

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 01-1/25 on January 30, 2025

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Amoxicillin + Clavulanic acid EXPRESS-Pharm-standard	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets dispersible	125mg+31,25mg; (14/7x2) in blister	Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 280- quality control, batch releaser, Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager	Russia	Pharmaceutical Firm «LEKKO» CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s. 278	Russia	PoM	22657 30.01.2025
2	Amoxicillin + Clavulanic acid EXPRESS-Pharm-standard	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets dispersible	250mg+62,5mg; (14/7x2) in blister	Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 280- quality control, batch releaser, Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager	Russia	Pharmaceutical Firm «LEKKO» CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s. 278	Russia	PoM	22658 30.01.2025
3	Amoxicillin + Clavulanic acid EXPRESS-Pharm-standard	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets dispersible	500mg+125mg; (14/7x2) in blister	Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 280- quality control, batch releaser, Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager	Russia	Pharmaceutical Firm «LEKKO» CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s. 278	Russia	PoM	22659 30.01.2025

4	Amoxicillin + Clavulanic acid EXPRESS-Pharm-standard	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets dispersible	875mg+125mg: (14/7x2) in blister	Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 280- quality control, batch releaser, Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager	Russia	Pharmaceutical Firm «LEKKO» CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s. 278	Russia	PoM	22660 30.01.2025
5	AqVirubicin	epirubicin (epirubicin hydrochloride)	solution for injection	2mg/ml; glass vial 5ml	AqVida GmbH, Kaiser-Wilhelm-Str. 89, Hamburg, 20355- batch releaser, AqVida GmbH, Werkstrasse 21, Dassow 23942, Germany- bulk manufacturer, packager, quality control	Germany	Aversi-Rational Ltd, David Kobahidze str. 33, 0198 Tbilisi	Georgia	PoM	22661 30.01.2025
6	AqVirubicin	epirubicin (epirubicin hydrochloride)	solution for injection	2mg/ml; glass vial 25ml	AqVida GmbH, Kaiser-Wilhelm-Str. 89, Hamburg, 20355- batch releaser, AqVida GmbH, Werkstrasse 21, Dassow 23942, Germany- bulk manufacturer, packager, quality control	Germany	Aversi-Rational Ltd, David Kobahidze str. 33, 0198 Tbilisi	Georgia	PoM	22662 30.01.2025
7	Validol Tatpharm	levomenthol solution in menthyl isovalerate	tablets sublingual	60mg; (100/10x10) 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	22663 30.01.2025
8	Clivas Plus	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets film-coated	10mg+10mg; (30/3x10) in blister	ELPEN Pharmaceutical CO., INC, Marathonos Ave. 95, Pikermi Attiki, 19009	Greece	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	22664 30.01.2025
9	Clivas Plus	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets film-coated	20mg+10mg; (30/3x10) in blister	ELPEN Pharmaceutical CO., INC, Marathonos Ave. 95, Pikermi Attiki, 19009	Greece	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	22665 30.01.2025
10	Clivas Plus	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets film-coated	40mg+10mg; (30/3x10) in blister	ELPEN Pharmaceutical CO., INC, Marathonos Ave. 95, Pikermi Attiki, 19009	Greece	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	22666 30.01.2025
11	Paracetamol B. Braun	paracetamol	solution for iinfusion	10mg/ml; 50ml plastic bottle, 100ml plastic bottle	B. Braun Medical S.A., Ctra. de Terrassa, 121, Rubi (Barcelona) 08191	Spain	B.Braun Melsungen AG, Carl-Braun-Strasse 1, Melsungen, 34212	Germany	PoM	22667 30.01.2025

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of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 01-1/25 on January 30,
2025

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Ovitrelle	choriogonadotropin alfa	solution for s/c injection	250mcg/0,5ml; (1) glass pre-filled syringe with needle in plastic pack	Merck Serono S.p.A., Via delle Magnolie 15, 70026 Modugno (BA)	Italy	Merck LLC, 35 Valovaya Street, Moscow 115054	Russia	PoM	22689 (009514) 30.01.2025
2	Verospiron	spironolactone	tablets	25mg; (20/1x20/) in blister, (60/3x20/) in blister, (100/5x20/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22690 (009834) 30.01.2025
3	Verospiron	spironolactone	tablets	25mg; (20/1x20/) in blister, (60/3x20/) in blister, (100/5x20/) 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	22691 (009834) 30.01.2025

4	Verospiron	spironolactone	tablets	25mg: (20/1x20/) in blister, (60/3x20/) in blister, (100/5x20/) 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	Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22692 (009834) 30.01.2025
5	JO CET	salbutamol (salbutamol sulfate), bromhexine hydrochloride, guaifenesin, menthol (levomenthol)	syrup	1mg/5ml+2mg/5ml+50mg/5ml+0,5mg/5ml; 100ml plastic container and measuring cup 15ml, 200ml plastic container and measuring cup 15ml	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	Unique Pharmaceutical Laboratories (a division of J. B. Chemicals & Pharmaceuticals Ltd.), Neelam Centre, B wing, 4th floor, Hind Cycle Road, Worli, Gujarat State, Mumbai 400 030	India	PoM	22693 (009834) 30.01.2025

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of the medicines recommended for the re-registration by the Center according to the meeting decision N 01-1/25 on January 30, 2025

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Coldrex MaxGrip	paracetamol, phenylephrine (phenylephrine hydrochloride), ascorbic acid	powder for oral solution with lemon flavour	1000mg+10mg+40mg; (10) sachets 6,427g	SmithKline Beecham S.A. Ctra. de Ajalvir, KM-2500-28806, Alcalá de Henares, Madrid	Spain	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	OTC	22676 30.01.2025
2	Tinctura menthae piperitae	folium menthae piperite, oil menthae piperitae	tincture	50mg/ml+ 50mg/ml; glass bottle 30ml	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	22677 30.01.2025
3	Metrofungyn	miconazole (miconazole nitrate), metronidazole	capsules vaginal	100mg+100mg; (10/2x5/)	Minskintercaps U.V., 26/3 bild. No2, Inzhenemaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhenemaya str., 220075, Minsk	Republic of Belarus	PoM	22678 30.01.2025
4	Co-Diroton	lisinopril (lisinopril dihydrate), hydrochlorothiazide	tablets	20mg+12,5mg; (10/1x10) in blister, (30/3x10) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Poland Sp. z o.o., ul. Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager, Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825, Poland- quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22679 30.01.2025

5	Co-Dirotan	lisinopril (lisinopril dihydrate), hydrochlorothiazide	tablets	10mg+12,5mg; (10/1x10/) in blister, (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Poland Sp. z o.o., ul. Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager, Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825, Poland- quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22680 30.01.2025
6	PARACETAMOL GIGA farm	paracetamol	tablets	500mg; (200/20x10/) in blister	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Giga Farm LLC, 3101, Gogunts st. 3/5, Gyumri	Republic of Armenia	OTC	22681 30.01.2025
7	Nuvaring	etonogestrel, ethinylestradiol	vaginal delivery system (vaginal ring)	11,7mg+2,7mg; (1) sachet	N.V. Organon, Kloosterstraat 6, 5349 AB Oss	Switzerland	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	22682 30.01.2025
8	Atracurium Besylate Injection 10mg/ml	atracurium (atracurium besylate)	solution for injection	10mg/ml; (5) ampoules 2,5ml	Swiss Parenterals Ltd., 808, 809 & 810 Kerala Industrial Estate , G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220, Gujarat	India	Swiss Parenterals Ltd., 808, 809 & 810 Kerala Industrial Estate , G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220, Gujarat	India	PoM	22683 30.01.2025
9	Atracurium Besylate Injection	atracurium (atracurium besylate)	solution for injection	10mg/ml; (5) ampoules 5ml	Swiss Parenterals Ltd., 808, 809, 810, Kerala Industrial Estate, G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220, Gujarat	India	Swiss Parenterals Ltd., 808, 809 & 810 Kerala Industrial Estate , G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220, Gujarat	India	PoM	22684 30.01.2025
10	Azimac	azithromycin (azithromycin dihydrate)	capsules	250mg; (6/2x3) in blister	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	22685 30.01.2025
11	Azimac	azithromycin (azithromycin dihydrate)	capsules	500mg; (3/1x3) in blister	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	22686 30.01.2025
12	Magnesium sulfate	magnesium sulfate	solution for i/v and i/m injection	250mg/ml; (10) ampoules 5ml and (10) ampoules 5ml label banderol	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, No10/1, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	22687 30.01.2025

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of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 01-1/25 on January 30, 2025

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Arbidol	umifenovir (umifenovir hydrochloride)	capsules	100mg; (10/1x10) in blister, (20/2x10) in blister, (40/4x10) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC «OTCPharm», Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	22668 30.01.2025
2	Puregon	follitropin beta (recombinant)	solution for s/c injection	300IU/0,36ml; cartridge 0,42ml and (6/2x3) needles	N.V. Organon, Molenstraat 110, 5342 CC OSS- secondary packager, quality control, batch releaser (legal address- N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands), Vetter Pharma-Fertigung GmbH & Co. KG, Mooswiesen 2, Ravensburg, Baden-Wuerttemberg, 88214, Germany- bulk manufacturer, primary packager	the Netherlands	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	22669 30.01.2025
3	Puregon	follitropin beta (recombinant)	solution for s/c injection	600IU/0,72ml; cartridge 0,78ml and (6/2x3) needles	N.V. Organon, Molenstraat 110, 5342 CC OSS- secondary packager, quality control, batch releaser (legal address- N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands), Vetter Pharma-Fertigung GmbH & Co. KG, Mooswiesen 2, Ravensburg, Baden-Wuerttemberg, 88214, Germany- bulk manufacturer, primary packager	the Netherlands	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	22670 30.01.2025
4	ODESTON	hymecromone	tablets	200mg; (50/5x10) in blister	Adamed Pharma S.A., 5 Marszalka Jozefa Pilsudskiego Str., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza St., 05-152 Czosnow	Poland	OTC	22671 30.01.2025

5	Diprosan	betamethasone (betamethasone dipropionate), betamethasone (betamethasone sodium phosphate)	suspension for injection	5mg/ml+2mg/ml; (5) ampoules 1ml	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	22672 30.01.2025
6	Tot` Hema	iron (iron gluconate), manganese (manganese gluconate), copper (copper gluconate)	solution oral	50mg/10ml+1,33mg/10ml+0,7mg/10ml; (20/2x10) ampoules 10ml in blister	Innothera Chouzy, Rue Rene Chantereau, Chouzy-sur-Cisse, Valloire-sur-Cisse, 41150	France	Laboratoire Innotech International, 22, Avenue Aristide Briand, 94110 Arcueil	France	PoM	22673 30.01.2025
7	ACC 100	acetylcysteine	powder for oral solution	100mg; (20) sachets 3g	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben- batch releaser, Lindopharm GmbH, Neustrasse 82, 40721 Hilden, Germany- bulk manufacturer, packager, quality control (physicochemical), IMQ- Institut fur mikrobiologische Qualitatssicherung GmbH, Benninghofer Weg 2, Mettmann, 40822, Germany- quality control (microbiological)	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	22674 30.01.2025
8	ACC 200	acetylcysteine	powder for oral solution	200mg; (20) sachets 3g	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben- batch releaser, Lindopharm GmbH, Neustrasse 82, 40721 Hilden, Germany- bulk manufacturer, packager, quality control (physicochemical), IMQ- Institut fur mikrobiologische Qualitatssicherung GmbH, Benninghofer Weg 2, Mettmann, 40822, Germany- quality control (microbiological)	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	22675 30.01.2025

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of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 01-1/25 on January 30,
2025

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Canephron N	centauri herba, levistici radix, rosmarini folia	tablets coated	18mg+18mg+18mg; (60/3x20) in blister	Bionorica SE, Kerschensteiner str. 11-15, 92318 Neumarkt in der Oberpfalz - packager, quality control, batch releaser, Rottendorf Pharma GmbH, Ostenfelder Strasse 51-61, 59320 Ennigerloh, Germany- bulk manufacturer	Germany	Bionorica SE, Kerschensteiner str. 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	20500/1/1 30.01.2025
2	Rinostop-Oticipharm	xylometazoline (xylometazoline hydrochloride)	spray nasal	0,5mg/ml;15ml plastic vial	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC «OTCPharm», Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	19319/1/1 30.01.2025

3	Rinostop-Oticipharm	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; 15ml plastic vial	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC «OTCPharm», Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	PoM	19320/1/1 30.01.2025
4	Polydexa	neomycin (neomycin sulfate), polymyxin B (polymyxin B sulfate), dexamethasone (dexamethasone sodium metasulfobenzoate)	drops ear	1g (650000U)/100ml+1000000U/100ml+0,1g/100ml; 10,5ml bottle-dropper	Pharmaster, Zone Industrielle de Krafft, 67150 Erstein- bulk manufacturer, packager, batch releaser, QUALI CONTROLE, 29 rue Paul Vaillant Couturier, 60110 MERU, France- quality control (physicochemical), SOLVIAS FRANCE, Zone Industrielle, rue du Canal d' Alsace, 68490 HOMBOURG, France- quality control (microbiological)	France	Laboratoires Bouchara-Recordati, Immeuble le Wilson, 70 avenue du General de Gaulle, 92800 Puteaux	France	PoM	20871/1/1 30.01.2025
5	Bifren	phenibut	capsules	250mg; (20/2x10) in blister, (60/6x10) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	22027/1/1 30.01.2025
6	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	19081/2/1 30.01.2025

7	Adaptol	temgicoluril	capsules	300mg; (20/2x10) in blister, (30/3x10) in blister, (40/4x10) 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	20547/2/2 30.01.2025
8	Adaptol	temgicoluril	tablets	500mg; (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	20597/2/2 30.01.2025
9	IBUPROFEN 400mg film-coated tablets	ibuprofen	tablets film-coated	400mg; (100/10x10) in blister	M/s Medopharm, No. 34-B, Industrial Area, Malur-563 160, Kolar District, Karnataka	India	Troge Medical GmbH, Milchstrasse 19, 20148 Hamburg	Germany	OTC	22294/1/1 30.01.2025

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of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 01-1/25 on January 30, 2025

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1	Paracetamol	paracetamol	tablets	500mg; (10) in blister, (10) in strip	Irbitskiy himfarmzavod OJSC, 124-a, K. Marksa str., Irbit, St. Sverdlovsk, 623856	Russia	Irbitskiy himfarmzavod OJSC, 172, Kirova str., Irbit, St. Sverdlovsk, 623856	Russia	OTC	18490/1 30.01.2025
2	Hexalyse	biclotymol, lysozyme (lysozyme hydrochloride), enoxolone	tablets orodispersible	5mg+5mg+5mg (30/3x10) in blister	Laboratoires Bouchara-Recordati, Parc Mecatronique 03410 Saint Victor	France	Laboratoires Bouchara-Recordati, Immeuble le Wilson, 70 avenue du General de Gaulle, 92800 Puteaux	France	OTC	19457/4 30.01.2025
3	Liprimar ST	atorvastatin (atorvastatin calcium)	tablets film-coated	10mg; (30/3x10) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau - packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	21149/2/1 30.01.2025
4	Liprimar ST	atorvastatin (atorvastatin calcium)	tablets film-coated	20mg; (30/3x10) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau - packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	21150/2/1 30.01.2025

5	Liprimar ST	atorvastatin (atorvastatin calcium)	tablets film-coated	40mg; (30/3x10) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau - packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	21151/2/1 30.01.2025
6	Liprimar ST	atorvastatin (atorvastatin calcium)	tablets film-coated	80mg; (30/3x10) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau - packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	21152/2/1 30.01.2025
7	Sermion	nicergoline	tablets coated	5mg; (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	19178/6/3 30.01.2025
8	Viagra	sildenafil (sildenafil citrate)	tablets film-coated	25mg; (4/1x4) in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	22086/1 30.01.2025
9	Viagra	sildenafil (sildenafil citrate)	tablets film-coated	50mg; (1) in blister, (4/1x4) in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	22275/1 30.01.2025
10	Viagra	sildenafil (sildenafil citrate)	tablets film-coated	100mg; (1) in blister, (4/1x4) in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	22276/1 30.01.2025
11	Lyrica	pregabalin	capsules hard	75mg; (14/1x14) in blister, (56/4x14) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	19207/5/2 30.01.2025
12	Lyrica	pregabalin	capsules hard	150mg; (14/1x14) in blister, (56/4x14) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	19208/5/2 30.01.2025

13	Lyrica	pregabalin	capsules hard	300mg; (14/1x14) in blister, (56/4x14) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	19209/4/2 30.01.2025
14	Xalatan	latanoprost	drops eye	50mcg/ml; 2,5ml plastic container	Pfizer Manufacturing Belgium, Rijksweg 12, Puurs-Sint-Amands, 2870	Belgium	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	22030/1 30.01.2025
15	Arbidol	umifenovir (umifenovir hydrochloride)	capsules	100mg (10/1x10) in blister, (20/2x10) in blister, (40/4x10) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC «OTCPharm», Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	19468/3 30.01.2025
16	Coldrex MaxGrip	paracetamol, phenylephrine (phenylephrine hydrochloride), ascorbic acid	powder for oral solution with lemon flavour	1000mg+10mg+40mg; (10) sachets 6,427g	SmithKline Beecham S.A. Ctra. de Ajalvir, KM-2500-28806, Alcala de Henares, Madrid	Spain	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	OTC	18670/3/1 30.01.2025
17	Fentanyl Kalceks	fentanyl (fentanyl citrate)	solution for injection	0,05mg/ml; (10/2x5) ampoules 2ml in plastic liner	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	19795/3/1 30.01.2025
18	Trachisan Lozenges	lidocaine (lidocaine hydrochloride), chlorhexidine (chlorhexidine digluconate), tyrothricin	lozenges	1mg+1mg+0,5mg; (20/2x10) in blister	Engelhard Arzneimittel GmbH & Co. KG, Herzbergstrasse 3, 61138 Niederdorfelden	Germany	Engelhard Arzneimittel GmbH & Co. KG, Herzbergstrasse 3, 61138 Niederdorfelden	Germany	OTC	19696/3 30.01.2025
19	Vurdon-Neo	diclofenac (diclofenac sodium)	solution for injection	25mg/ml; (5) ampoules 3ml in blister	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorfofi, Attiki	Greece	PoM	22357/1 30.01.2025
20	Enterogermina	spores of polyan-tibiotic-resistant Bacillus clausii	suspension oral	2x10 ⁹ /5ml; (10) plastic vials 5ml	Opella Healthcare Italy S.R.L., Viale Europa, 11, 21040 Origgio (VA)	Italy	Opella Healthcare Italy S.R.L., Viale Luigi Bodio 37/b, 20158 Milano(MI)	Italy	OTC	19188/4/1 30.01.2025

21	Paracetamol GIGAfarm	paracetamol	tablets	500mg; (200/20x10) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Giga Farm LLC, Gogunts st. 3/5, Gyumri	Republic of Armenia	OTC	19258/1 30.01.2025
22	Ketonal	ketoprofen	solution for injection	50mg/ml; (10) ampoules 2ml	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	22137/1 30.01.2025
23	Katarel	tenoxicam	powder lyophilized and solvent for solution for i/m/i/v injection	20mg; glass vial and solvent in ampoule 2ml	Anfarm Hellas S.A., 61st Km National Road Athens-Lamia, Schimatari Viotias, 32009	Greece	J&P Pharma UK LTD, 7 Becket Wood, Newdigate, Dorking RH5 5AQ	UK	PoM	20295/1 30.01.2025
24	ATRIUM	atracurium (atracurium besylate)	solution for injection	10mg/ml; (5) ampoules 2,5ml	Swiss Parenterals Ltd., 808, 809 & 810 Kerala Industrial Estate , G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220, Gujarat	India	Swiss Parenterals Ltd., 808, 809 & 810 Kerala Industrial Estate , G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220, Gujarat	India	PoM	18806/1 30.01.2025
25	Azimac	azithromycin (azithromycin dihydrate)	capsules	250mg; (6/2x3) in blister	GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi	Georgia	PoM	18834/2/1 30.01.2025
26	Azimac	azithromycin (azithromycin dihydrate)	capsules	500mg; (3/1x3) in blister	GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi	Georgia	PoM	18835/2/1 30.01.2025
27	Zithrocyn	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3) in blister	A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan- secondary packager, quality control, batch releaser, Centurion Laboratories Pvt. Ltd., P-2 Savli Bio-Tech Park, At Manjusar, Tal-Savli, Vadodara-390016, India- bulk manufacturer, primary packager	Republic of Armenia	A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan	Republic of Armenia	PoM	18949/2/1 30.01.2025
28	Magnesium sulfate	magnesium sulfate	solution for i/v and i/m injection	250mg/ml; (10) ampoules 5ml	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, No10/1, No11/1 ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	18987/1/1 30.01.2025

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 01-1/25 on January 30, 2025

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Bretaris Genuair	aclidinium (aclidinium bromide)	powder for inhalation	322mcg/dose; (1) inhaler (30 unit doses), (1) inhaler (60 unit doses), (3) inhaler (180/3x60/ unit doses)	Industrias Farmaceuticas Almirall S.A., Ctra. De Martorel 41-61, 08740 Sant Andreu de la Barca, Barcelona	Spain	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	000310 17.01.2025
2	Cevikap	ascorbic acid	drops oral	100mg/ml; glass bottle-dropper 10ml, glass bottle-dropper 30ml	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	003564 17.01.2025
3	Tantum Verde	benzydamine (benzydamine hydrochloride)	spray for local use	0,255mg/dose; 30ml (176 doses) plastic container with pump dispenser	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	OTC	000747 17.01.2025
4	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	5mg+1,25mg+5mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	002311 17.01.2025
5	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	5mg+1,25mg+5mg; (30) plastic container, (90) plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	002311 17.01.2025

6	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	5mg+1,25mg+5mg; (30) plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland-bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	002311 17.01.2025
7	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	5mg+2,5mg+10mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	002311 17.01.2025
8	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	5mg+2,5mg+10mg; (30) plastic container, (90) plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	002311 17.01.2025
9	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	5mg+2,5mg+10mg; (30) plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland-bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	002311 17.01.2025
10	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	10mg+1,25mg+5mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	002311 17.01.2025
11	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	10mg+1,25mg+5mg; (30) plastic container, (90) plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	002311 17.01.2025
12	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	10mg+1,25mg+5mg; (30) plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland-bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	002311 17.01.2025
13	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	10mg+2,5mg+10mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	002311 17.01.2025

14	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	10mg+2,5mg+10mg; (30) plastic container, (90) plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	002311 17.01.2025
15	Triplixam	amlodipine (amlodipine besilate), indapamide, perindopril (perindopril arginine)	tablets film-coated	10mg+2,5mg+10mg; (30) plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	002311 17.01.2025
16	Preductal MR	trimetazidine (trimetazidine dihydrochloride)	tablets film-coated modified-release	35mg; (60/2x30) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000386 30.01.2025
17	Preductal MR	trimetazidine (trimetazidine dihydrochloride)	tablets film-coated modified-release	35mg; (60/2x30) 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	000386 30.01.2025
18	Alecensa	alectinib (alectinib hydrochloride)	capsules hard	150mg; (56/8x7) in blister, (224/4x56) in blister	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4058 Basel- batch releaser, Excella GmbH & Co. KG, Nummerger Strasse 12, 90537 Feucht, Germany- bulk manufacturer, Delpharm Milano S.r.l., Via Carnevale 1, 20054 Segrate, Milano, Italy- packager, quality control	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4070 Basel	Switzerland	PoM	000150 30.01.2025