

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 03-2/25 on March 31, 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	Tingora	ticagrelor	tablets film-coated	60mg; (56/4x14) in blister	ALKALOID AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- batch releaser, Elpen Pharmaceutical Co. Inc., Marathonos Avenue 95, Pikermi Attiki, 19009, Greece- bulk manufacturer, packager, quality control	Republic of North Macedonia	ALKALOID AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	22881 31.03.2025
2	Tingora	ticagrelor	tablets film-coated	90mg; (56/4x14) in blister	ALKALOID AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- batch releaser, Elpen Pharmaceutical Co. Inc., Marathonos Avenue 95, Pikermi Attiki, 19009, Greece- bulk manufacturer, packager, quality control	Republic of North Macedonia	ALKALOID AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	22882 31.03.2025
3	Cordarone	amiodarone (amiodarone hydrochloride)	solution for i/v injection	50mg/ml; (6) ampoules 3ml	Sanofi S. r. l, Via Valcanello 4, 03012 Anagni	Italy	Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly	France	PoM	22883 31.03.2025

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of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 03-2/25 on March 31,
2025

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1	Chondroxid Artra	chondroitin sulfate (chondroitin sulfate sodium)	ointment for external use	50mg/g; 30g aluminium tube or plastic tube	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, s.1- quality control, batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia- bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	22884 (006986) 31.03.2025
2	Sintus	butamirate (butamirate citrate)	solution oral	1,5mg/ml; glas bottle 100ml, 200ml	Vetprom AD, Otets Paisiy str. 26, Radomir 2400	Bulgaria	Danhson-BG, Otets Paisiy str. 26, Radomir 2400	Bulgaria	OTC	22885 (002216) 31.03.2025
3	No-spa	drotaverine (drotaverine hydrochloride)	tablets	40mg; (24/1x24) in blister, (100) in plastic container	Opella Healthcare Hungary Ltd., 2112 Veresegyhaz, Levai u. 5- bulk manufacturer, packager, quality control (physicochemical), batch releaser, CHINOIN Private Co. Ltd.- Ujpest site, To utca 1-5., Budapest, 1045, Hungary- quality control (microbiological)	Hungary	Opella Healthcare Commercial Ltd., 1138 Budapest, st.Vachi 133, b.E, floor 3	Hungary	OTC	22886 (002216) 31.03.2025
4	No-spa	drotaverine (drotaverine hydrochloride)	tablets	40mg; (24/1x24) in blister, (100) in plastic container	Opella Healthcare Hungary Ltd., 2112 Veresegyhaz, Levai u. 5- bulk manufacturer, packager, quality control (physicochemical), batch releaser, EUROAPI Hungary Ltd., To utca 1-5, Budapest, 1045, Hungary- quality control (microbiological)	Hungary	Opella Healthcare Commercial Ltd., 1138 Budapest, st.Vachi 133, b.E, floor 3	Hungary	OTC	22887 (002216) 31.03.2025

5	Amprilan	ramipril	tablets	1,25mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- quality control, batch releaser, KRKA d.d., Novo mesto Novomeska cesta 22, Sentjernej 8310, Slovenia- bulk manufacturer, packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22888 (003598) 31.03.2025
6	Amprilan	ramipril	tablets	2,5mg; (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	22889 (003598) 31.03.2025
7	Amprilan	ramipril	tablets	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	22890 (003598) 31.03.2025
8	Amprilan	ramipril	tablets	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	22891 (003598) 31.03.2025
9	Postinor	levonorgestrel	tablets	0,75mg; (2/1x2) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- bulk manufacturer, packager, batch releaser, Gedeon Richter PLC, Quality Control Laboratory, Gyomroi ut 19-21, 1103 Budapest, Hungary- quality control (physicochemical), Gedeon Richter PLC, 2510 Dorog, Esztergomi st. 27, Hungary- quality control (microbiological)	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	OTC	22892 (002476) 31.03.2025
10	Cefecon D	paracetamol	suppositories rectal	50mg; (10/2x5)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	22893 (005191) 31.03.2025
11	Cefecon D	paracetamol	suppositories rectal	100mg; (10/2x5)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	22894 (005191) 31.03.2025
12	Cefecon D	paracetamol	suppositories rectal	250mg; (10/2x5)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	22895 (005191) 31.03.2025

13	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	22896 (011589) 31.03.2025
14	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	22897 (011589) 31.03.2025
15	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	22898 (011589) 31.03.2025

16	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	22899 (011589) 31.03.2025
17	Sentor	losartan (losartan potassium)	tablets film-coated	50mg; (10/1x10) in blister, (30/3x10) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35,Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager, Gedeon Richter Polska Sp. z o.o. ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825, Poland- quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22900 (008778) 31.03.2025
18	Sentor	losartan (losartan potassium)	tablets film-coated	100mg; (10/1x10) in blister, (30/3x10) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35,Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager, Gedeon Richter Polska Sp. z o.o. ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825, Poland- quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22901 (008778) 31.03.2025
19	Thyrozol	thiamazole	tablets film-coated	5mg; (50/5x10) in blister, (50/2x25) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	22902 (006045) 31.03.2025
20	Thyrozol	thiamazole	tablets film-coated	10mg; (50/5x10) in blister, (50/2x25) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	22903 (006045) 31.03.2025

21	Efleira	netakimab	solution for subcutaneous injection	60mg/ml; (2/2x1/) in blister, (2/2x1/) in blister and N2 alcohol swabs, (2/1x2/) in blister, (2/1x2/) in blister and (2) alcohol swabs	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeschch. 89, Saint Petersburg, 198515	Russia	PoM	22904 (010919) 31.03.2025
22	Efleira	netakimab	solution for subcutaneous injection	60mg/ml; (2/2x1/) in blister, (2/2x1/) in blister and (2) alcohol swabs, (2/1x2/) in blister, (2/1x2/) in blister and (2) alcohol swabs	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422- quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422, Russia- bulk manufacturer, packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeschch. 89, Saint Petersburg, 198515	Russia	PoM	22905 (010919) 31.03.2025
23	Boleoff	ibuprofen	capsules	200mg; (10/10x1/) in blister, (20/10x2) in blister	Minskintercaps U.E., 26/3, Inzhenernaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.E., 26, Inzhenernaya str., 220075, Minsk	Republic of Belarus	OTC	22906 (015925) 31.03.2025

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of the medicines recommended for the re-registration by the Center according to the meeting decision N 03-2/25 on March 31, 2025

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1	Gangleron	ganglefene	capsules	40mg; (30) plastic container	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	the Scientific Technological Center of Organic and Pharmaceutical Chemistry A.L. Mndjoyan Institute of Fine Organic Chemistry NAS RA , Yerevan, Azatutyun avenue 26	Republic of Armenia	PoM	22907 31.03.2025
2	Gangleron	ganglefene	solution for injection	15mg/ml; (10) ampoules 2ml	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	the Scientific Technological Center of Organic and Pharmaceutical Chemistry A.L. Mndjoyan Institute of Fine Organic Chemistry NAS RA , Yerevan, Azatutyun avenue 26	Republic of Armenia	PoM	22908 31.03.2025
3	Maxicold Rhino	phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid, paracetamol	powder for oral solution with lemon flavour	10mg+20mg+50mg+325mg; (5) sachets 15g, (10) sachets 15g	Pharmstandard-Leksredstva JSC, 305022, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	22909 31.03.2025
4	Maxicold Rhino	phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid, paracetamol	powder for oral solution with orange flavour	10mg+20mg+50mg+325mg; (5) sachets 15g, (10) sachets 15g	Pharmstandard-Leksredstva JSC, 305022, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	22910 31.03.2025
5	Maxicold Rhino	phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid, paracetamol	powder for oral solution with raspberry flavour	10mg+20mg+50mg+325mg; (5) sachets 15g, (10) sachets 15g	Pharmstandard-Leksredstva JSC, 305022, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	22911 31.03.2025

6	ThyroTop D 0,5-37 MBq hard capsule	131I sodium iodide	capsules hard	0,5-37MBq; (10) in glass vials	Institute of Isotopes Co. Ltd. Konkoly Thege Miklos str.29-33, Budapest 1121	Hungary	Institute of Isotopes Co. Ltd. Konkoly Thege Miklos str.29-33, Budapest 1121	Hungary	PoM	22912 31.03.2025
7	KetoFLEX	ketoprofen	solution for injection	50mg/ml; (10) ampoules 2ml	Vetprom AD, Otets Paisiy str. 26, Radomir 2400	Bulgaria	Danhson-BG, Otets Paisiy str. 26, Radomir 2400	Bulgaria	PoM	22913 31.03.2025
8	Zumm-25	dexketoprofen (dexketoprofen trometamol)	tablets film-coated	25mg; (10) in blister	GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi	Georgia	OTC	22914 31.03.2025
9	Peo	ceftriaxone (ceftriaxone sodium)	powder for solution for i/m and i/v injection	1000mg; glass vial	Laboratorio Reig Jofre, S.A., C/ Jarama 111 Poligono Industrial, Toledo, 45007 Toledo	Spain	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	22915 31.03.2025
10	Deflacortin	deflazacort	tablets	6mg; (20/1x20) in blister	LACER, S.A., C/ Boters, 5. Parc Tecnologic del Valles, Cerdanyola del Valles, Barcelona, 08290	Spain	Eurodrug Laboratories S.A., Kortrijksesteenweg 214, 9830 Sint-Martens-Latem	Belgium	PoM	22916 31.03.2025
11	Deflacortin	deflazacort	tablets	30mg; (20/2x10) in blister	LACER, S.A., C/ Boters, 5. Parc Tecnologic del Valles, Cerdanyola del Valles, Barcelona, 08290	Spain	Eurodrug Laboratories S.A., Kortrijksesteenweg 214, 9830 Sint-Martens-Latem	Belgium	PoM	22917 31.03.2025
12	Midazolam Kalceks	midazolam	solution for injection/infusion	5mg/ml; (5) ampoules 1ml, (10) ampoules 1ml	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	22918 31.03.2025
13	Midazolam Kalceks	midazolam	solution for injection/infusion	5mg/ml; (5) ampoules 3ml, (10) ampoules 3ml	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	22919 31.03.2025

14	Metabet SR	metformin (metformin hydrochloride)	tablets prolonged-release	500mg; (28/2x14) in blister	Morningside Pharmaceuticals Ltd, 5 Pavilion Way, Loughborough, LE115GW- batch releaser, USV Ltd, H-17/ H-18, O IDC, Mahatma Gandhi Udyog Nagar, Dabhel, Daman, 396210, India- bulk manufacturer, packager, Zeta Analytical LTD, Colonial Way, Unit 3, Watford Hertfordshire, WD24 4YR, United Kingdom- quality control (physicochemical), Kennet Bioservices Limited, 6 Kingsdown Orchard, Hyde Road, Swindon, SN2 7RR, UK- quality control (microbiological)	UK	Morningside Healthcare Ltd. Unit C, Harcourt Way Leicester LE19 1WP	UK	PoM	22920 31.03.2025
15	Metabet SR	metformin (metformin hydrochloride)	tablets prolonged-release	1000mg; (28/2x14) in blister	Morningside Pharmaceuticals Ltd, 5 Pavilion Way, Loughborough, LE115GW- batch releaser, USV Ltd, H-17/ H-18, O IDC, Mahatma Gandhi Udyog Nagar, Dabhel, Daman, 396210, India- bulk manufacturer, packager, Zeta Analytical LTD, Colonial Way, Unit 3, Watford Hertfordshire, WD24 4YR, United Kingdom- quality control (physicochemical), Kennet Bioservices Limited, 6 Kingsdown Orchard, Hyde Road, Swindon, SN2 7RR, UK- quality control (microbiological)	UK	Morningside Healthcare Ltd. Unit C, Harcourt Way Leicester LE19 1WP	UK	PoM	22921 31.03.2025
16	Omniscan	gadodiamide	solution for i/v injection	287mg/ml (0,5mmol/ml); (10) glass vials 20ml	GE Healthcare Ireland Limited, IDA Business Park, Carrigtohill, Cork, T45 AV60	Ireland	GE Healthcare AS, P.O. Box 4220, Nydalen, 0401 Oslo	Norway	PoM	22922 31.03.2025

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of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 03-2/25 on March 31, 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	Polcortolon	triamcinolone	tablets	4mg; (50/2x25) in blister	Adamed Pharma S.A., 5, Marszałka Jozefa Pilsudskiego St., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	PoM	22923 31.03.2025
2	VITAMIN C	ascorbic acid	tablets	250mg; (10/1x10) 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	22924 31.03.2025
3	Strepsils	dichlorobenzyl alcohol, amylmetacresol	lozenges with strawberry flavour, sugar free	1,2mg+0,6mg; (16/2x8) in blister	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	OTC	22925 31.03.2025
4	Lendacin	ceftriaxone (ceftriaxone sodium)	powder for solution for injection/infusion	1000mg; (5) glass vials, (10) glass vials	Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl	Australia	Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl	Australia	PoM	22926 31.03.2025
5	Combilipen	thiamine (thiamine hydrochloride), pyridoxine (pyridoxine hydrochloride), cyanocobalamin, lidocaine (lidocaine hydrochloride)	solution for i/m injection	50mg/ml+50mg/ml+0,5mg/ml+10mg/ml; (5/1x5) ampoules 2ml in blister, (10/2x5) ampoules 2ml in blister	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	PoM	22927 31.03.2025

6	Metformin Denk 500	metformin (metformin hydrochloride)	tablets film-coated	500mg; (30/3x10) in blister, (100/10x10) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LSSE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	22928 31.03.2025
7	Deslora-Denk 5mg	desloratadine	tablets film-coated	5mg; (10/1x10) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LSSE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	22929 31.03.2025
8	Stronger Neo- Minophagen C	monoammonium glycyrrhizinate (glycyrrhizic acid), glycine, L-cysteine hydrochloride hydrate (L-cysteine hydrochloride)	solution for injection	40mg/20ml+400mg/20ml+ 20mg/20ml; (30) ampoules 20ml	Minophagen Pharmaceutical Co., Ltd. Factory: 2-2-3, Komatsubara, Zama-shi, Kanagawa	Japan	Minophagen Pharmaceutical Co., Ltd., 3-2-11, Nishi- Shinjuku, Shinjuku-ku, Tokyo	Japan	PoM	22930 31.03.2025
9	Paclitaxel-Ebewe	paclitaxel	concentrate for solution for infusion	6mg/ml; glass vial 5ml	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	22931 31.03.2025
10	Paclitaxel-Ebewe	paclitaxel	concentrate for solution for infusion	6mg/ml; glass vial 16,7ml	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	22932 31.03.2025
11	Paclitaxel-Ebewe	paclitaxel	concentrate for solution for infusion	6mg/ml; glass vial 25ml	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	22933 31.03.2025

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of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 03-2/25 on March 31, 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	VITAMIN C	ascorbic acid	tablets	250mg; (10/1x10) 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	19193/2/1 31.03.2025
2	VITAMIN C	ascorbic acid	tablets	500mg; (20) in plastic container	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	20761/1/1 31.03.2025
3	Xynazole	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; plastic vial 10ml with dispenser device	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk- bulk manufacturer, packager, batch releaser, Rubicon" LLC, 62-2, M. Gorky street, 210002, Vitebsk, Republic of Belarus- quality control	Republic of Belarus	"Rubicon" LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	OTC	20600/1/1 31.03.2025
4	Doktor Mom	adhatoda vasika, aloe barbadensis, ocimum sanctum, inula racemosa, zingiber officinale, curcuma longa, solanum indicum, piper cubeba, glycyrrhiza glabra, terminalia belerica, levomenthol	syrup	6mg/ml+5mg/ml+10mg/ml+2mg/ml+1mg/ml+5mg/ml+2mg/ml+1mg/ml+6mg/ml+2mg/ml+0,6mg/ml; 100ml plastic bottle and measuring cup, 150ml plastic bottle and measuring cup	Unique Pharmaceutical Laboratories (a division of J. B. Chemicals & Pharmaceuticals Ltd.), Plot No 215-216, G.I.D.C Industrial Area, Panoli: 394 116, Dist: Bharuch, Gujarat State	India	JTNL LLC, 121614, Moscow, Krylatskaya intercity municipal district, Krylatskaya str., 17, bld. 3	Russia	OTC	22192/1/1 31.03.2025
5	Zumm-25	dexketoprofen (dexketoprofen trometamol)	tablets film-coated	25mg; (10) in blister	GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi	Georgia	OTC	19152/1/1 31.03.2025

6	Gamlate B6	magnesium glutamate hydrobromide, gamma-aminobutyric acid, gamma-amino-beta-hydroxybutyric acid, vitamin B6	solution oral	20mg/ml+20mg/ml+10mg/ml+10mg/ml; 80ml glass bottle	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	19326/1/2 31.03.2025
7	Grippoflu-MBP Extra cold and flu	paracetamol, phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid	powder for oral solution with lemon flavour	650mg+10mg+20mg+50mg; (3) sachets 13g, (8) sachets 13g	Marbiopharm JSC, 424006, the Republic of Mari El, Yoshkar-Ola, st. Karl Marx 121	Russia	Marbiopharm JSC, 424006, the Republic of Mari El, Yoshkar-Ola, st. Karl Marx 121	Russia	OTC	19144/1/1 31.03.2025
8	Xynazole	xylometazoline (xylometazoline hydrochloride)	spray nasal with menthol and eucalypt flavour	1mg/ml; plastic vial 10ml with dispenser device	"Rubicon" LLC, 62B, M. Gorky street, 210002, Vitebsk- bulk manufacturer, packager, batch releaser, "Rubicon" LLC, 62-2, M. Gorky street, 210002, Vitebsk, Republic of Belarus- quality control	Republic of Belarus	"Rubicon" LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	OTC	20064/1/1 31.03.2025

LIST

of the variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 03-2/25 on March 31, 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	Riqulatron	rivaroxaban	tablets film-coated	2,5mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (168/12x14) in blister, (196/14x14) in blister, (20/2x10) in blister, (30/3x10) in blister, (60/6x10) in blister, (100/10x10) in blister	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°003000-ITI-AM 31.03.2025
2	Riqulatron	rivaroxaban	tablets film-coated	2,5mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (168/12x14) in blister, (196/14x14) in blister, (20/2x10) in blister, (30/3x10) in blister, (60/6x10) in blister, (100/10x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoje, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, batch releaser, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoje, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoje, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoje, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°003000-ITI-AM 31.03.2025

3	Riqulatron	rivaroxaban	tablets film-coated	2,5mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (168/12x14) in blister, (196/14x14) in blister, (20/2x10) in blister, (30/3x10) in blister, (60/6x10) in blister, (100/10x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoe, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoe, Moscow region, Yegoriyevsky district, 140342, Russia-packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoe, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoe, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°003000-ITI-AM 31.03.2025
4	Riqulatron	rivaroxaban	tablets film-coated	10mg; (5/1x5) in blister, (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (10/1x10) in blister, (30/3x10) in blister, (100/10x10) in blister	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°003000-ITI-AM 31.03.2025
5	Riqulatron	rivaroxaban	tablets film-coated	10mg; (5/1x5) in blister, (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (10/1x10) in blister, (30/3x10) in blister, (100/10x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoe, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, batch releaser, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoe, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoe, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoe, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°003000-ITI-AM 31.03.2025

6	Riqulatron	rivaroxaban	tablets film-coated	10mg: (5/1x5) in blister, (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (10/1x10) in blister, (30/3x10) in blister, (100/10x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- 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	PoM	JITI-N°003000-ITI-AM 31.03.2025
7	Riqulatron	rivaroxaban	tablets film-coated	15mg: (14/1x14) in blister, (28/2x14) in blister, (42/3x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (10/1x10) in blister, (100/10x10) in blister	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°003000-ITI-AM 31.03.2025
8	Riqulatron	rivaroxaban	tablets film-coated	15mg: (14/1x14) in blister, (28/2x14) in blister, (42/3x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (10/1x10) in blister, (100/10x10) 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	PoM	JITI-N°003000-ITI-AM 31.03.2025

9	Riqulatron	rivaroxaban	tablets film-coated	15mg; (14/1x14) in blister, (28/2x14) in blister, (42/3x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (10/1x10) in blister, (100/10x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoje, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoje, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoje, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoje, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°003000-ITI-AM 31.03.2025
10	Riqulatron	rivaroxaban	tablets film-coated	20mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (10/1x10) in blister, (100/10x10) in blister	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°003000-ITI-AM 31.03.2025
11	Riqulatron	rivaroxaban	tablets film-coated	20mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (10/1x10) in blister, (100/10x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoje, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, batch releaser, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoje, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoje, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoje, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°003000-ITI-AM 31.03.2025

12	Riquilatron	rivaroxaban	tablets film-coated	20mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (10/1x10) in blister, (100/10x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoe, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoe, Moscow region, Yegoriyevsky district, 140342, Russia-packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoe, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoe, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°003000-ITI-AM 31.03.2025
13	Bisoprolol-AKOS	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (30/3x10) in blister, (50/5x10) in blister, (60/6x10) in blister, (70/7x10) in blister, (80/8x10) in blister, (90/9x10) in blister, (100/10x10) in blister	Biocom JSC, 54 Chapaevsky Cr., Stavropol, 355016	Russia	Biocom JSC, 54 Chapaevsky Cr., Stavropol, 355016	Russia	PoM	JITI-N°000792-ITI-AM 31.03.2025
14	Bisoprolol-AKOS	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg; (30/3x10) in blister, (50/5x10) in blister, (60/6x10) in blister, (70/7x10) in blister, (80/8x10) in blister, (90/9x10) in blister, (100/10x10) in blister	Biocom JSC, 54 Chapaevsky Cr., Stavropol, 355016	Russia	Biocom JSC, 54 Chapaevsky Cr., Stavropol, 355016	Russia	PoM	JITI-N°000792-ITI-AM 31.03.2025
15	Nolpaza control	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	20mg; (7/1x7) in blister, (14/2x7) in blister, (14/1x14) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500	Russia	OTC	JITI-N°005110-PT-AM 31.03.2025

16	Nolpaza control	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	20mg; (7/1x7) in blister, (14/2x7) in blister, (14/1x14) 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-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500	Russia	OTC	ЖП-№005110-ПТ-AM 31.03.2025
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LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 03-2/25 on March 31, 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	Benzonal Tatpharm	benzobarbital	tablets	100mg; (50/5x10) in blister	Tatchempharmpreparaty JSC, 420091, Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091, Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	PoM	22143/1 31.03.2025
2	ThyroTop D 0.5-37 MBq hard capsule	131I sodium iodide	capsules hard	0.5-37MBq; (10) in glass vial	Institute of Isotopes Co. Ltd. Konkoly Thege Miklos str.29-33, Budapest 1121	Hungary	Institute of Isotopes Co. Ltd. Konkoly Thege Miklos str.29-33, Budapest 1121	Hungary	PoM	18842/1 31.03.2025
3	Hexaspray	biclotymol	aerosol for local use	750mg/30g 30g glass bottle with pump dispenser	Laboratoires Bouchara-Recordati, Parc Mecatronic 03410 Saint Victor	France	Laboratoires Bouchara-Recordati, Immeuble le Wilson, 70 avenue du General de Gaulle, 92800 Puteaux	France	OTC	19455/1 31.03.2025
4	Zavicefta	ceftazidime (ceftazidime pentahydrate), avibactam (avibactam sodium)	powder for solution for infusion	2g+0,5g; (10) glass vials 20ml	ACS DOBFAR SpA, Via Alesandro Fleming, 2, Verona, 37135	Italy	Pfizer Limited Ramsgate Road, Sandwich, Kent, CT13 9NJ	UK	PoM	21818/1 31.03.2025
5	Nanotropil novo	fonturacetam	tablets	100mg; (10/1x10) in blister, (30/3x10) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Centemo LTD, Moscow Region, Shchelkovo, Fabrichnaya St., 2, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	PoM	22106/1 31.03.2025

6	KetoFLEX	ketoprofen	solution for injection	50mg/ml; (10) ampoules 2ml	Vetprom AD, Otez Paissij str. 26, Radomir 2400	Bulgaria	Dahnson-BG Co Ltd., Otez Paissij str. 26, Radomir 2400	Bulgaria	PoM	19047/1 31.03.2025
7	Anginovag	dequalinium (dequalinium chloride), tyrothricin, enoxolone, hydrocortisone (hydrocortisone acetate), lidocaine (lidocaine hydrochloride)	spray oromucosal	1mg/ml+ 4mg/ml+0.6mg/ml+0.6mg/ml+1mg/ml; 20ml (200 doses) plastic container and pump dispenser	Ferrer Internacional, S.A., Joan Buscalla, 1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer Internacional, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	OTC	19327/3/1 31.03.2025
8	Levemir FlexPen	insulin detemir (recombinant)	solution for injection	100U/ml; (5) pre-filled pen 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	21637/3 31.03.2025
9	NovoRapid FlexPen	insulin aspart	solution for s/c or i/v injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd- bulk manufacturer, primary packager, batch releaser, Novo Nordisk A/S, Brennum Park, DK-3400 Hillerod, Denmark- secondary packager, quality control	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	20594/5 31.03.2025
10	Tresiba FlexTouch	insulin degludec	solution for injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd- bulk manufacturer, primary packager, batch releaser, Novo Nordisk A/S, Brennum Park, Hillerod, 3400, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	20828/4 31.03.2025
11	Victoza	liraglutide	solution for s/c injection	6mg/ml; (2) pre-filled pen 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd- bulk manufacturer, packager, quality control, batch releaser, Novo Nordisk A/S, Hallas Alle, DK-4400 Kalundborg, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	20181/5 31.03.2025
12	Hexpanthen	dexpanthenol, chlorhexidine (chlorhexidine bigluconate)	suppositories vaginal	100mg+16mg; (10/2x5)	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	OTC	19036/1 31.03.2025

13	Neurexan	Avena sativa D2, Coffea Arabica D12, Passiflora incarnata D2, Zincum isovalerianicum D4	tablets	0.6mg+0.6mg+0.6mg+0.6mg; (25) plastic container, (50) plastic container	Biologische Heilmittel Heel GmbH, Dr.-Reckeweg-Strasse 2-4, 76532 Baden-Baden	Germany	Biologische Heilmittel Heel GmbH, Dr.-Reckeweg-Strasse 2-4, 76532 Baden-Baden	Germany	OTC	18289/2 31.03.2025
14	Metformin Denk 500	metformin (metformin hydrochloride)	tablets film-coated	500mg; (30/3x10/) in blister, (100/10x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- 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)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	19249/3/1 31.03.2025
15	Phlogenzym	bromelain, trypsin, rutin	tablets gastro-resistant	450FIP-U+1440FIP-U(24mckat)+100mg; (40/2x20) in blister, (100/5x20) in blister, (200/10x20) in blister, (800) in plastic container	Mucos Emulsions GmbH, Miraustrasse 17, D-13509 Berlin	Germany	Mucos Pharma GmbH & Co. KG, Miraustrasse 17, D-13509 Berlin	Germany	OTC	22057/2 31.03.2025
16	Combilipen	thiamine (thiamine hydrochloride), pyridoxine (pyridoxine hydrochloride), cyanocobalamin, lidocaine (lidocaine hydrochloride)	solution for i/m injection	50mg/ml+50mg/ml+0,5mg/ml+10mg/ml; (5/1x5) ampoules 2ml in blister, (10/2x5) ampoules 2ml in blister	Pharmstandard-Ufa VITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	Pharmstandard-Ufa VITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	PoM	19507/2/1 31.03.2025

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 03-2/25 on March 31, 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	Detraproct	lidocaine (lidocaine hydrochloride monohydrate), fluocinolone acetonide	cream rectal	21,2mg/g+0,1mg/g; 15g aluminium tube and applicator	Galenica Pharmaceutical Industry S.A. Asklipiou 4-6, Kryoneri (Attiki), 14568	Greece	Servier JSC, 125196, Lesnaya str., 7, floor 7/8/9, Moscow	Russia	PoM	ЛПТ-№000915-ITI-AM 31.03.2025
2	Trifas	torasemide	solution for injection	10mg/2ml; (5) ampoules 2ml	A. Menarini Manufacturing Logistics and Services S.r.l., Via Sette Santi, 3 50131 Florence	Italy	Menarini International Operations Luxembourg S.A., 1, avenue de la Gare, 1611	Luxembourg	PoM	ЛПТ-№006644-PT-AM 31.03.2025
3	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	ЛПТ-№000215-ITI-AM 31.03.2025
4	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	ЛПТ-№000215-ITI-AM 31.03.2025
5	Thiogamma	thioctic acid	solution for infusion	12mg/ml; (1) glass vial 50ml, (5) glass vials 50ml, (10) glass vials 50ml	Solpharm Pharmazeutische Erzeugnisse GmbH, Industriestrasse 3, 34212 Melsungen	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boblingen	Germany	PoM	ЛПТ №001968-ITI-AM 31.03.2025
6	Detralex	diosmin, hesperidin	suspension oral	1000mg/10ml; (15) sachets 10g, (30) sachets 10g	Unither Liquid Manufacturing, 1-3 Allee de la Neste, Z.I. d' En Sigal, 31770, Colomiers	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	OTC	ЛПТ-№000102-ITI-AM 31.03.2025

7	Caffetin SC	paracetamol, propyphenazone, caffeine	tablets	250mg+210mg+50mg; (6/1x6) in strip, (10/1x10) in strip, (12/2x6) in strip	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	OTC	ЈИП-№001987-ITI-AM 31.03.2025
8	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	5mg+5mg; (29) in plastic container, (30) in plastic container, (90/3x30) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЈИП №000575-ITI-AM 31.03.2025
9	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	5mg+10mg; (29) in plastic container, (30) in plastic container, (90/3x30) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЈИП №000575-ITI-AM 31.03.2025
10	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	10mg+5mg; (29) in plastic container, (30) in plastic container, (90/3x30) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЈИП №000575-ITI-AM 31.03.2025
11	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	10mg+10mg; (29) in plastic container, (30) in plastic container, (90/3x30) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЈИП №000575-ITI-AM 31.03.2025
12	Berlithion 600 capsules	thioctic acid	capsules soft	600mg; (30/3x10) in blister	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- packager, batch releaser, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany- bulk manufacturer, quality control (physicochemical), Gelita AG, Gammelsbacher Str. 2, Bau 11, 4. OG 69412 Eberbach Deutschland, Germany- quality control (microbiological)	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	PoM	ЈИП-№007189-PI-AM 31.03.2025