufacturer, packager, quality control (physicochemical), batch releaser, FARMOBORONA LLC, bldg. 72A, Serkovo village, Shchelkovo city district, Moscow region, Russia - quality control (microbiological)	Russia	Besins Healthcare SA, Rue Washington 80, Ixelles 1050	Belgium	PoM	23584 (012686) 03.11.2025

52	Utrogestan	progesterone	capsules soft	100mg; (28/2x14) in blister	Besins Manufacturing Rus LLC, 1-st Technologicheskaya st., 14, Yaroslavl, Yaroslavl region, 150066- bulk manufacturer, packager, quality control (physicochemical), batch releaser, FARMOBORONA LLC, Gagarin st., 46A, Korolev, Moscow region, Russia- quality control (microbiological)	Russia	Besins Healthcare SA, Rue Washington 80, Ixelles 1050	Belgium	PoM	23585 (012686) 03.11.2025
53	Utrogestan	progesterone	capsules soft	200mg; (14/2x7) in blister	Cyndeia Pharma S.L., Poligono Industrial Emiliano Revilla Sanz, Avenida de Agreda, 31, Olvega 42110, (Soria)	Spain	Besins Healthcare SA, Rue Washington 80, Ixelles 1050	Belgium	PoM	23586 (012686) 03.11.2025
54	Utrogestan	progesterone	capsules soft	200mg; (14/2x7) in blister	Besins Manufacturing Rus LLC, 1-st Technologicheskaya st., 14, Yaroslavl, Yaroslavl region, 150066- bulk manufacturer, packager, quality control (physicochemical), batch releaser, FSBI "IMCEAACMP" of Roszdravnadzor, 1-st Technologicheskaya st., 4, Yaroslavl, Yaroslavl city district, Yaroslavl region, Russia- quality control (microbiological)	Russia	Besins Healthcare SA, Rue Washington 80, Ixelles 1050	Belgium	PoM	23587 (012686) 03.11.2025
55	Utrogestan	progesterone	capsules soft	200mg; (14/2x7) in blister	Besins Manufacturing Rus LLC, 1-st Technologicheskaya st., 14, Yaroslavl, Yaroslavl region, 150066- bulk manufacturer, packager, quality control (physicochemical), batch releaser, FARMOBORONA LLC, bldg. 72A, Serkovo village, Shchelkovo city district, Moscow region, Russia - quality control (microbiological)	Russia	Besins Healthcare SA, Rue Washington 80, Ixelles 1050	Belgium	PoM	23588 (012686) 03.11.2025

56	Utrogestan	progesterone	capsules soft	200mg; (14/2x7) in blister	Besins Manufacturing Rus LLC, 1-st Technologicheskaya st., 14, Yaroslavl, Yaroslavl region, 150066- bulk manufacturer, packager, quality control (physicochemical), batch releaser, FARMOBORONA LLC, Gagarin st., 46A, Korolev, Moscow region, Russia- quality control (microbiological)	Russia	Besins Healthcare SA, Rue Washington 80, Ixelles 1050	Belgium	PoM	23589 (012686) 03.11.2025
57	Ambroxol	ambroxol (ambroxol hydrochloride)	tablets	30mg; (20/2x10) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov, Minsk region, 222518-batch releaser, Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64A, ul. Chapaeva, Borisov, Minsk region, 222518, Republic of Belarus-bulk manufacturer, quality control (physicochemical), Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64A, No4, ul. Chapaeva, Borisov, Minsk region, 222518, Republic of Belarus- packager, Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64/27, ul. Chapaeva, Borisov, Minsk region, 222518, Republic of Belarus- quality control (microbiological)	Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov, Minsk region, 222518	Republic of Belarus	OTC	23590 (016374) 03.11.2025
58	TheraFlu Extra Lemon	paracetamol, phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate)	powder for oral solution with lemon flavour	650mg+10mg+20mg; (1) sachet 15g, (2) sachets 15g, (3) sachets 15g, (4) sachets 15g, (5) sachets 15g, (6) sachets 15g, (7) sachets 15g, (8) sachets 15g, (10) sachets 15g, (12) sachets 15g, (25) sachets 15g	Delpharm Orleans, 5 avenue de Concyr, Orleans Cedex 2, 45071	France	JSC "Haleon Rus", Presnenskaya Naberezhnaya, 10, unit III, room 9, 6 floor, Moscow, 123112	Russia	OTC	23591 (010523) 03.11.2025

59	Milurit	allopurinol	tablets	150mg; (30) in glass bottle, (50) in glass bottle	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	23592 (029824) 03.11.2025
60	Milurit	allopurinol	tablets	200mg; (30) in glass bottle, (50) in glass bottle	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	23593 (029824) 03.11.2025
61	Ziglip tablets 145mg	fenofibrate	tablets	145mg; (30/3x10) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- packager, quality control, batch releaser, Ethypharm-Le Grand Quevilly, chemin de la Poudriere, Le Grand Quevilly, 76120, France- I-bulk granules, Ethypharm- Chateauneuf En Thymerais, Zone Industrielle de Saint-Arnoult, Chateauneuf En Thymerais, 28170, France- II-tableting	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	23533 (023839) 03.11.2025

LIST

of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 10-2/25 on
November 03, 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	Ibuprofen Tablets USP 400 mg	ibuprofen	tablets film-coated	400mg; (100) in plastic bottle	Amneal Pharmaceuticals Pvt. Ltd., Oral Solid Unit, Plot No-16 & 17, Pharmez SEZ, Sarkhej-Bavla Highway, Vil. Matoda, TA-Sanand, Dist. Ahmedabad, 382213, Gujarat State	India	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	23594 03.11.2025
2	Ibuprofen Tablets USP 600 mg	ibuprofen	tablets film-coated	600mg; (100) in plastic bottle	Amneal Pharmaceuticals Pvt. Ltd., Oral Solid Unit, Plot No-16 & 17, Pharmez SEZ, Sarkhej-Bavla Highway, Vil. Matoda, TA-Sanand, Dist. Ahmedabad, 382213, Gujarat State	India	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	23595 03.11.2025
3	Ibuprofen Tablets USP 800 mg	ibuprofen	tablets film-coated	800mg; (100) in plastic bottle	Amneal Pharmaceuticals Pvt. Ltd., Oral Solid Unit, Plot No-16 & 17, Pharmez SEZ, Sarkhej-Bavla Highway, Vil. Matoda, TA-Sanand, Dist. Ahmedabad, 382213, Gujarat State	India	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	23596 03.11.2025

LIST

of the registered variations under the EAEU procedure requiring registration approved by the Center according to the meeting decision N 10-2/25 on
November 03, 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	Nalgesin	naproxen (naproxen sodium)	tablets film-coated	275mg; (10/1x10) in blister, (20/2x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Labena, d.o.o, Teslova 30, 1000 Lyublyana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	JIT-N°000256-ITI-AM 03.11.2025
2	Nalgesin forte	naproxen (naproxen sodium)	tablets film-coated	550mg; (10/1x10) in blister, (20/2x10) in blister, (60/6x10) in blister	KRKA, d.d., Novo mesto, Smarjaska cesta 6, 8501 Novo mesto- packager, quality control (microbiological), batch releaser, Unichem Laboratories Limited, Plots 15-18, Pileme Industrial Estate, Pileme, Bardez GoA, India- bulk manufacturer, KRKA, tovarna zdravil, d.d., Novo mesto, Povahova ulica 5, 8501 Novo Mesto, Slovenia- quality control (physicochemical)	Slovenia	KRKA, d.d., Novo mesto, Smarjaska cesta 6, 8501 Novo mesto	Slovenia	PoM	JIT-N°000259-ITI-AM 03.11.2025

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 10-2/25 on November 03, 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	Lecrolyn	cromoglicic acid (sodium cromoglicate)	drops eye	40mg/ml; 5ml plastic vial-dropper	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	OTC	23526 03.11.2025
2	Oftan Catachrom	cytochrome C, adenosine, nicotinamide	drops eye	0,675mg/ml+2mg/ml+20mg/ml; 10ml plastic bottle-dropper	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	23527 03.11.2025
3	Moxifloxan	moxifloxacin (moxifloxacin hydrochloride)	drops eye (solution)	5mg/ml; plastic vial-dropper 5ml	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	Antibiotic-Razgrad AD, 68, Aprilsko vastanie Blvd, Razgrad, 7200	Bulgaria	PoM	23528 03.11.2025
4	Caffeine-benzoate sodium Tatpharm	caffeine (caffeine-benzoate sodium)	tablets	100mg; (6) in strip	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	PoM	23529 03.11.2025

5	Tivicay	dolutegravir (dolutegravir sodium)	tablets film-coated	50mg; (30) in plastic container	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos- packager, batch releaser, Glaxo Operations UK Ltd, Priory street, Ware, SG 12 0DJ, UK- bulk manufacturer, quality control	Spain	ViiV Healthcare B.V. Huister Heideweg 62, Zeist, 3705 LZ	the Netherlands	PoM	23530 03.11.2025
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of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 10-2/25 on November 03, 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	Cardiolife	acetylsalicylic acid, magnesium hydroxide	tablets coated	75mg+15,2mg; (96/4x24) 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	OTC	23518 03.11.2025
2	Dexamethasone	dexamethasone (dexamethasone sodium phosphate)	solution for i/m and i/v injection	4mg/ml; (10/2x5) ampoules 1ml 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	23519 03.11.2025
3	Ringer	sodium chloride, potassium chloride, calcium chloride (calcium chloride dihydrate)	solution for infusion	8,6mg/ml+0,3mg/ml+0,33mg/ml; 100ml plastic pack, 200ml plastic pack, 250ml plastic pack, 500ml plastic pack, 1000ml plastic pack, 2000ml plastic pack, 3000ml plastic pack	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	23520 03.11.2025
4	Rheopolyglucin-PharmaTech	dextran 40	solution for infusion	100mg/ml; 100ml plastic pack, 200ml plastic pack, 250ml plastic pack, 400ml plastic pack, 500ml plastic pack	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	23521 03.11.2025
5	Armenicum	iodine, potassium iodide, lithium chloride, polyvinyl alcohol, dextrin, sodium chloride	paste for external use	13,6mg/g+20,4mg/g+0,3mg/g+5,1mg/g+170,3mg/g+15,3mg/g; 25g aluminium tube, 50g aluminium tube	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	'Armenicum+' CJSC, 37 Nalbandyan, Yerevan 0001	Republic of Armenia	PoM	23522 03.11.2025

6	AMIKATON 500mg/2ml	amikacin (amikacin sulfate)	solution for injection/ infusion	500mg/2ml; (10) ampoules 2ml	Medochemie Ltd., 48 Iapetou street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupoleos street, 3011 Limassol	Cyprus	PoM	23523 03.11.2025
7	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	23524 03.11.2025
8	Encifer	Iron sucrose complex	solution for i/v injection	20mg/ml; (5) ampoules 5ml	Samrudh Pharmaceuticals Pvt. Ltd., Plot No. J-174, J-168, J-168/1, MIDC, Tarapur, Boisar, Thane 401506 Maharashtra State	India	Emcure Pharmaceuticals Ltd., T-184, M.I.D.C., Bhosari, Pune- 411026, Maharashtra State	India	PoM	23525 03.11.2025

LIST

of the medicines recommended for the re-registration under the EAEU procedure by the Center according to the meeting decision N 10-2/25 on
November 03, 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	B12 Ankermann	cianocobalamina	tablets coated	1mg; (50/2x25/) in blister, (100/4x25/) in blister	Artesan Pharma GmbH & Co. KG, Wendlandstrasse 1, 29439 Luechow- bulk manufacturer, packager, quality control (physico-chemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological)	Austria	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boblingen	Germany	PoM	23532 (027841) 03.11.2025

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 10-2/25 on November 03, 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	Octolipen-Pharmstandard	thioctic acid (alfa-lipoic acid)	capsules	300mg; (30/3x10) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	PoM	21609/1/1 03.11.2025
2	Paclitaxel-Ebewe	paclitaxel	concentrate for solution for infusion	6mg/ml; glass vial 5ml	Fareva Unterach GmbH, Mondseestrasse 11, Unterach, Unterach Am Attersee, Oberoesterreich, 4866	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	22931/1/1 03.11.2025
3	Paclitaxel-Ebewe	paclitaxel	concentrate for solution for infusion	6mg/ml; glass vial 16,7ml	Fareva Unterach GmbH, Mondseestrasse 11, Unterach, Unterach Am Attersee, Oberoesterreich, 4866	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	22932/1/1 03.11.2025
4	Paclitaxel-Ebewe	paclitaxel	concentrate for solution for infusion	6mg/ml; glass vial 25ml	Fareva Unterach GmbH, Mondseestrasse 11, Unterach, Unterach Am Attersee, Oberoesterreich, 4866	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	22933/1/1 03.11.2025
5	Pantoprazole Sodium Delayed-Release Tablets USP 20 mg	pantoprazole (pantoprazole sodium sesquihydrate)	delayed-release tablets	20mg; (90) plastic container	Amneal Pharmaceuticals Pvt. Ltd., Survey No. 634, 637 to 641, Near Hotel Kankavati, Sarkhej-Bavla Highway Vill. Rajoda, Tal.-Bavla, Dist.-Ahmedabad, 382 220, Gujarat State	India	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22852/1/1 03.11.2025
6	Pantoprazole Sodium Delayed-Release Tablets USP 40 mg	pantoprazole (pantoprazole sodium sesquihydrate)	delayed-release tablets	40mg; (90) plastic container	Amneal Pharmaceuticals Pvt. Ltd., Survey No. 634, 637 to 641, Near Hotel Kankavati, Sarkhej-Bavla Highway Vill. Rajoda, Tal.-Bavla, Dist.-Ahmedabad, 382 220, Gujarat State	India	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22853/1/1 03.11.2025

7	Influecin	oseltamivir (oseltamivir phosphate)	capsules hard	75mg; (10/1x10) 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, packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100	Russia	PoM	21775/1/1 03.11.2025
8	AqViplatin	oxaliplatin	concentrate for solution for infusion	50mg/10ml; glass vial 10ml	AqVida GmbH, Kaiser-Wilhelm-Str. 89, Hamburg, 20355- batch releaser, AqVida GmbH, werkstrasse 21, Dassow, Mecklenburg-Vorpommern 23942, Germany- bulk manufacturer, packager, quality control	Germany	Aversi-Rational Ltd, David Kobahidze str. 33, 0198 Tbilisi	Georgia	PoM	19951/1/1 03.11.2025
9	AqViplatin	oxaliplatin	concentrate for solution for infusion	100mg/20ml; glass vial 20ml	AqVida GmbH, Kaiser-Wilhelm-Str. 89, Hamburg, 20355- batch releaser, AqVida GmbH, werkstrasse 21, Dassow, Mecklenburg-Vorpommern 23942, Germany- bulk manufacturer, packager, quality control	Germany	Aversi-Rational Ltd, David Kobahidze str. 33, 0198 Tbilisi	Georgia	PoM	19952/1/1 03.11.2025
10	CARDIO ASPIRIN- ASTERIA	acetylsalicylic acid	tablets	100mg; (60/6x10) in blister	Medinfar Manufacturing S.A, Parque Industrial Armando Martins Tavares, Rua Outeiro Da Armada No 5, Coimbra, Condeixa-A-Nova, 3150-194, Sebal	Portugal	Asteria LLC, 72/3 Nairi Zaryan, 0051 Yerevan	Republic of Armenia	OTC	23230/1/1 03.11.2025
11	Lisinopril	lisinopril	tablets	5mg; (30/3x10) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64a No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	PoM	20434/1/1 03.11.2025
12	Lisinopril	lisinopril	tablets	10mg; (30/3x10) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64a No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	PoM	20435/1/1 03.11.2025

13	Codelac Broncho- Oticipharm Pro	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 oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov 6 str., building 1, 238315	Russia	OTC	23169/1/1 03.11.2025
14	Spironolactone Tablets USP 25 mg	spironolactone	tablets film-coated	25mg; (100) in plastic container	Amneal Pharmaceuticals Pvt. Ltd., Survey No. 634, 637 to 641, Near Hotel Kankavati, Sarkhej-Bavla Highway Vill. Rajoda, Tal.-Bavla, Dist.-Ahmedabad, 382 220, Gujarat State	India	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22724/1/1 03.11.2025
15	Spironolactone Tablets USP 50 mg	spironolactone	tablets film-coated	50mg; (100) in plastic container	Amneal Pharmaceuticals Pvt. Ltd., Survey No. 634, 637 to 641, Near Hotel Kankavati, Sarkhej-Bavla Highway Vill. Rajoda, Tal.-Bavla, Dist.-Ahmedabad, 382 220, Gujarat State	India	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22725/1/1 03.11.2025
16	Spironolactone Tablets USP 100 mg	spironolactone	tablets film-coated	100mg; (100) in plastic container	Amneal Pharmaceuticals Pvt. Ltd., Survey No. 634, 637 to 641, Near Hotel Kankavati, Sarkhej-Bavla Highway Vill. Rajoda, Tal.-Bavla, Dist.-Ahmedabad, 382 220, Gujarat State	India	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22726/1/1 03.11.2025

LIST

of variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting decision N

10-2/25 on November 03, 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	Vabysmo	faricimab	solution for intraocular injection	120mg/ml; glass vial and filter needle	F. Hoffmann-La Roche Ltd., Wurmisweg 4303 Kaiseraugst	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, 4058, Basel	Switzerland	PoM	JITI-N°001664-ITI-AM 03.11.2025
2	Telmista H	hydrochlorothiazide, telmisartan	tablets	12,5mg+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	JITI-N°000335-ITI-AM 03.11.2025
3	Telmista H	hydrochlorothiazide, telmisartan	tablets	12,5mg+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	JITI-N°000335-ITI-AM 03.11.2025
4	Telmista H	hydrochlorothiazide, telmisartan	tablets	25mg+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	JITI-N°000335-ITI-AM 03.11.2025
5	Detrombin	nadroparin calcium	solution for s/c injection	2850anti-XaIU/0,3ml; (2/1x2/) pre-filled syringes 0,3ml in blister, (10/5x2/) pre-filled syringes 0,3ml in blister	SotexPharmFirm" CJSC, bld. 11, village Belikovo, Sergiev-Posad municipal district, Moscow Region- quality control, batch releaser, "Sotex"PharmFirm" CJSC, bld. 11, section 1, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- bulk manufacturer, primary packager, "Sotex"PharmFirm" CJSC, bld. 12, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- secondary packager	Russia	"Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, city Sergiev-Posad, Moscow Region, 141345	Russia	PoM	JITI-N°000337-ITI-AM 03.11.2025

6	Detrombin	nadroparin calcium	solution for s/c injection	2850anti-XaIU/0,3ml; (2/1x2/) pre-filled syringes 0,3ml in blister, (10/5x2/) pre-filled syringes 0,3ml in blister	SotexPharmFirm" CJSC, bld. 11, village Belikovo, Sergiev-Posad municipal district, Moscow Region- quality control, batch releaser, "Sotex"PharmFirm" CJSC, bld. 10, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- bulk manufacturer, primary packager, "Sotex"PharmFirm" CJSC, bld. 11, section 1, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- secondary packager	Russia	"Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, city Sergiev-Posad, Moscow Region, 141345	Russia	PoM	ЖИТ-№000337-ИТИ-AM 03.11.2025
7	Detrombin	nadroparin calcium	solution for s/c injection	3800anti-XaIU/0,4ml; (2/1x2/) pre-filled syringes 0,4ml in blister, (10/5x2/) pre-filled syringes 0,4ml in blister	SotexPharmFirm" CJSC, bld. 11, village Belikovo, Sergiev-Posad municipal district, Moscow Region- quality control, batch releaser, "Sotex"PharmFirm" CJSC, bld. 11, section 1, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- bulk manufacturer, primary packager, "Sotex"PharmFirm" CJSC, bld. 12, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- secondary packager	Russia	"Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, city Sergiev-Posad, Moscow Region, 141345	Russia	PoM	ЖИТ-№000337-ИТИ-AM 03.11.2025
8	Detrombin	nadroparin calcium	solution for s/c injection	3800anti-XaIU/0,4ml; (2/1x2/) pre-filled syringes 0,4ml in blister, (10/5x2/) pre-filled syringes 0,4ml in blister	SotexPharmFirm" CJSC, bld. 11, village Belikovo, Sergiev-Posad municipal district, Moscow Region- quality control, batch releaser, "Sotex"PharmFirm" CJSC, bld. 10, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- bulk manufacturer, primary packager, "Sotex"PharmFirm" CJSC, bld. 11, section 1, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- secondary packager	Russia	"Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, city Sergiev-Posad, Moscow Region, 141345	Russia	PoM	ЖИТ-№000337-ИТИ-AM 03.11.2025

9	Detrombin	nadroparin calcium	solution for s/c injection	5700anti-XaIU/0,6ml; (2/1x2/) pre-filled syringes 0,6ml in blister, (10/5x2/) pre-filled syringes 0,6ml in blister	SotexPharmFirm" CJSC, bld. 11, village Belikovo, Sergiev-Posad municipal district, Moscow Region- quality control, batch releaser, "Sotex"PharmFirm" CJSC, bld. 11, section 1, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- bulk manufacturer, primary packager, "Sotex"PharmFirm" CJSC, bld. 12, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- secondary packager	Russia	"Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, city Sergiev-Posad, Moscow Region, 141345	Russia	PoM	ЛПТ-№000337-ЛТИ-AM 03.11.2025
10	Detrombin	nadroparin calcium	solution for s/c injection	5700anti-XaIU/0,6ml; (2/1x2/) pre-filled syringes 0,6ml in blister, (10/5x2/) pre-filled syringes 0,6ml in blister	SotexPharmFirm" CJSC, bld. 11, village Belikovo, Sergiev-Posad municipal district, Moscow Region- quality control, batch releaser, "Sotex"PharmFirm" CJSC, bld. 10, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- bulk manufacturer, primary packager, "Sotex"PharmFirm" CJSC, bld. 11, section 1, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- secondary packager	Russia	"Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, city Sergiev-Posad, Moscow Region, 141345	Russia	PoM	ЛПТ-№000337-ЛТИ-AM 03.11.2025
11	Detrombin	nadroparin calcium	solution for s/c injection	7600anti-XaIU/0,8ml; (2/1x2/) pre-filled syringes 0,8ml in blister, (10/5x2/) pre-filled syringes 0,8ml in blister	SotexPharmFirm" CJSC, bld. 11, village Belikovo, Sergiev-Posad municipal district, Moscow Region- quality control, batch releaser, "Sotex"PharmFirm" CJSC, bld. 11, section 1, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- bulk manufacturer, primary packager, "Sotex"PharmFirm" CJSC, bld. 12, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- secondary packager	Russia	"Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, city Sergiev-Posad, Moscow Region, 141345	Russia	PoM	ЛПТ-№000337-ЛТИ-AM 03.11.2025

12	Detrombin	nadroparin calcium	solution for s/c injection	7600anti-XaIU/0,8ml; (2/1x2/) pre-filled syringes 0,8ml in blister, (10/5x2/) pre-filled syringes 0,8ml in blister	SotexPharmFirm" CJSC, bld. 11, village Belikovo, Sergiev-Posad municipal district, Moscow Region- quality control, batch releaser, "Sotex"PharmFirm" CJSC, bld. 10, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- bulk manufacturer, primary packager, "Sotex"PharmFirm" CJSC, bld. 11, section 1, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- secondary packager	Russia	"Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, city Sergiev-Posad, Moscow Region, 141345	Russia	PoM	ЛПТ-№000337-ЛПТ-AM 03.11.2025
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LIST

of variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 10-2/25 on November 03, 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	Tonoxib	etoricoxib	tablets film-coated	90mg; (30/3x10) in blister	Mash for Pharmaceutical Industries & Cosmetic (Mash Premiere)-pharmaceuticals, Third industrial zone-part No.54/2-Badr city for Mash	Egypt	Pharmaceutical Industries & Cosmetic (Mash Premiere), S6-3 Region 6, Second District 90 st., Fifth Settlement, New Cairo City	Egypt	PoM	23250/1 03.11.2025
2	Sodium chloride	sodium chloride	solution for injection	9mg/ml; (10/1x10) ampoules 5ml label banderol, (10/1x10) ampoules 5ml dividella, (10/1x10) ampoules 5ml CAMA	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, N1 ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	PoM	20465/3/1 03.11.2025
3	Magnesium sulfate	magnesium sulfate	solution for i/v and i/m injection	250mg/ml; (10) ampoules 5ml, (10) ampoules 5ml label banderol, (10) ampoules 5ml dividella	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, No10/1, No11/1 ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	22687/1 03.11.2025
4	Fluconazole	fluconazole	tablets coated	150mg; (2/1x2) in blister	PJSC "Technolog", 8, Stara prrizna street, Uman, Cherkassy region, 20300	Ukraine	PJSC "Technolog", 8, Stara prrizna street, Uman, Cherkassy region, 20300	Ukraine	PoM	21911/1 03.11.2025
5	Ondansetron	ondansetron (ondansetron hydrochloride dihydrate)	solution for injection	2mg/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	21198/1 03.11.2025
6	Ondansetron	ondansetron (ondansetron hydrochloride dihydrate)	solution for injection	2mg/ml; (5) ampoules 4ml, (5/1x5) ampoules 4ml 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	21199/1 03.11.2025

7	Armenicum	iodine, potassium iodide, lithium chloride, polyvinyl alcohol, dextrin, sodium chloride	paste for external use	13,6mg/g+20,4mg/g+0,3mg/g+5,1mg/g+170,3mg/g+15,3mg/g; 25g aluminium tube, 50g aluminium tube	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	'Armenicum+' CJSC, 37 Nalbandyan, Yerevan 0001	Republic of Armenia	PoM	19847/1 03.11.2025
8	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	21141/3/2 03.11.2025
9	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	21142/3/2 03.11.2025
10	Mexidol	ethylmethylhydroxypyridine succinate	tablets film-coated	125mg; (30/3x10) in blister, (50/5x10) in blister	CJSC Â«ZiO-ZdorovieÂ», 142103, Moscow region, Podolsk, str. Zheleznodorozhnaya, 2	Russia	LLC Â«RPC Â«PHARMASOFTÂ», 115407, Moscow, Sudostroitel' naya str., bld. 41, floor 1, premises 12	Russia	PoM	21946/1 03.11.2025
11	Dolgit	ibuprofen	gel for external use	5g/100g; 20g aluminium tube, 50g aluminium tube, 100g aluminium tube	Dolorgiet GmbH & Co.KG, Otto-von-Guericke-Strasse 1, 53757 Sankt Augustin- bulk manufacturer, packager, batch releaser, Dolorgiet GmbH & Co.KG, Otto-von-Guericke-Strasse 1, 53757 Sankt Augustin, Germany, 2.GBA Pharma GmbH, Anna-Sigmund-Strasse 82061 Neuried, Germany- quality control (physicochemical), BAV INSTITUT fur Hygiene und Qualitatssicherung GmbH ,Hanns-Martin-Schleyer-Str. 25, D-77656 Offenburg, Germany- quality control (microbiological)	Germany	Dolorgiet GmbH & Co.KG, Otto-von-Guericke Str. 1, 53757 Sankt Augustin	Germany	OTC	20836/4/1 03.11.2025
12	Caffeine-benzoate sodium Tatpharm	caffeine (caffeine-benzoate sodium)	tablets	100mg; (6) in strip	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	PoM	19376/1 03.11.2025
13	Amikaton 500mg/2ml	amikacin (amikacin sulfate)	solution for injection/infusion	500mg/2ml; (10) ampoules 2ml	Medochemie Ltd., 48 Iapetou street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupoleos street, 3011 Limassol	Cyprus	PoM	19884/3 03.11.2025

14	Paclitaxel 6mg/ml	paclitaxel	concentrate for solution for infusion	6mg/ml; 5ml glass vial	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY - batch releaser, Sichuan Huiyu Pharmaceuticals Co.,Ltd, Building 3, No.333, Hanyang Road, Shizhong District, Neijiang, Sichuan, China- bulk manufacturer, packager, quality control	UK	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY	UK	PoM	20768/2/1 03.11.2025
15	Paclitaxel 6mg/ml	paclitaxel	concentrate for solution for infusion	6mg/ml; 16,7ml glass vial	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY - batch releaser, Sichuan Huiyu Pharmaceuticals Co.,Ltd, Building 3, No.333, Hanyang Road, Shizhong District, Neijiang, Sichuan, China- bulk manufacturer, packager, quality control	UK	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY	UK	PoM	20769/1/1 03.11.2025
16	Paclitaxel 6mg/ml	paclitaxel	concentrate for solution for infusion	6mg/ml; 50ml glass vial	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY - batch releaser, Sichuan Huiyu Pharmaceuticals Co.,Ltd, Building 3, No.333, Hanyang Road, Shizhong District, Neijiang, Sichuan, China- bulk manufacturer, packager, quality control	UK	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY	UK	PoM	20770/1/1 03.11.2025
17	Tivicay	dolutegravir (dolutegravir sodium)	tablets film- coated	50mg; (30) in plastic container	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos- packager, batch releaser, Glaxo Operations UK Ltd, Priory street, Ware, SG 12 0DJ, UK- bulk manufacturer, quality control	Spain	ViiV Healthcare B.V. Huister Heideweg 62, Zeist, 3705 LZ	the Netherlands	PoM	19332/1 03.11.2025
18	Zanotazon	colecalfiferol	capsules soft	50000IU; (20/1x20) in blister	Zahravi Pharmaceutical Company, Alinasab Industrial Town, Serum Darou St., Opp. Agricultural Training Center, 19th Km. Tehran Road, Tabriz	Iran	Giga Farm LLC, Gogunc str.3/5, Gyumri	Republic of Armenia	PoM	21275/3 03.11.2025
19	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	19463/5 03.11.2025

LIST

of registered variations under the EAEU procedure requiring registration and reformulation of registration certificate approved by the Center according to the meeting decision N 10-2/25 on November 03, 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	Xalkori	crizotinib	capsules	200mg; (10/1x10/) in blister, (60/6x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Mosswaldalee 1, 79090 Freiburg	Germany	Pfizer Inc., 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	ЖИТ-№002125-ИТИ-AM 03.11.2025
2	Xalkori	crizotinib	capsules	250mg; (10/1x10/) in blister, (60/6x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Mosswaldalee 1, 79090 Freiburg	Germany	Pfizer Inc., 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	ЖИТ-№002125-ИТИ-AM 03.11.2025
3	Xalkori	crizotinib	capsules	250mg; (60/6x10/) in blister	Pharmstandard-UfaVITA OJSC, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	Pfizer Inc., 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	ЖИТ-№002125-ИТИ-AM 03.11.2025

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 10-2/25 on November 03, 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	Cavinton Forte	vinpocetine	tablets	10mg; (30/2x15/) in blister, (90/6x15/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°002183-ITI-AM 03.11.2025
2	Cavinton Forte	vinpocetine	tablets	10mg; (30/2x15/) in blister, (90/6x15/) in blister	Gedeon Richter-RUS JSC, Lesnaya st. 40, Shuvoe, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, quality control, batch releaser, Gedeon Richter-RUS JSC, Lesnaya st. 43/5, Shuvoe, Moscow region, Yegoriyevsky district, 140342, Russia- packager	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°002183-ITI-AM 03.11.2025
3	ARIFON Retard	indapamide	tablets film-coated prolonged-release	1,5mg; (30/1x30/) in blister, (90/3x30/) 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	JITI-N°000156-ITI-AM 03.11.2025
4	Panangin	magnesium aspartate (magnesium aspartate tetrahydrate), potassium aspartate (potassium aspartate hemihydrate)	tablets film-coated	140mg+158mg; (50) in plastic container, (60/3x20/) in blister, (100/5x20/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Gedeon Richter Plc., 2510 Dorog, Esztergomi st. 27, Hungary- quality control (microbiological)	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	OTC	JITI-N°005141-ITI-AM 03.11.2025

5	Panangin	magnesium aspartate (magnesium aspartate tetrahydrate), potassium aspartate (potassium aspartate hemihydrate)	tablets film-coated	140mg+158mg; (50) in plastic container, (100/4x25/) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, batch releaser, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	OTC	ЖИТ-№005141-ИТИ-AM 03.11.2025
6	Panangin	magnesium aspartate (magnesium aspartate tetrahydrate), potassium aspartate (potassium aspartate hemihydrate)	tablets film-coated	140mg+158mg; (50) in plastic container, (50/2x25/) in blister, (100/4x25/) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest, Hungary- bulk manufacturer, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	OTC	ЖИТ-№005141-ИТИ-AM 03.11.2025

7	Panangin	magnesium aspartate (magnesium aspartate tetrahydrate), potassium aspartate (potassium aspartate hemihydrate)	tablets film-coated	140mg+158mg; (50) in plastic container, (50/2x25/) in blister, (100/4x25/) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest, Hungary- bulk manufacturer, primary packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- secondary packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	OTC	ЖИТ-№005141-ИТИ-AM 03.11.2025
8	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	ЖИТ-№000215-ИТИ-AM 03.11.2025
9	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	ЖИТ-№000215-ИТИ-AM 03.11.2025
10	D3-CAPS ULTRA	colecalfiferol	capsules chewing with banana flavour	500IU; (30/3x10/) in blister	Minskintercaps U.V., 26/3, Inzhennemaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhennemaya str., 220075, Minsk	Republic of Belarus	OTC	ЖИТ-№001288-ИТИ-AM 03.11.2025
11	D3-CAPS ULTRA	colecalfiferol	capsules chewing with orange flavour	500IU; (30/3x10/) in blister	Minskintercaps U.V., 26/3, Inzhennemaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhennemaya str., 220075, Minsk	Republic of Belarus	OTC	ЖИТ-№001288-ИТИ-AM 03.11.2025

12	Sea Buckthorn Oil	hippopheae oil	suppositories rectal	500mg; (10/2x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, s.1- quality control and 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	ЖИТ-№002256-ИТИ-AM 03.11.2025
13	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	ЖИТ-№000545-ИТИ-AM 03.11.2025
14	Bioson	dry extract of passiflora, doxylamine (doxylamine hydrogen succinate)	tablets film-coated	300mg+3,75mg; (10/1x10/) in blister, (30/3x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	OTC	ЖИТ-№007499-ПТ-AM 03.11.2025
15	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	ЖИТ-№004230-ИТИ-AM 03.11.2025
16	Aspirin Cardio	acetylsalicylic acid	tablets gastro-resistant	100mg; (28/2x14/) in blister	Bayer Bitterfeld GmbH, Ortsteil Greppin, Salegaster Chaussee 1, 06803 Bitterfeld-Wolfen- packager, quality control, batch releaser, Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen, Germany- bulk manufacturer	Germany	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	OTC	ЖИТ-№004558-ИТИ-AM 03.11.2025
17	Aspirin Cardio	acetylsalicylic acid	tablets gastro-resistant	100mg; (28/2x14/) in blister	Bayer Bitterfeld GmbH, Ortsteil Greppin Salegaster Chaussee 1, 06803 Bitterfeld-Wolfen	Germany	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	OTC	ЖИТ-№004558-ИТИ-AM 03.11.2025
18	Ovitrelle	choriogonadotropin alfa	solution for s/c injection	250mcg/0,5ml; (1) glass pre-filled syringe with needle in plastic pack	Merck Serono S.p.A., Via delle Magnolie 15, 70026 Modugno (BA)	Italy	Merck LLC, 35 Valovaya Street, Moscow 115054	Russia	PoM	ЖИТ-№004594-ИТИ-AM 03.11.2025

19	Co-Dirotan	lisinopril (lisinopril dihydrate), hydrochlorothiazide	tablets	10mg+12,5mg; (10/1x10') in blister, (30/3x10') in blister	Gedeon Richter Polska Poland Co. Ltd., str. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control (microbiological), batch releaser, Gedeon Richter Poland Co. Ltd., str. Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager, quality control (physicochemical)	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°005758-ITI-AM 03.11.2025
20	Co-Dirotan	lisinopril (lisinopril dihydrate), hydrochlorothiazide	tablets	20mg+12,5mg; (10/1x10') in blister, (30/3x10') in blister	Gedeon Richter Polska Poland Co. Ltd., str. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control (microbiological), batch releaser, Gedeon Richter Poland Co. Ltd., str. Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager, quality control (physicochemical)	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°005758-ITI-AM 03.11.2025
21	Noliprel A	perindopril arginine, indapamide	tablets film-coated	2,5mg+0,625mg; (14) in plastic container, (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000179-ITI-AM 03.11.2025
22	Noliprel A	perindopril arginine, indapamide	tablets film-coated	2,5mg+0,625mg; (14) in plastic container, (29) in plastic container, (30) in plastic container, (90) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000179-ITI-AM 03.11.2025
23	Noliprel A	perindopril arginine, indapamide	tablets film-coated	2,5mg+0,625mg; (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	JITI-N°000179-ITI-AM 03.11.2025
24	Noliprel A	perindopril arginine, indapamide	tablets film-coated	2,5mg+0,625mg; (14) in plastic container, (30) in plastic container, (90) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000179-ITI-AM 03.11.2025

25	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	ЖПІ-№000179-ІТІ-АМ 03.11.2025
26	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	ЖПІ-№000175-ІТІ-АМ 03.11.2025
27	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	ЖПІ-№000175-ІТІ-АМ 03.11.2025
28	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	ЖПІ-№000175-ІТІ-АМ 03.11.2025
29	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	5mg+1,25mg+5mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЖПІ-№002311-ІТІ-АМ 03.11.2025
30	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	5mg+1,25mg+5mg; (30) plastic container, (90) 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	ЖПІ-№002311-ІТІ-АМ 03.11.2025
31	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	5mg+1,25mg+5mg; (30) plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЖПІ-№002311-ІТІ-АМ 03.11.2025

32	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	5mg+2,5mg+10mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЖПІ-№002311-ІТІ-АМ 03.11.2025
33	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	5mg+2,5mg+10mg; (30) plastic container, (90) 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	ЖПІ-№002311-ІТІ-АМ 03.11.2025
34	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	5mg+2,5mg+10mg; (30) plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЖПІ-№002311-ІТІ-АМ 03.11.2025
35	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	10mg+1,25mg+5mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЖПІ-№002311-ІТІ-АМ 03.11.2025
36	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	10mg+1,25mg+5mg; (30) plastic container, (90) 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	ЖПІ-№002311-ІТІ-АМ 03.11.2025
37	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	10mg+1,25mg+5mg; (30) plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЖПІ-№002311-ІТІ-АМ 03.11.2025
38	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	10mg+2,5mg+10mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЖПІ-№002311-ІТІ-АМ 03.11.2025

39	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	10mg+2,5mg+10mg; (30) plastic container, (90) plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЖПТ-N°002311-ПТ-AM 03.11.2025
40	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	10mg+2,5mg+10mg; (30) plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakorskoye, Moscow- packager, batch releaser, Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЖПТ-N°002311-ПТ-AM 03.11.2025
41	Skudexa	tramadol (tramadol hydrochloride), dextetoprofen	tablets film-coated	75mg+25mg; (15/1x15/) in blister	Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden	Germany	Menarini International Operations Luxembourg S.A., 1, avenue de la Gare, 1611	Luxembourg	PoM	ЖПТ-N°002976-ПТ-AM 03.11.2025