

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 04-1/25 on April 16, 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	Dacepton	apomorphine hydrochloride hemihydrate	solution for injection	10mg/ml; (5) cartridges 3ml in plastic tray	EVER Pharma Jena GmbH, Bruesseler Strasse 18, 07747 Jena	Germany	EVER Neuro Pharma GmbH, Oberburgau 3, 4866 Unterach am Attersee	Austria	PoM	22934 16.04.2025
2	Vitaprost	prostate extract	tablets gastro-resistant	20mg; (20/2x10/) in blister, (60/6x10/) in blister	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, c.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	22935 16.04.2025
3	Paclitaxel-Teva	paclitaxel	concentrate for solution for infusion	6mg/ml; 50ml glass vial	Pharmachemie B.V. Swensweg 5, 2031 GA Haarlem	the Netherlands	Teva Pharmaceutical Industries Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020	Israel	PoM	22936 16.04.2025
4	Avegra BIOCAD	bevacizumab	concentrate for solution for infusion	25mg/ml; glass vial 4ml	BIOCAD JSC, Intracity Municipality the Settlement of Strelina, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelina, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515	Russia	PoM	22937 16.04.2025
5	Avegra BIOCAD	bevacizumab	concentrate for solution for infusion	25mg/ml; glass vial 16ml	BIOCAD JSC, Intracity Municipality the Settlement of Strelina, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelina, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515	Russia	PoM	22938 16.04.2025

LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 04-1/25 on April 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	Theraflu MAXtab	paracetamol, caffeine, phenylephrine (phenylephrine hydrochloride), terpin hydrate, ascorbic acid	tablets	500mg+25mg+5mg+20mg+30mg; (12/1x12) in blister	GlaxoSmithKline Dungarvan Limited, Knockbrack, Dungarvan, Co. Waterford	Russia	GlaxoSmithKline Healthcare JSC, Presnenskaya Naberezhnaya, 10, unit III, room 9, 6 floor, Moscow, 123112	Russian	OTC	22943 (008573) 16.04.2025
2	Siofor Long	metformin (metformin hydrochloride)	tablets prolonged-release	500mg; (60/4x15) in blister	Berlin-Chemie AG, Glienicke Weg 125, 12489 Berlin- packager, quality control (microbiological), batch releaser, Centaur Pharmaceuticals Private Limited, Plot No 4, International Biotech park, Hinjewadi, Phase II, Pune, 411057 Maharashtra, India-bulk manufacturer, 1. Berlin-Chemie AG, Glienicke Weg 125, 12489 Berlin, Germany, 2. Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany, 3. A. Menarini Manufacturing Logistics and Services S.r.l., Via Sette Santi, 3, 50131 Florence, Italy- quality control (physicochemical)	Germany	Berlin-Chemie AG, Glienicke Weg 125, 12489 Berlin	Germany	PoM	22944 (002469) 16.04.2025

3	Siofor Long	metformin (metformin hydrochloride)	tablets prolonged-release	500mg; (60/4x15/) in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1. Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin, Germany, 2. Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany, 3. A. Menarini Manufacturing Logistics and Services S.r.l., Via Sette Santi, 3, 50131 Florence, Italy- quality control (physicochemical)	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	22945 (002469) 16.04.2025
4	Siofor Long	metformin (metformin hydrochloride)	tablets prolonged-release	1000mg; (60/4x15/) in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, quality control (microbiological), batch releaser, Centaur Pharmaceuticals Private Limited, Plot No 4, International Biotech park, Hinjewadi, Phase II, Pune, 411057 Maharashtra, India-bulk manufacturer, 1. Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin, Germany, 2. Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany, 3. A. Menarini Manufacturing Logistics and Services S.r.l., Via Sette Santi, 3, 50131 Florence, Italy- quality control (physicochemical)	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	22946 (002469) 16.04.2025
5	Siofor Long	metformin (metformin hydrochloride)	tablets prolonged-release	1000mg; (60/4x15/) in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1. Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin, Germany, 2. Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany, 3. A. Menarini Manufacturing Logistics and Services S.r.l., Via Sette Santi, 3, 50131 Florence, Italy- quality control (physicochemical)	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	22947 (002469) 16.04.2025

6	Glycerin	glycerol	suppositories rectal	1,24g; (10/2x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, build. 1- quality control, batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Sal- ganskaya st., 7, Russia- bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Sal- ganskaya st., 7	Russia	OTC	22948 (007163) 16.04.2025
7	Glycerin	glycerol	suppositories rectal	2,11g; (10/2x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, build. 1- quality control, batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Sal- ganskaya st., 7, Russia- bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Sal- ganskaya st., 7	Russia	OTC	22949 (007163) 16.04.2025
8	Cortexin	complex of water-soluble polypeptide fractions	powder lyophilized for solution for i/m injection	5mg; (10/2x5/) glass vials 3ml in blister	GEROPHARM Ltd., Moscow region, Serpukhov city district, Obolensk work settlement, «Kvartal A» area, bldg. 5- bulk manufacturer, packager, quality control (physicochemical), batch releaser, «GEROPHARM» Ltd., Moscow region, Serpukhov city district, Obolensk work settlement, «Kvartal A» area, lane 82, bldg. 4, Russia- quality control (microbiological)	Russia	«GEROPHARM» Ltd, 9 Zvenigorodskaya st., 191119 Saint Petersburg	Russia	PoM	22950 (001516) 16.04.2025
9	Cortexin	complex of water-soluble polypeptide fractions	powder lyophilized for solution for i/m injection	5mg; (10/2x5/) glass vials 3ml in blister	GEROPHARM Ltd., Moscow region, Serpukhov city district, Obolensk work settlement, «Kvartal A» area, lane 82, bldg. 4- quality control, batch releaser, «GEROPHARM» Ltd., Moscow region, Serpukhov city district, Obolensk work settlement, «Kvartal A» area, bldg. 5, Russia- bulk manufacturer, packager	Russia	«GEROPHARM» Ltd, 9 Zvenigorodskaya st., 191119 Saint Petersburg	Russia	PoM	22951 (001516) 16.04.2025
10	Cortexin	complex of water-soluble polypeptide fractions	powder lyophilized for solution for i/m injection	5mg; (10/2x5/) glass vials 3ml in blister	GEROPHARM Ltd., Moscow region, Serpukhov city district, Obolensk work settlement, «Kvartal A» area, bldg. 5- bulk manufacturer, packager, batch releaser, «GEROPHARM» Ltd., Moscow region, Serpukhov city district, Obolensk work settlement, «Kvartal A» area, lane 82, bldg. 4, Russia- quality control	Russia	«GEROPHARM» Ltd, 9 Zvenigorodskaya st., 191119 Saint Petersburg	Russia	PoM	22952 (001516) 16.04.2025

11	Cortexin	complex of water-soluble polypeptide fractions	powder lyophilized for solution for i/m injection	5mg; (10/2x5/) glass vials 3ml in blister	GEROPHARM Ltd., Moscow region, Serpukhov city district, Obolensk work settlement, «Kvartal A» area, lane 82, bldg. 4- quality control (microbiological), batch releaser, «GEROPHARM» Ltd., Moscow region, Serpukhov city district, Obolensk work settlement, «Kvartal A» area, bldg. 5, Russia- bulk manufacturer, packager, quality control (physicochemical)	Russia	«GEROPHARM» Ltd, 9 Zvenigorodskaya st., 191119 Saint Petersburg	Russia	PoM	22953 (001516) 16.04.2025
12	Cortexin	complex of water-soluble polypeptide fractions	powder lyophilized for solution for i/m injection	10mg; (10/2x5/) glass vials 5ml in blister	GEROPHARM Ltd., Moscow region, Serpukhov city district, Obolensk work settlement, «Kvartal A» area, bldg. 5- bulk manufacturer, packager, quality control (physicochemical), batch releaser, «GEROPHARM» Ltd., Moscow region, Serpukhov city district, Obolensk work settlement, «Kvartal A» area, lane 82, bldg. 4, Russia- quality control (microbiological)	Russia	«GEROPHARM» Ltd, 9 Zvenigorodskaya st., 191119 Saint Petersburg	Russia	PoM	22954 (001517) 16.04.2025
13	Cortexin	complex of water-soluble polypeptide fractions	powder lyophilized for solution for i/m injection	10mg; (10/2x5/) glass vials 5ml in blister	GEROPHARM Ltd., Moscow region, Serpukhov city district, Obolensk work settlement, «Kvartal A» area, lane 82, bldg. 4- quality control, batch releaser, «GEROPHARM» Ltd., Moscow region, Serpukhov city district, Obolensk work settlement, «Kvartal A» area, bldg. 5, Russia- bulk manufacturer, packager	Russia	«GEROPHARM» Ltd, 9 Zvenigorodskaya st., 191119 Saint Petersburg	Russia	PoM	22955 (001517) 16.04.2025
14	Cortexin	complex of water-soluble polypeptide fractions	powder lyophilized for solution for i/m injection	10mg; (10/2x5/) glass vials 5ml in blister	GEROPHARM Ltd., Moscow region, Serpukhov city district, Obolensk work settlement, «Kvartal A» area, bldg. 5- bulk manufacturer, packager, batch releaser, «GEROPHARM» Ltd., Moscow region, Serpukhov city district, Obolensk work settlement, «Kvartal A» area, lane 82, bldg. 4, Russia- quality control	Russia	«GEROPHARM» Ltd, 9 Zvenigorodskaya st., 191119 Saint Petersburg	Russia	PoM	22956 (001517) 16.04.2025

15	Cortixin	complex of water-soluble polypeptide fractions	powder lyophilized for solution for i/m injection	10mg; (10/2x5/) glass vials 5ml in blister	GEROPHARM Ltd., Moscow region, Serpukhov city district, Obolensk work settlement, «Kvartal A» area, lane 82, bldg. 4- quality control (microbiological), batch releaser, «GEROPHARM» Ltd., Moscow region, Serpukhov city district, Obolensk work settlement, «Kvartal A» area, bldg. 5, Russia- bulk manufacturer, packager, quality control (physicochemical)	Russia	«GEROPHARM» Ltd, 9 Zvenigorodskaya st., 191119 Saint Petersburg	Russia	PoM	22957 (001517) 16.04.2025
16	Tyrez	bisoprolol (bisoprolol fumarate)	tablets film-coated	2,5mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	22958 (000117) 16.04.2025
17	Tyrez	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	22959 (000117) 16.04.2025
18	Tyrez	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	22960 (000117) 16.04.2025
19	Actilyse	alteplase	powder lyophilized for solution for infusion with solvent	50mg; glass vial and glass vial with solvent 50ml	Boehringer Ingelheim Pharma GmbH & Co. KG, Birkendorfer str. 65, 88397 Biberach a.d.R.	Germany	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein	Germany	PoM	22961 (009984) 16.04.2025
20	Fungoderil	naftifine (naftifine hydrochloride)	solution for external use	10mg/ml; 15ml glass vial with dropper, 25ml glass vial with dropper	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	22962 (001496) 16.04.2025
21	Cardilopin	amlodipine (amlodipine besilate)	tablets	2,5mg; (10/1x10/) in blister, (20/2x10/) in blister, (30/3x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22963 (015057) 16.04.2025
22	Cardilopin	amlodipine (amlodipine besilate)	tablets	5mg; (10/1x10/) in blister, (20/2x10/) in blister, (30/3x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22964 (015057) 16.04.2025

23	Cardilopin	amlodipine (amlodipine besilate)	tablets	10mg; (10/1x10) in blister, (20/2x10) in blister, (30/3x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22965 (015057) 16.04.2025
24	Sermion	nicergoline	tablets film-coated	30mg; (30/2x15) in blister	Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno (AP)	Italy	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	22966 (009915) 16.04.2025
25	Papaverin	papaverine (papaverine hydrochloride)	suppositories rectal	20mg; (10/2x5)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, build. 1- quality control, batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia- bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	22967 (005724) 16.04.2025
26	Vibrocil	dimethindene (dimethindene maleate), phenylephrine	drops nasal	0,25mg/ml+2,5mg/ml; 15ml glass vial	Haleon CH SARI, Route de l' Etraz, Nyon, 1260	Switzerland	JSC «Haleon Rus», Presnenskaya Naberezhnaya, 10, unit III, room 9, 6 floor, Moscow, 123112	Russia	OTC	22968 (005591) 16.04.2025
27	IMvolol	nebivolol (nebivolol hydrochloride)	tablets	5mg; (28/2x14) in blister	Severnaya Zvezda CJSC, Leningradsky region, municipalni district Lomonosovski, Nizinskoe rural settlement, Kuzneci zone, str. Aptekarskaya, bld. 2, lit. E- quality control (physicochemical), batch releaser, Severnaya Zvezda CJSC, Leningradsky region, municipalni district Lomonosovski, Nizinskoe rural settlement, Kuzneci zone, str. Aptekarskaya, bld. 2, lit. B, Russia- bulk manufacturer, packager, Severnaya Zvezda CJSC, Leningradsky region, municipalni district Lomonosovski, Nizinskoe rural settlement, Kuzneci zone, str. Aptekarskaya, bld. 2, lit. K, Russia- quality control (microbiological)	Russia	Immunofarm LLC, 0014, Yerevan, Hrachya Nersisyan St., 10-3/1 Building	Republic of Armenia	PoM	22942 (018411) 16.04.2025
28	Myoxant	cisatracurium (cisatracurium besylate)	solution for i/v injection	2mg/ml; (5) glass vials 2,5ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	22941 (018167) 16.04.2025

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of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 04-1/25 on April 16, 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	Kirsty	insulin aspart	solution for injection	100U/ml; (1) glass vial 10ml	Biosmillar Collaborations Irleand Limited, Block B, The Crescent Building, Santry Demense Dublin, D09 C6X8- batch releaser, Biocon Snd. Bhd., No.1, Jalan Bioteknologi 1, Kawasan Perindustrian SiLC, 79200, Iskandar Puteri, Johor, Malaysia- bulk manufacturer, packager, quality control	Ireland	Biosimilar Collaborations Ireland Limited, Block B, The Crescent Building, Santry Demesne,	Ireland	PoM	22939 16.04.2025
2	Kirsty	insulin aspart	solution for injection	100U/ml; (1) pre-filled pens 3ml, (5) pre-filled pens 3ml	Biosmillar Collaborations Irleand Limited, Block B, The Crescent Building, Santry Demense Dublin, D09 C6X8- batch releaser, Biocon Snd. Bhd., No.1, Jalan Bioteknologi 1, Kawasan Perindustrian SiLC, 79200, Iskandar Puteri, Johor, Malaysia- bulk manufacturer, packager, quality control	Ireland	Biosimilar Collaborations Ireland Limited, Block B, The Crescent Building, Santry Demesne,	Ireland	PoM	22940 16.04.2025

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of the medicines recommended for the re-registration by the Center according to the meeting decision N 04-1/25 on April 16, 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	Tyzine	xylometazoline (xylometazoline hydrochloride)	spray nasal	0,5mg/ml; glass bottle 10ml (140 dose) with dosator	Delpharm Orleans, 5 avenue de Concyr, 45071 Orleans, Cedex 2	France	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	OTC	22969 16.04.2025
2	Tyzine	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; glass bottle 10ml (70 dose) with dosator	Delpharm Orleans, 5 avenue de Concyr, 45071 Orleans, Cedex 2	France	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	OTC	22970 16.04.2025
3	Neoton	phosphocreatine (phosphocreatine sodium)	powder for solution for infusion	1000mg; glass vial	Alfasigma S.p.A., Via Enrico Fermi, 1-65020, Alanno (Pescara)	Italy	Alfasigma S.p.A., Via Ragazzi del, 99, 5-40133 Bologna (BO)	Italy	PoM	22971 16.04.2025
4	Pantoprazole Canon	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	20mg; (28/4x7/) in blister	CJSC Canonpharma production, 105B, 11, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100- quality control, batch releaser, CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100, Russia- bulk manufacturer, packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	OTC	22972 16.04.2025
5	Pantoprazole Canon	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	40mg; (28/4x7/) in blister	CJSC Canonpharma production, 105B, 11, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100- quality control, batch releaser, CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100, Russia- bulk manufacturer, packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	PoM	22973 16.04.2025

6	Bonjigar	eclipta alba, picrorrhiza kurrooa, solanum nigrum, cichorium intybus, glycyrrhiza glabra, tamarix gallica, raphanus sativus, berberis aristata, silbyum marianum, spherantus indica, boerhavia diffusa	syrup	83mg/10ml+33mg/10ml+17 mg/10ml+58mg/10ml+67mg /10ml+33mg/10ml+17mg/10 ml+50mg/10ml+67mg/10ml+ 17mg/10ml+33mg/10ml; (90) glass bottle, (120) glass bottle, (150) glass bottle	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	PoM	22974 16.04.2025
7	Duodart	dutasteride, tamsulosin (tamsulosin hydrochloride)	capsules	0,5mg+0,4mg; (30) plastic container	Catalent Germany Schorndorf GmbH, Steinbeisstrasse 1 und 2, 73614, Schorndorf	Germany	GlaxoSmithKline GmbH & Co. KG, Prinzregentenplatz 9, 81675 Munich	Germany	PoM	22975 16.04.2025
8	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	22976 16.04.2025
9	Ortophen Tatpharm	diclofenac (diclofenac sodium)	tablets gastro- resistant film- coated	25mg; (30/3x10) in blister, (30/2x15) 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	22977 16.04.2025

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 04-1/25 on April 16, 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	Azitrox	azithromycin (azithromycin dihydrate)	capsules	250mg; (6/1x6) in blister	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	PoM	22978 16.04.2025
2	Azitrox	azithromycin (azithromycin dihydrate)	capsules	500mg; (2/1x2) in blister, (3/1x3) in blister	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	PoM	22979 16.04.2025
3	Orgalutran	ganirelix (ganirelix acetate)	solution for s/c injection	0,25mg/0,5ml; (5) pre-filled syringes 0,5ml	N.V. Organon, Kloosterstraat 6, 5349 AB Oss- secondary packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Schutzenstrasse 87 and 99/101, D-88212 Ravensburg, Germany- bulk manufacturer, primary packager, quality control	the Netherlands	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	22980 16.04.2025
4	Vitamin C-Asteria	ascorbic acid	tablets	500mg; (100/10x10) in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-si, Chungcheongbuk-do	Republic of Korea	Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan	Republic of Armenia	OTC	22981 16.04.2025

5	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	22982 16.04.2025
6	Grippoflu-MBP cold and flu	paracetamol, phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid	powder for oral solution with raspberry flavour	325mg+10mg+20mg+50mg; (10) 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	22983 16.04.2025
7	Diclac ID 75	diclofenac (diclofenac sodium) with immediate release, diclofenac (diclofenac sodium) with prolonged release	tablets modified-release	12,5mg+ 62,5mg; (20/2x10) in blister	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	22984 16.04.2025
8	Diclac ID 150	diclofenac (diclofenac sodium) with immediate release, diclofenac (diclofenac sodium) with prolonged release	tablets modified-release	25mg+125mg; (100/10x10) in blister	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	22985 16.04.2025
9	Efferalgan	paracetamol	solution oral	30mg/ml; plastic bottle 90ml and measuring spoon	UPSA SAS, 304, avenue du Docteur Jean Bru, 47000 AGEN- bulk manufacturer, packager, batch releaser, UPSA SAS, 979, avenue des Pyrenees, 47520 Le Passage, France- quality control	France	UPSA SAS, 3, rue Joseph Monier- 92500 Rueil-Malmaison	France	OTC	22986 16.04.2025
10	Artrum	ketoprofen	gel for external use	25mg/g 50g aluminium tube	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	PoM	22987 16.04.2025

11	Artrum	ketoprofen	gel for external use	50mg/g 50g aluminium tube	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	PoM	22988 16.04.2025
12	Xefocam	lornoxicam	tablets film-coated	8mg; (10/1x10) in blister	Takeda GmbH, Lehnitz str. 70-98, 16515 Oranienburg	Germany	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	22989 16.04.2025
13	Codelac Neo	butamirate (butamirate citrate)	tablets film-coated prolonged-release	50mg; (10/1x10) in blister	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	JSC "OTCPharm", Testovskaya street, room II, flr.12, h.10, off. 29, Moscow 123112	Russia	OTC	22990 16.04.2025

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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	Noofen	gamma-amino-beta-phenylbutyric acid hydrochloride	capsules	250mg; (20/2x10/) in blister	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	PoM	20379/3/1 16.04.2025
2	Noofen	gamma-amino-beta-phenylbutyric acid hydrochloride	capsules	500mg; (24/4x6/) in blister	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	PoM	20380/3/1 16.04.2025
3	Noofen 100	gamma-amino-beta-phenylbutyric acid hydrochloride	powder for oral solution	100mg; (15) sachets 1g	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	PoM	20426/2/1 16.04.2025
4	Maxitrol	dexamethasone, neomycin (neomycin sulfate), polymyxin B (polymyxin B sulfate)	drops eye (suspension)	1mg/ml+3500IU/ml+6000IU/ml; 5ml plastic vial	Novartis Manufacturing N.V., Rijksweg 14, Puurs-Sint- Amands, 2870	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	21672/1/1 16.04.2025
5	Phosphogliv-Pharmstandard	phospholipids, sodium glycyrrhizinate (glycyrrhizinic acid trisodium)	capsules	65mg+35mg; (50/5x10/) in blister, (96/8x12/) in blister	Pharmstandard-Leksredstva OJSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva OJSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	22542/1/1 16.04.2025

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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	Dicloberl retard	diclofenac (diclofenac sodium)	capsules prolonged-release	100mg; (20/2x10') in blister	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- batch releaser, Hennig Arzneimittel GmbH & Co. KG, Liebigstrasse 1-2, 65439 Floersheim-am-Main, Germany- bulk manufacturer, quality control (phisicochemical), Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden, Germany- packager, quality control (microbiological)	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	PoM	JITI-N*003063-PT-AM 16.04.2025
2	Dicloberl retard	diclofenac (diclofenac sodium)	capsules prolonged-release	100mg; (20/2x10') in blister	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- batch releaser, Hennig Arzneimittel GmbH & Co. KG, Liebigstrasse 1-2, 65439 Floersheim-am-Main, Germany- bulk manufacturer, Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden, Germany- packager, quality control	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	PoM	JITI-N*003063-PT-AM 16.04.2025
3	Bobotic	simeticone	drops oral	66,66mg/ml; 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	OTC	JITI-N*001892-TTI-AM 16.04.2025

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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	Neoton	phosphocreatine (phosphocreatine sodium)	powder for solution for infusion	1000mg; glass vial	Alfasigma S.p.A., Via Enrico Fermi, 1-65020, Alanno (Pescara)	Italy	Alfasigma S.p.A., Via Ragazzi del 99, 5-40133 Bologna (BO)	Italy	PoM	19216/4/1 16.04.2025
2	Azitrox	azithromycin (azithromycin dihydrate)	capsules	500mg; (2/1x2/) in blister, (3/1x3/) in blister	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	PoM	19213/4/1 16.04.2025
3	Dimedrol	diphenhydramine (diphenhydramine hydrochloride)	solution for i/m and i/v injection	10mg/ml; (10) ampoules 1ml label banderol, (10) ampoules 1ml dividella, (10) ampoules 1ml CAMA	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	PoM	20780/2/1 16.04.2025
4	Duodart	dutasteride, tamsulosin (tamsulosin hydrochloride)	capsules	0,5mg+0,4mg; (30) plastic container	Catalent Germany Schorndorf GmbH, Steinbeisstrasse 1 und 2, 73614, Schorndorf	Germany	GlaxoSmithKline GmbH & Co. KG, Prinzregentenplatz 9, 81675 Munich	Germany	PoM	18867/4 16.04.2025

5	Bonjigar	eclipta alba, picrorrhiza kurrooa, solanum nigrum, cichorium intybus, glycyrrhiza glabra, tamarix gallica, raphanus sativus, berberis aristata, silbyum marianum, spherantus indica, boerhavia diffusa	syrup	83mg/10ml+33mg/10ml+1 7mg/10ml+58mg/10ml+6 7mg/10ml+33mg/10ml+1 7mg/10ml+50mg/10ml+67 mg/10ml+17mg/10ml+33 mg/10ml; (90) glass bottle, (120) glass bottle, (150) glass bottle	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	PoM	18983/1 16.04.2025
6	Ortophen Tatpharm	diclofenac (diclofenac sodium)	tablets gastro- resistant film- coated	25mg; (30/3x10/) in blister, (30/2x15/) 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	19080/1 16.04.2025
7	Azitrox	azithromycin (azithromycin dihydrate)	capsules	250mg; (6/1x6) in blister	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	PoM	19212/2/1 16.04.2025
8	METRONIDAZOLE- ASTERIA	metronidazole	tablets	500mg; (30/3x10) in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-Si, Chungcheongbuk-do	Republic of Korea	Asteria LLC, 72/3 Nairi Zaryan str., 0051 Yerevan	Republic of Armenia	PoM	19396/2 16.04.2025

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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	Oncaspar	Pegaspargase	lyophilizate for solution for i/m injection and infusion	750IU/ml; glass vial 5ml	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy- quality control, batch releaser, Lyophilization Services of New England, Inc (LSNE), 25 Commerce Drive, Bedford, New Hampshire (NH) 03110, USA- bulk manufacturer, primary packager, Exelead Inc., 6925 Guion Road, Indianapolis, Indiana (IN) 46268, USA- secondary packager	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№000545-ITI-AM 16.04.2025
2	Riquatron	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	ЛПТ-№003000-ITI-AM 16.04.2025

3	Riquatron	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., 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	ЛПТ-№003000-ITI-AM 16.04.2025
4	Riquatron	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., 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	ЛПТ-№003000-ITI-AM 16.04.2025
5	Riquatron	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	ЛПТ-№003000-ITI-AM 16.04.2025

6	Riquatron	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	ЛПТ-№003000-ITI-AM 16.04.2025
7	Riquatron	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- 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	ЛПТ-№003000-ITI-AM 16.04.2025
8	Riquatron	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	ЛПТ-№003000-ITI-AM 16.04.2025

9	Riquatron	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- 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	ЛПТ-№003000-ITI-AM 16.04.2025
10	Riquatron	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	ЛПТ-№003000-ITI-AM 16.04.2025
11	Riquatron	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	ЛПТ-№003000-ITI-AM 16.04.2025

12	Riquatron	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., 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	ЛПТ-№003000-ITI-AM 16.04.2025
13	Riquatron	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., 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	ЛПТ-№003000-ITI-AM 16.04.2025