

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 02-2/25 on February 18, 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	Ferum Lek	iron (III)-hydroxide dextran complex	solution for i/m injection	50mg/ml; (5) ampoules 2ml, (50) ampoules 2ml	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	22759 28.02.2025
2	Rinostop-Oticipharm	xylometazoline (xylometazoline hydrochloride)	spray nasal	0,5mg/ml; 15ml plastic vial	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, room II, flr.12, h.10, off. 29, Moscow 123112	Russia	OTC	22760 28.02.2025
3	Rinostop-Oticipharm	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; 15ml plastic vial	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, room II, flr.12, h.10, off. 29, Moscow 123112	Russia	OTC	22761 28.02.2025
4	Moxi-Tech	moxifloxacin (moxifloxacin hydrochloride)	solution for infusion	1,6mg/ml; plastic pack 250ml	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	22762 28.02.2025
5	Oticaine	phenazone, lidocaine (lidocaine hydrochloride)	drops ear	40mg/g+10mg/g; plastic bottle 5g, plastic bottle 15g	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	22763 28.02.2025
6	ACC Long	acetylcysteine	tablets effervescent	600mg; (10) in plastic container	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben-batch releaser, Hermes Pharma GmbH, Hans-Urmiler-Ring 52, 82515 Wolfratshausen, Germany -bulk manufacturer, packager, quality control	Germany	Sandoz Pharmaceuticals d.d. Verevskova 57,1000, Ljubljana	Slovenia	OTC	22764 28.02.2025

LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 02-2/25 on February 18, 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	Caffetin	paracetamol, propyphenazone, caffeine, codeine (codeine phosphate)	tablets	250mg+210mg+50mg+10mg; (12/2x6) in strip, (10/1x10) 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	PoM	22769 (004085) 28.02.2025
2	Sinaflan	fluocinolone acetonide	ointment	0,25mg/g; 10g aluminium tube, 15g aluminium tube	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	PoM	22770 (009455) 28.02.2025
3	Suprastin	chloropyramine (chloropyramine hydrochloride)	tablets	25mg; (20/2x10) in blister, (40/4x10) in blister, (20/1x20) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	OTC	22771 (008871) 28.02.2025
4	Aevit	retinol palmitate (vitamin A), alfa-tocopherol acetate (vitamin E)	capsules	55,036mg (100000IU)+100mg; (15/1x15) in blister, (30/2x15) in blister, (60/4x15) in blister	Minskintercaps U.V., 26/3, Inzhenernaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Republic of Belarus	PoM	22772 (008405) 28.02.2025

5	Ekvator	lisinopril (lisinopril dihydrate), amlodipine (amlodipine besilate)	tablets	20mg+10mg; (10/1x10/) in blister, (30/3x10/) in blister, (60/6x10/) 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	PoM	22773 (007894) 28.02.2025
6	Ekvator	lisinopril (lisinopril dihydrate), amlodipine (amlodipine besilate)	tablets	20mg+10mg; (10/1x10/) in blister, (30/3x10/) in blister, (60/6x10/) 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	22774 (007894) 28.02.2025
7	Atoris	atorvastatin (atorvastatin calcium)	tablets film-coated	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	22775 (001866) 28.02.2025
8	Atoris	atorvastatin (atorvastatin calcium)	tablets film-coated	20mg; (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	22776 (001866) 28.02.2025
9	Lorista H	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	50mg+12,5mg; (28/2x14/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22777 (004783) 28.02.2025
10	Lorista H	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	50mg+12,5mg; (28/2x14/) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	PoM	22778 (004783) 28.02.2025

11	Lorista H	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	50mg+12.5mg; (28/2x14) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, batch releaser, Labena, d.o.o, Teslova 30, 1000 Lyublyana, Slovenia-quality control	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22779 (004783) 28.02.2025
12	Terbisil	terbinafine (terbinafine hydrochloride)	tablets	250mg; (14/1x14) in blister, (28/2x14) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22780 (013498) 28.02.2025
13	Spitomin	bupirone	tablets	5mg; (60/6x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65, Hungary-bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22781 (009772) 28.02.2025
14	Spitomin	bupirone	tablets	10mg; (60/6x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65, Hungary-bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22782 (009772) 28.02.2025
15	Betadine	povidone-iodine	suppositories vaginal	200mg; (7/1x7) in blister, (14/2x7) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	OTC	22783 (005908) 28.02.2025
16	Lorista	losartan (losartan potassium)	tablets film-coated	25mg; (28/2x14) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22784 (004616) 28.02.2025
17	Lorista	losartan (losartan potassium)	tablets film-coated	25mg; (28/2x14) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22785 (004616) 28.02.2025
18	Lorista	losartan (losartan potassium)	tablets film-coated	50mg; (28/2x14) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22786 (004616) 28.02.2025
19	Lorista	losartan (losartan potassium)	tablets film-coated	50mg; (28/2x14) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22787 (004616) 28.02.2025

20	Lorista	losartan (losartan potassium)	tablets film-coated	100mg; (28/2x14) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22788 (004616) 28.02.2025
21	Lorista	losartan (losartan potassium)	tablets film-coated	100mg; (28/2x14) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22789 (004616) 28.02.2025
22	Escapelle	levonorgestrel	tablets	1,5mg; (1) in blister	Gedeon Richter Plc., Gyomroi st. 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	22790 (002664) 28.02.2025
23	Glucovance	glibenclamide, metformin (metformin hydrochloride)	tablets film-coated	2,5mg+500mg; (30/2x15) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400 Semoy	France	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	22791 (002664) 28.02.2025
24	Glucovance	glibenclamide, metformin (metformin hydrochloride)	tablets film-coated	5mg+500mg; (30/2x15) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400 Semoy	France	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	22792 (002664) 28.02.2025
25	Septanazal	xylometazoline (xylometazoline hydrochloride), dexpanthenol	spray nasal	0,5mg/ml+50mg/ml 10ml (90 doses) plastic container with pump dispenser	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	22793 (006478) 28.02.2025
26	Septanazal	xylometazoline (xylometazoline hydrochloride), dexpanthenol	spray nasal	1mg/ml+50mg/ml; 10ml (90 doses) plastic container with pump dispenser	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	22794 (006479) 28.02.2025
27	Respiforb	budesonide, formoterol	capsules for inhalation	80mcg/dose+4,mcg/dose; (30/3x10) in blister, (30/3x10) in blister with inhaler, (60/6x10) in blister, (60/6x10) in blister with inhaler, (60/2x30) in plastic container with inhaler, (120/12x10) in blister, (120/12x10) in blister with inhaler, (120/4x30) in plastic container, (120/4x30) in plastic container with inhaler	PSK Pharma Ltd., Moscow Region, Dubna urban district, Dubna city, 5 Programmistov St., building 1	Russia	PSK Pharma Ltd., Moscow Region, Dubna urban district, Dubna city, 5 Programmistov St., building 1	Russia	PoM	22795 (006479) 28.02.2025

28	Respiforb	budesonide, formoterol	capsules for inhalation	160mcg/dose+4,5cg/dose; (30/3x10) in blister, (30/3x10) in blister with inhaler, (60/6x10) in blister, (60/6x10) in blister with inhaler, (60/2x30) in plastic container, (60/2x30) in plastic container with inhaler, (120/12x10) in blister, (120/12x10) in blister with inhaler, (120/4x30) in plastic container, (120/4x30) in plastic container with inhaler	PSK Pharma Ltd., Moscow Region, Dubna urban district, Dubna city, 5 Programmistov St., building 1	Russia	PSK Pharma Ltd., Moscow Region, Dubna urban district, Dubna city, 5 Programmistov St., building 1	Russia	PoM	22796 (006479) 28.02.2025
29	Respiforb	budesonide, formoterol	capsules for inhalation	320mcg/dose+9mcg/dose; (30/3x10) in blister, (30/3x10) in blister with inhaler, (60/6x10) in blister, (60/6x10) in blister with inhaler, (60/2x30) in plastic container, (60/2x30) in plastic container with inhaler, (120/12x10) in blister, (120/12x10) in blister with inhaler, (120/4x30) in plastic container, (120/4x30) in plastic container with inhaler	PSK Pharma Ltd., Moscow Region, Dubna urban district, Dubna city, 5 Programmistov St., building 1	Russia	PSK Pharma Ltd., Moscow Region, Dubna urban district, Dubna city, 5 Programmistov St., building 1	Russia	PoM	22797 (006479) 28.02.2025
30	Respisalf	salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)	capsules for inhalation	50mcg+100mcg; (30/3x10) in blister, (30/3x10) in blister with inhaler, (30) in plastic container, (30) plastic container with inhaler, (60/6x10) in blister, (60/6x10) in blister with inhaler, (60/2x30) plastic container, (60/2x30) plastic container with inhaler, (90/9x10) in blister, (90/9x10) in blister with inhaler	PSK Pharma Ltd., Moscow Region, Dubna urban district, Dubna city, 5 Programmistov St., building 1	Russia	PSK Pharma Ltd., Moscow Region, Dubna urban district, Dubna city, 5 Programmistov St., building 1	Russia	PoM	22798 (010061) 28.02.2025

31	Respisalf	salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)	capsules for inhalation	50mcg+250mcg; (30/3x10) in blister, (30/3x10) in blister with inhaler, (30) in plastic container, (30) plastic container with inhaler, (60/6x10) in blister, (60/6x10) in blister with inhaler, (60/2x30) plastic container, (60/2x30) plastic container with inhaler, (90/9x10) in blister, (90/9x10) in blister with inhaler	PSK Pharma Ltd., Moscow Region, Dubna urban district, Dubna city, 5 Programmistov St., building 1	Russia	PSK Pharma Ltd., Moscow Region, Dubna urban district, Dubna city, 5 Programmistov St., building 1	Russia	PoM	22799 (010061) 28.02.2025
32	Respisalf	salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)	capsules for inhalation	50mcg+500mcg; (30/3x10) in blister, (30/3x10) in blister with inhaler, (30) in plastic container, (30) plastic container with inhaler, (60/6x10) in blister, (60/6x10) in blister with inhaler, (60/2x30) plastic container, (60/2x30) plastic container with inhaler, (90/9x10) in blister, (90/9x10) in blister with inhaler	PSK Pharma Ltd., Moscow Region, Dubna urban district, Dubna city, 5 Programmistov St., building 1	Russia	PSK Pharma Ltd., Moscow Region, Dubna urban district, Dubna city, 5 Programmistov St., building 1	Russia	PoM	22800 (010061) 28.02.2025
33	Levomecol	chloramphenicol, methyluracil	ointment for external use	7,5mg/g+40mg/g; 40g aluminium 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	22801 (010061) 28.02.2025

LIST

of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 02-2/25 on
February 18, 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	Levobupivacaina BIOINDUSTRIA L.I.M.	levobupivacaine (levobupivacaine hydrochloride)	solution for injection/ infusion	2,5mg/ml; (10) ampoules 10ml	Bioindustria Laboratorio Italiano Medicinali S.p.A., Via De Ambrosiis 2/6, Novi Ligure, 15067	Italy	Bioindustria Laboratorio Italiano Medicinali S.p.A., Via De Ambrosiis 2, Novi Ligure, 15067	Italy	PoM	22765 28.02.2025
2	Levobupivacaina BIOINDUSTRIA L.I.M.	levobupivacaine (levobupivacaine hydrochloride)	solution for injection/ infusion	5mg/ml; (10) ampoules 10ml	Bioindustria Laboratorio Italiano Medicinali S.p.A., Via De Ambrosiis 2/6, Novi Ligure, 15067	Italy	Bioindustria Laboratorio Italiano Medicinali S.p.A., Via De Ambrosiis 2, Novi Ligure, 15067	Italy	PoM	22766 28.02.2025
3	Levobupivacaina BIOINDUSTRIA L.I.M.	levobupivacaine (levobupivacaine hydrochloride)	solution for injection/ infusion	7,5mg/ml; (10) ampoules 10ml	Bioindustria Laboratorio Italiano Medicinali S.p.A., Via De Ambrosiis 2/6, Novi Ligure, 15067	Italy	Bioindustria Laboratorio Italiano Medicinali S.p.A., Via De Ambrosiis 2, Novi Ligure, 15067	Italy	PoM	22767 28.02.2025
4	BATROG	vigabatrin	tablets film- coated	500mg; (100) in plastic container	Amneal Pharmaceuticals Pvt. Ltd., Oral Solid Unit, Plot No. - 16 & 17, Pharmed SEZ, Sarkhej - Bavla Highway, Vil.- Matoda, Ta. - Sanand, Dist.- Ahmedabad - 382 213, Gujarat State	India	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22768 28.02.2025

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 02-2/25 on February 18, 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	Propofol-Lipuro	propofol	emulsion for injection/infusion	10mg/ml; (5) ampoules 20ml	B.Braun Melsungen AG, Mistelweg 2, Berlin, 12357	Germany	B.Braun Melsungen AG, Carl-Braun-Strasse 1,34212 Melsungen	Germany	PoM	22756 28.02.2025
2	Propofol-Lipuro	propofol	emulsion for injection/infusion	10mg/ml; (10) glass vials 50ml	B.Braun Melsungen AG, Carl-Braun-Strasse 1, Melsungen, Hessen, 34212	Germany	B.Braun Melsungen AG, Carl-Braun-Strasse 1,34212 Melsungen	Germany	PoM	22757 28.02.2025
3	Izoconazol-M	isoconazole (isoconazole nitrate)	cream	10mg/g; aluminium tube 25g	Esco-Pharm LLC, Nor-Norq, Mikoyan 13, Yerevan	Republic of Armenia	Medical Horizon LLC, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	PoM	22758 28.02.2025

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 02-2/25 on February 18, 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	Ferrum Lek	iron (III)-hydroxide dextran complex	solution for i/m injection	50mg/ml; (5) ampoules 2ml, (50) ampoules 2ml	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	22759 28.02.2025
2	Rinostop-Oticipharm	xylometazoline (xylometazoline hydrochloride)	spray nasal	0,5mg/ml; 15ml plastic vial	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, room II, flr.12, h.10, off. 29, Moscow 123112	Russia	OTC	22760 28.02.2025
3	Rinostop-Oticipharm	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; 15ml plastic vial	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, room II, flr.12, h.10, off. 29, Moscow 123112	Russia	OTC	22761 28.02.2025
4	Moxi-Tech	moxifloxacin (moxifloxacin hydrochloride)	solution for infusion	1,6mg/ml; plastic pack 250ml	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	22762 28.02.2025
5	Oticaine	phenazone, lidocaine (lidocaine hydrochloride)	drops ear	40mg/g+10mg/g; plastic bottle 5g, plastic bottle 15g	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	22763 28.02.2025
6	ACC Long	acetylcysteine	tablets effervescent	600mg; (10) in plastic container	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben-batch releaser, Hermes Pharma GmbH, Hans-Urmiler-Ring 52, 82515 Wolfratshausen, Germany -bulk manufacturer, packager, quality control	Germany	Sandoz Pharmaceuticals d.d. Verevska 57,1000, Ljubljana	Slovenia	OTC	22764 28.02.2025

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 02-2/25 on February 18,
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	Metrogyl denta	metronidazole (metronidazole benzoate), chlorhexidine digluconate (chlorhexidine digluconate 20% solution)	gel dental	10mg/g+0,5mg/g: 5g plastic tube, 10g plastic tube, 20g plastic tube	Unique Pharmaceutical Laboratories (a division of J. B. Chemicals & Pharmaceuticals Ltd.), Plot No. 304-308, G.I.D.C. Industrial Area, Panoli: 394 116, Gujarat State	India	JTNL LLC, 121614, Moscow, Krylatskaya intercity municipal district, Krylatskaya str., 17, bld. 3	Russia	OTC	21128/1/1 28.02.2025
2	Be-Bo	benzyl benzoate	emulsion	200mg/g; plastic bottle 100ml	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	OTC	21702/1/1 28.02.2025
3	Broncho-munal P	lyophilized bacterial lysate	capsules hard	3,5mg; (10/1x10) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- batch releaser, OM Pharma SA, Rue Du Bois-Du-Lan 22, Meyrin 1217, Switzerland- bulk manufacturer, quality control, Novartis Pharmaceutical Manufacturing LLC, Verovskova ulica 57, Ljubljana, 1000, Slovenia- packager	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19713/5/1 28.02.2025

4	Broncho-munal	lyophilized bacterial lysate	capsules hard	7mg; (10/1x10) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- batch releaser, OM Pharma SA, Rue Du Bois-Du-Lan 22, Meyrin 1217, Switzerland- bulk manufacturer, quality control, Novartis Pharmaceutical Manufacturing LLC, Verovskova ulica 57, Ljubljana, 1000, Slovenia- packager	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19712/5/1 28.02.2025
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LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 02-2/25 on February 18,
2025

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1	Inestom	levocarnitine	solution oral	100mg/ml; (10) glass vials 10ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamor-fosi, Attiki	Greece	PoM	21320/2 28.02.2025
2	Gangleron	ganglefene	capsules	40mg; (30) plastic container	Arpimed LLC, Kotayk Marz, 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	19182/2 28.02.2025
3	Linex forte	lyophilized viable lactic acid bacterias (Lactobacillus acidophilus, Bifidobacterium animalis subsp. Lactis)	capsules	2x10 ⁹ CFU; (14/2x7) in blister, (28/4x7) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- quality control, batch releaser, Lek Pharmaceuticals d.d., Kolodvorska cesta 27, Menges, 1234, Slovenia- bulk manufacturer, packager	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	21534/2 28.02.2025
4	Legalon 140	silibinin	capsules	140mg; (20/2x10) in blister, (30/3x10) in blister, (60/6x10) in blister	Madaus GmbH, Luetticher Strasse 5, Troisdorf, 53842	Germany	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg	Germany	OTC	21041/1 28.02.2025
5	Gliatilin	choline alfoscerate	solution for injection	250mg/ml; (3) ampoules 4ml	Italfarmaco S.p.A., Viale Fulvio Testi, 330 - 20126 Milan	Italy	Italfarmaco S.p.A., Viale Fulvio Testi, 330 - 20126 Milan	Italy	PoM	22096/2 28.02.2025

6	Oticaine	phenazone, lidocaine (lidocaine hydrochloride)	drops ear	40mg/g+10mg/g; plastic bottle 5g, plastic bottle 15g	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	18805/1 28.02.2025
7	Izoconazol-M	isokonazole (isokonazole nitrate)	cream	10mg/g; aluminium tube 25g	Esco-Pharm LLC, Nor-Norq, Mikoyan 13, Yerevan	Republic of Armenia	Medical Horizon LLC, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	PoM	18961/2/1 28.02.2025
8	Monox	etoricoxib	tablets film-coated	60mg; (30/3x10) in blister	Synthon Hispania,S.L., C/ Castello, N 1, Sant Boi de Llobregat, Barcelona, 08830	Spain	Family Pharm Group LLC., 85 Marshal Baghramyan ave., 0033, Yerevan	Republic of Armenia	PoM	20604/2 28.02.2025
9	Monox	etoricoxib	tablets film-coated	90mg; (30/3x10) in blister	Synthon Hispania,S.L., C/ Castello, N 1, Sant Boi de Llobregat, Barcelona, 08830	Spain	Family Pharm Group LLC., 85 Marshal Baghramyan ave., 0033, Yerevan	Republic of Armenia	PoM	20605/2 28.02.2025
10	Monox	etoricoxib	tablets film-coated	120mg; (28/4x7) in blister	Synthon Hispania,S.L., C/ Castello, N 1, Sant Boi de Llobregat, Barcelona, 08830	Spain	Family Pharm Group LLC., 85 Marshal Baghramyan ave., 0033, Yerevan	Republic of Armenia	PoM	20606/2 28.02.2025
11	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	19020/2/1 28.02.2025
12	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	19019/2/1 28.02.2025

13	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	19018/2/1 28.02.2025
14	Thiotriazolin	thiotriazoline (tiazotic acid morpholinate)	tablets	200mg; (90/9x10) in blister, (90/6x15) in blister	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	22028/4/1 28.02.2025
15	Trimedat	trimebutine	tablets	100mg; (10/1x10) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	PoM	19737/4/1 28.02.2025
16	Trimedat	trimebutine	tablets	200mg; (30/3x10) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	PoM	19738/4/1 28.02.2025

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 02-2/25 on February 18, 2025

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1	Zolaxa ODT	olanzapine	tablets orodispersible	10mg; (28/2x14/) in blister, (30/5x6/) in blister, (56/4x14/) in blister	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	PoM	ЛПТ-№000239-PT-AM 28.02.2025
2	Trittico	trazodone (trazodone hydrochloride)	tablets prolonged-release	150mg; (20/2x10/) in blister, (60/6x10/) in blister, (90/6x15/) in blister	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. Via Vecchia Del Pinocchio, 22, 60131 Ancona	Italy	Angelini Pharma S.p.A., Viale, Amelia 70, 00181, Rome	Italy	PoM	ЛПТ-№001171-TTI-AM 28.02.2025
3	Brimica Genuair	acridinium (acridinium bromide), formoterol fumarate dihydrate	powder for inhalation	340mcg/dose+12mcg/dose; (1) inhaler with 60 unit doses, (3) inhalers with 180(3x60) unit doses	Industrias Farmaceuticas Almirall S.A., Ctra. De Martorell 41-61, 08740 Sant Andreu de la Barca, Barcelona	Spain	Berlin-Chemie AG, Glienicke Weg 125, 12489 Berlin	Germany	PoM	ЛПТ-№008504-PT-AM 28.02.2025