

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 03-1/25 on March 14, 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	Gastritol	anserinae herba, matricariae flos, liquiritiae radix, angelicae radix, cnici benedicti herba, absinthii herba	drops oral	0,35ml/ml+0,2ml/ml+0,15ml/ml+0,05ml/ml+0,05ml/ml+0,05ml/ml glass vial-dropper 20ml, glass vial-dropper 50ml, glass vial-dropper 100ml	Dr. Gustav Klein GmbH & Co. KG, Steinenfeld 3, 77736 Zell am Harmersbach- bulk manufacturer, packager, quality control (physicochemical), batch releaser, GBA Pharma GmbH, Ernst-Abbe-Str. 40, Ulm, Baden-Wuerttemberg, 89079, Germany- quality control (microbiological)	Germany	Alpen Pharma GmbH, Steinenfeld 3 Zell am Harmersbach, 77736	Germany	OTC	22811 14.03.2025
2	On.setron-Denk 4mg ODT	ondansetron	tablets orodispersible	4mg; (6/1x6) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, quality control (physicochemical), batch releaser, Swiss Caps GmbH, Grassingerstrasse 9, 83043 Bad Aibling, Germany- packager, Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	22812 14.03.2025
3	Acellbia	rituximab	concentrate for solution for infusion	10mg/ml; 50ml glass vial	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeschch. 89, Saint Petersburg, 198515	Russia	PoM	22813 14.03.2025
4	Acellbia	rituximab	concentrate for solution for infusion	10mg/ml; (2/1x2) glass vial 10ml in blister	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeschch. 89, Saint Petersburg, 198515,	Russia	PoM	22814 14.03.2025

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of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 03-1/25 on March 14,
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	Pipolphen	promethazine (promethazine hydrochloride)	solution for i/v and i/m injection	25mg/ml; (10/2x5) ampoules 2ml in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22819 (000472) 14.03.2025
2	Lorista HD	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+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	22820 (004784) 14.03.2025
3	Lorista HD	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+25mg; (28/2x14) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, batch releaser, Chemilab d.o.o, Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22821 (004784) 14.03.2025
4	Lorista HD	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+25mg; (28/2x14) in blister	Krka-RUS LLC 50 Moskovskaya str., Istra, Moscow region 143500	Slovenia	Krka-RUS LLC 50 Moskovskaya str., Istra, Moscow region 143500	Slovenia	PoM	22822 (004784) 14.03.2025
5	No-spa forte	drotaverine (drotaverine hydrochloride)	tablets	80mg; (24/1x24) in blister	Opella Healthcare Hungary Ltd., 2112 Veresegyhaz, Levai u. 5- bulk manufacturer, packager, quality control (physicochemical), batch releaser, CHINOIN Private Co. Ltd.- Ujpest site, To utca 1-5., Budapest, 1045, Hungary- quality control (microbiological)	Hungary	Opella Healthcare Commercial Ltd., 1138 Budapest, st.Vachi 133, b.E, floor 3	Hungary	OTC	22823 (003819) 14.03.2025

6	No-spa forte	drotaverine (drotaverine hydrochloride)	tablets	80mg; (24/1x24) in blister	Opella Healthcare Hungary Ltd., 2112 Veresegyhaz, Levai u. 5- bulk manufacturer, packager, quality control (physicochemical), batch releaser, EUROAPI Hungary Ltd., To utca 1-5, Budapest, 1045, Hungary- quality control (microbiological)	Hungary	Opella Healthcare Commercial Ltd., 1138 Budapest, st. Vachi 133, b.E, floor 3	Hungary	OTC	22824 (003819) 14.03.2025
7	Amaryl	glimepiride	tablets	1mg; (30/1x30) in blister, (60/2x30) in blister, (90/3x30) in blister, (120/4x30) in blister	SANOFI S.r.L., S.S. 17 km 22, 67019 Scoppito (AQ)	Italy	Sanofi-Aventis Deutschland GmbH, Bruningstrasse 50, D-65926 Frankfurt am Main	Germany	PoM	22825 (006135) 14.03.2025
8	Amaryl	glimepiride	tablets	2mg; (30/2x15) in blister, (60/4x15) in blister, (90/6x15) in blister, (120/8x15) in blister	SANOFI S.r.L., S.S. 17 km 22, 67019 Scoppito (AQ)	Italy	Sanofi-Aventis Deutschland GmbH, Bruningstrasse 50, D-65926 Frankfurt am Main	Germany	PoM	22826 (006135) 14.03.2025
9	Amaryl	glimepiride	tablets	3mg; (30/2x15) in blister, (60/4x15) in blister, (90/6x15) in blister, (120/8x15) in blister	SANOFI S.r.L., S.S. 17 km 22, 67019 Scoppito (AQ)	Italy	Sanofi-Aventis Deutschland GmbH, Bruningstrasse 50, D-65926 Frankfurt am Main	Germany	PoM	22827 (006135) 14.03.2025
10	Amaryl	glimepiride	tablets	4mg; (30/2x15) in blister, (60/4x15) in blister, (90/6x15) in blister, (120/8x15) in blister	SANOFI S.r.L., S.S. 17 km 22, 67019 Scoppito (AQ)	Italy	Sanofi-Aventis Deutschland GmbH, Bruningstrasse 50, D-65926 Frankfurt am Main	Germany	PoM	22828 (006135) 14.03.2025
11	Diflucan	fluconazole	solution for i/v infusion	2mg/ml; glass vial 50ml, glass vial 100ml, glass vial 200ml	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	Pfizer Inc., 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	22829 (008317) 14.03.2025
12	Donormyl	doxylamine (doxylamine succinate)	tablets coated	15mg; (10) in plastic container, (30) in plastic container	UPSA SAS, 304, avenue du Docteur Jean Bru, 47000 AGEN	France	UPSA SAS, 3, rue Joseph Monier- 92500 Rueil- Malmaison	France	PoM	22830 (002663) 14.03.2025
13	Klion-D 100	metronidazole, miconazole (miconazole nitrate)	tablets vaginal	100mg+100mg; (10/1x10) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- bulk manufacturer, packager, 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	22831 (002663) 14.03.2025

14	Klion-D 100	metronidazole, miconazole (miconazole nitrate)	tablets vaginal	100mg+100mg; (10/1x10) 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	22832 (002663) 14.03.2025
15	Klion-D 100	metronidazole, miconazole (miconazole nitrate)	tablets vaginal	100mg+100mg; (10/1x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest, Hungary- bulk manufacturer, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22833 (002663) 14.03.2025
16	Enap	enalapril (enalapril maleate)	tablets	2,5mg; (20/2x10) 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	22834 (003443) 14.03.2025
17	Enap	enalapril (enalapril maleate)	tablets	5mg; (20/2x10) 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	22835 (003443) 14.03.2025

18	Enap	enalapril (enalapril maleate)	tablets	10mg; (20/2x10') 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	22836 (003443) 14.03.2025
19	Enap	enalapril (enalapril maleate)	tablets	20mg; (20/2x10') 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	22837 (003443) 14.03.2025
20	Enap	enalapril (enalapril maleate)	tablets	2,5mg; (20/2x10') in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, batch releaser, Nacional Laboratory of Health, Environment and Food (NLZOH), Dalmatinova 3, Novo mesto, 8000, Slovenia- quality control	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22838 (003443) 14.03.2025
21	Enap	enalapril (enalapril maleate)	tablets	5mg; (20/2x10') in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, batch releaser, Nacional Laboratory of Health, Environment and Food (NLZOH), Dalmatinova 3, Novo mesto, 8000, Slovenia- quality control	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22839 (003443) 14.03.2025
22	Enap	enalapril (enalapril maleate)	tablets	10mg; (20/2x10') in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, batch releaser, Nacional Laboratory of Health, Environment and Food (NLZOH), Dalmatinova 3, Novo mesto, 8000, Slovenia- quality control	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22840 (003443) 14.03.2025
23	Enap	enalapril (enalapril maleate)	tablets	20mg; (20/2x10') in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, batch releaser, Nacional Laboratory of Health, Environment and Food (NLZOH), Dalmatinova 3, Novo mesto, 8000, Slovenia- quality control	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22841 (003443) 14.03.2025
24	Enap	enalapril (enalapril maleate)	tablets	2,5mg; (20/2x10') 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	22842 (003443) 14.03.2025
25	Enap	enalapril (enalapril maleate)	tablets	5mg; (20/2x10') 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	22843 (003443) 14.03.2025

26	Enap	enalapril (enalapril maleate)	tablets	10mg; (20/2x10) 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	22844 (003443) 14.03.2025
27	Enap	enalapril (enalapril maleate)	tablets	20mg; (20/2x10) 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	22845 (003443) 14.03.2025
28	Enap	enalapril (enalapril maleate)	tablets	2,5mg; (20/2x10) in blister	AO Vector-Medica, 630559, Novosibirsk Region, City District Industrial Community Koltsovo, rp Koltsovo, Reaserach and Production Zone, bld, 13, Russia- secondary packager, quality control, batch releaser, KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, primary packager	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22846 (003443) 14.03.2025
29	Enap	enalapril (enalapril maleate)	tablets	5mg; (20/2x10) in blister	AO Vector-Medica, 630559, Novosibirsk Region, City District Industrial Community Koltsovo, rp Koltsovo, Reaserach and Production Zone, bld, 13, Russia- secondary packager, quality control, batch releaser, KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, primary packager	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22847 (003443) 14.03.2025
30	Enap	enalapril (enalapril maleate)	tablets	10mg; (20/2x10) in blister	AO Vector-Medica, 630559, Novosibirsk Region, City District Industrial Community Koltsovo, rp Koltsovo, Reaserach and Production Zone, bld, 13, Russia- secondary packager, quality control, batch releaser, KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, primary packager	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22848 (003443) 14.03.2025

31	Enap	enalapril (enalapril maleate)	tablets	20mg; (20/2x10) in blister	AO Vector-Medica, 630559, Novosibirsk Region, City District Industrial Community Koltsovo, rp Koltsovo, Reaserach and Production Zone, bld, 13, Russia- secondary packager, quality control, batch releaser, KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, primary packager	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22849 (003443) 14.03.2025
32	Tulosin	tamsulosin (tamsulosin hydrochloride)	capsules modified-release	0,4mg; (10/1x10) in blister, (30/3x10) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	22850 (011595) 14.03.2025

LIST

of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 03-1/25 on March 14, 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	FULVAM	fulvestrant	solution for injection	250mg/5ml; (2) glass pre-filled syringes 5ml	Amneal Pharmaceuticals Pvt. Ltd., Parenteral Unit Plot No. 15, Pharmez (Special Economic Zone-Sez), Sarkhej-Bavla National Highway, Vill. -Matoda, Ta. -Sanand, Dist. -Ahmedabad - 382 213	India	Amneal EU Limited, Cahir Road, Cashel, Co. Tipperary -E25 XD51	Ireland	PoM	22851 14.03.2025
2	STROFLUX	pantoprazole (pantoprazole sodium sesquihydrate)	delayed-release tablets	20mg; (90) plastic container	Amneal Pharmaceuticals Pvt. Ltd., Survey No. 634, 637 to 641, Near Hotel Kankavati, Sarkhej-Bavla Highway Vill. Rajoda, Tal-Bavla, Dist.-Ahmedabad, 382 220, Gujarat State	India	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22852 14.03.2025
3	STROFLUX	pantoprazole (pantoprazole sodium sesquihydrate)	delayed-release tablets	40mg; (90) plastic container	Amneal Pharmaceuticals Pvt. Ltd., Survey No. 634, 637 to 641, Near Hotel Kankavati, Sarkhej-Bavla Highway Vill. Rajoda, Tal-Bavla, Dist.-Ahmedabad, 382 220, Gujarat State	India	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22853 14.03.2025
4	EZORI	temozolamide	capsules hard gelatin	5mg; (5) in plastic container	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	Amneal Pharmaceuticals LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22854 14.03.2025
5	EZORI	temozolamide	capsules hard gelatin	20mg; (5) in plastic container	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	Amneal Pharmaceuticals LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22855 14.03.2025

6	EZORI	temozolamide	capsules hard gelatin	100mg; (5) in plastic container	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	Amneal Pharmaceuticals LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22856 14.03.2025
7	EZORI	temozolamide	capsules hard gelatin	140mg; (5) in plastic container	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	Amneal Pharmaceuticals LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22857 14.03.2025
8	EZORI	temozolamide	capsules hard gelatin	180mg; (5) in plastic container	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	Amneal Pharmaceuticals LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22858 14.03.2025
9	EZORI	temozolamide	capsules hard gelatin	250mg; (5) in plastic container	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	Amneal Pharmaceuticals LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22859 14.03.2025

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 03-1/25 on March 14, 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	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	22860 14.03.2025
2	Risperidone-Remedica 2mg	risperidone	tablets film-coated	2mg; (60/6x10) in blister	Remedica Ltd, BUILDING 1-MAIN, Aharmon Street, Limassol Industrial Estate, 3056 Limassol	Cyprus	Remedica Ltd, BUILDING 1-MAIN, Aharmon Street, Limassol Industrial Estate, 3056 Limassol	Cyprus	PoM	22861 14.03.2025
3	Clopi-Denk 75	clopidogrel (clopidogrel besylate)	tablets film-coated	75mg; (30/3x10) in blister	Artesan Pharma GmbH & Co. KG, Wendlandstrasse 1, 29439 Luechow	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	22862 14.03.2025
4	NEWKOFEN	acetylsalicylic acid, paracetamol, caffeine	tablets	200mg+200mg+40mg; (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	22863 14.03.2025
5	Oxypan Kids	oxymetazoline (oxymetazoline hydrochloride), dexpanthenol	spray nasal	0,25mg/ml+50mg/ml; plastic or glass bottle 10ml	Arsanit Ltd, Masis, Masis-Ranchpar highway 07- secondary packager, batch releaser, PharmaTech CJSC, 111 Raffi str., 0064, Yerevan, Republic of Armenia-bulk manufacturer, primary packager, quality control	Republic of Armenia	Arsanit Ltd, Masis, Masis-Ranchpar highway 07	Republic of Armenia	OTC	22864 14.03.2025
6	Oxypan Kids	oxymetazoline (oxymetazoline hydrochloride), dexpanthenol	drops nasal	0,25mg/ml+50mg/ml; plastic bottle-dropper 5ml and 10ml	Arsanit Ltd, Masis, Masis-Ranchpar highway 07- secondary packager, batch releaser, PharmaTech CJSC, 111 Raffi str., 0064, Yerevan, Republic of Armenia-bulk manufacturer, primary packager, quality control	Republic of Armenia	Arsanit Ltd, Masis, Masis-Ranchpar highway 07	Republic of Armenia	OTC	22865 14.03.2025

7	Oxypan	oxymetazoline (oxymetazoline hydrochloride), dexpanthenol	spray nasal	0,5mg/ml+50mg/ml; plastic or glass bottle 10ml	Arsanit Ltd, Masis, Masis-Ranchpar highway 07- secondary packager, batch releaser, PharmaTech CJSC, 111 Raffi str., 0064, Yerevan, Republic of Armenia-bulk manufacturer, primary packager, quality control	Republic of Armenia	Arsanit Ltd, Masis, Masis-Ranchpar highway 07	Republic of Armenia	OTC	22866 14.03.2025
8	Oxypan	oxymetazoline (oxymetazoline hydrochloride), dexpanthenol	drops nasal	0,5mg/ml+50mg/ml; plastic bottle-dropper 5ml and 10ml	Arsanit Ltd, Masis, Masis-Ranchpar highway 07- secondary packager, batch releaser, PharmaTech CJSC, 111 Raffi str., 0064, Yerevan, Republic of Armenia-bulk manufacturer, primary packager, quality control	Republic of Armenia	Arsanit Ltd, Masis, Masis-Ranchpar highway 07	Republic of Armenia	OTC	22867 14.03.2025
9	Ondansetron	ondansetron (ondansetron hydrochloride dihydrate)	solution for injection	2mg/ml; (5) ampoules 4ml in blister	SIC "Borshchahivskiy Chemical-Pharmaceutical Plant" PJSC, 17, Mira St, Kyiv, 03134	Ukraine	SIC "Borshchahivskiy Chemical-Pharmaceutical Plant" PJSC, 17, Mira St, Kyiv, 03134	Ukraine	PoM	22868 14.03.2025
10	Phistoclozanid 500	oxiclosanide	tablets	500mg (50) plastic container, (300) plastic container	Biotecsi Ltd., Jumashevi str. N8, Tbilisi	Georgia	Biotecsi Ltd., Jumashevi str. N8, Tbilisi	Georgia	PoM	22869 14.03.2025

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 03-1/25 on March 14, 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	Silvadev	silver sulfadiazine	cream for external use	10mg/g; aluminum tube 40g	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	22870 14.03.2025
2	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	5mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22871 14.03.2025
3	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	7,5mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22872 14.03.2025
4	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	15mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22873 14.03.2025
5	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	10mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22874 14.03.2025
6	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	20mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22875 14.03.2025

7	Amaryl M	glimepiride, metformin (metformin hydrochloride)	tablets film-coated	2mg+500mg; (30/3x10) in blister	Handok Inc., 78 Daepungsandan- ro, Daeso-myeon, Eumseong-gun, Chungcheongbuk-do	Republic of Korea	Sanofi-aventis group, 54, rue La Boetie, 75008 Paris	France	PoM	22876 14.03.2025
8	Helmintox	pyrantel (pyrantel embonate)	tablets film-coated	250mg; (3/1x3) 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	22877 14.03.2025
9	Helmintox	pyrantel (pyrantel embonate)	tablets film-coated	125mg; (6/1x6) 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	22878 14.03.2025
10	Flucopt	fluconazole	drops eye	3mg/ml; vial-dropper 5ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	22879 14.03.2025

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of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 03-1/25 on March 14, 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	Risperidone-Remedica 2mg	risperidone	tablets film-coated	2mg (60/6x10) in blister	Remedica Ltd, BUILDING 1-MAIN, Aharon Street, Limassol Industrial Estate, 3056 Limassol	Cyprus	Remedica Ltd, BUILDING 1-MAIN, Aharon Street, Limassol Industrial Estate, 3056 Limassol	Cyprus	OTC	19300/2/1 14.03.2025
2	Fervex	paracetamol, ascorbic acid, pheniramine (pheniramine maleate)	powder for oral solution with lemon flavor, sugar free	500mg+200mg+25mg; (8) sachets 4,95g	UPSA SAS, 979, Avenue des Pyrenees, 47520 Le Passage	France	UPSA SAS, 3, rue Joseph Monier-92500 Rueil-Malmaison	France	PoM	21831/1/1 14.03.2025
3	Octolipen-Pharmstandard	thioctic acid (alfa-lipoic acid)	concentrate for solution for infusion	30mg/ml; (10/2x5) ampoules 10ml	Pharmstandard-Ufa VITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	Pharmstandard-Ufa VITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	PoM	20847/1/1 14.03.2025
4	Laticort	hydrocortisone (hydrocortisone 17-n-butyrate)	ointment for external use	1mg/g; 15g aluminium tube	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	BAUSCH HEALTH IRELAND LIMITED, 3012 Lake Drive, Citywest Business Campus, Dublin 24, D24 PPT3	Ireland	PoM	20533/2/1 14.03.2025
5	Grippoflu-MBP cold and flu	paracetamol, phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid	powder for oral solution with raspberry flavour	0.325g+0,01g+0,02g+0,05g; (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	19145/1/1 14.03.2025
6	Grippoflu-MBP cold and flu	paracetamol, phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid	powder for oral solution with cranberry 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	21123/1/1 14.03.2025

7	Novosept	benzyltrimethyl ammonium chloride monohydrate	solution for topical and external use	0,1mg/ml; 50ml plastic container (pump dispenser and applicator), 150ml (dispenser), 200ml plastic container (measuring applicator)	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	IE Sergey Sergeevich Patvakanov, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	OTC	22626/1/1 14.03.2025
8	Canephron N	centauri herba, levistici radix, rosmarini folia	drops oral	6mg/g+6mg/g+6mg/g; glass container-dropper 100ml	Bionorica SE, Kerschensteiner str. 11-15, 92318 Neumarkt in der Oberpfalz	Germany	Bionorica SE, Kerschensteiner str. 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	20376/1/1 14.03.2025
9	Clexane	enoxaparin (enoxaparin sodium)	solution for injection	40mg/0,4ml; (10/5x2) pre-filled syringes 0,4ml	SANOFI WINTHROP INDUSTRIE, MAISONS-ALFORT, 180 rue Jean Jaures, 94700	France	SANOFI WINTHROP INDUSTRIE, 82 avenue Raspail, 94250 Gentilly	France	PoM	21188/1/1 14.03.2025
10	Azithromycin	azithromycin (azithromycin dihydrate)	capsules	250mg; (6/1x6) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaveva, Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaveva, Borisov 222518, Minsk region	Republic of Belarus	PoM	20341/1/1 14.03.2025
11	Anaprilin	propranolol (propranolol hydrochloride)	tablets	40mg; (50/5x10) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaveva, Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaveva, Borisov 222518, Minsk region	Republic of Belarus	PoM	20453/1/1 14.03.2025

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of the variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 03-1/25 on March 14, 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	Telmista H	hydrochlorothiazide, telmisartan	tablets	12,5mg+40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°000335-ITI-AM 14.03.2025
2	Telmista H	hydrochlorothiazide, telmisartan	tablets	12,5mg+80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°000335-ITI-AM 14.03.2025
3	Telmista H	hydrochlorothiazide, telmisartan	tablets	25mg+80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°000335-ITI-AM 14.03.2025

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of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 03-1/25 on March 14, 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	Paclitaxel-Ebewe	paclitaxel	concentrate for solution for infusion	6mg/ml; (1) glass vial 16,7ml	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	18763/1 14.03.2025
2	Paclitaxel-Ebewe	paclitaxel	concentrate for solution for infusion	6mg/ml; (1) glass vial 16,7ml	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	18764/1 14.03.2025
3	Paclitaxel-Ebewe	paclitaxel	concentrate for solution for infusion	6mg/ml; (1) glass vial 5ml	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	18765/1 14.03.2025
4	Cerebrolysin	porcine brain peptides	solution for injection	215,2mg/ml; (5/1x5) ampoules 20ml in blister	EVER Neuro Pharma GmbH, Oberburgau 3, 4866 Unterach am Attersee- quality control, batch releaser, EVER Pharma Jena GmbH, Otto-Schott-Strasse 15, 07745 Jena, Thuringen, Germany- bulk manufacturer, primary packager, EVER Pharma Jena GmbH, Bruesseler Strasse 18, 07747 Jena, Thuringen, Germany- secondary packager	Austria	EVER Neuro Pharma GmbH, Oberburgau 3, 4866 Unterach am Attersee	Austria	PoM	22034/2 14.03.2025

5	Inestom	levocarnitine	solution for injection	200mg/ml; (5) ampoules 5ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorphosis, Attica	Greece	PoM	21321/1 14.03.2025
6	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	18358/4/1 14.03.2025
7	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	18357/4/1 14.03.2025
8	Strepsils Intensive	flurbiprofen	lozenges with honey and lemon flavour	8,75mg; (24/3x8/) in blister	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	OTC	19149/3 14.03.2025
9	Clopi-Denk 75	clopidogrel (clopidogrel besylate)	tablets film-coated	75mg; (30/3x10) in blister	Artesan Pharma GmbH & Co. KG, Wendlandstrasse 1, 29439 Luechow, Germany- bulk manufacturer, packager, quality control (physico-chemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4-6, Grossenbrach, Bad Bocklet, Bavaria, 97708, Germany-quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	19168/1 14.03.2025
10	NEWKOFEN	acetylsalicylic acid, paracetamol, caffeine	tablets	200mg+200mg+40mg; (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	19022/1 14.03.2025
11	Silvadev	silver sulfadiazine	cream for external use	10mg/g; aluminum tube 40g	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	19549/4 14.03.2025

12	Oxypan Kids	oxymetazoline (oxymetazoline hydrochloride), dexpanthenol	spray nasal	0,25mg/ml+50mg/ml; plastic or glass bottle 10ml	Arsanit Ltd, Masis, Masis-Ranchpar highway 07- secondary packager, batch releaser, PharmaTech CJSC, 111 Raffi str., 0064, Yerevan, Republic of Armenia-bulk manufacturer, primary packager, quality control	Republic of Armenia	Arsanit Ltd, Masis, Masis-Ranchpar highway 07	Republic of Armenia	OTC	17976/1 14.03.2025
13	Oxypan Kids	oxymetazoline (oxymetazoline hydrochloride), dexpanthenol	drops nasal	0,25mg/ml+50mg/ml; plastic bottle-dropper 5ml and 10ml	Arsanit Ltd, Masis, Masis-Ranchpar highway 07- secondary packager, batch releaser, PharmaTech CJSC, 111 Raffi str., 0064, Yerevan, Republic of Armenia-bulk manufacturer, primary packager, quality control	Republic of Armenia	Arsanit Ltd, Masis, Masis-Ranchpar highway 07	Republic of Armenia	OTC	17974/1 14.03.2025
14	Oxypan	oxymetazoline (oxymetazoline hydrochloride), dexpanthenol	spray nasal	0,5mg/ml+50mg/ml; plastic or glass bottle 10ml	Arsanit Ltd, Masis, Masis-Ranchpar highway 07- secondary packager, batch releaser, PharmaTech CJSC, 111 Raffi str., 0064, Yerevan, Republic of Armenia-bulk manufacturer, primary packager, quality control	Republic of Armenia	Arsanit Ltd, Masis, Masis-Ranchpar highway 07	Republic of Armenia	OTC	17975/1 14.03.2025
15	Lopraxer-Neo	citalopram (citalopram hydrochloride)	drops oral (solution)	40mg/ml; 15ml glass bottle	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorfofi, Attiki	Greece	PoM	21094/2/1 14.03.2025
16	Ondansetron	ondansetron (ondansetron hydrochloride dihydrate)	solution for injection	2mg/ml; (5) ampoules 4ml in blister	SIC "Borshchahivskiy Chemical-Pharmaceutical Plant" PJSC, 17, Mira St, Kyiv, 03134	Ukraine	SIC "Borshchahivskiy Chemical-Pharmaceutical Plant" PJSC, 17, Mira St, Kyiv, 03134	Ukraine	PoM	18657/1 14.03.2025
17	Oxypan	oxymetazoline (oxymetazoline hydrochloride), dexpanthenol	drops nasal	0,5mg/ml+50mg/ml; plastic bottle-dropper 5ml and 10ml	Arsanit Ltd, Masis, Masis-Ranchpar highway 07- secondary packager, batch releaser, PharmaTech CJSC, 111 Raffi str., 0064, Yerevan, Republic of Armenia-bulk manufacturer, primary packager, quality control	Republic of Armenia	Arsanit Ltd, Masis, Masis-Ranchpar highway 07	Republic of Armenia	OTC	17977/1 14.03.2025
18	MIG for children forte	ibuprofen	suspension oral	40mg/ml; 100ml plastic bottle and measuring syringe 5ml	Alcala Farma, S.L., Avenida de Madrid, 82, Alcala de Henares 28802-Madrid	Spain	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	OTC	21583/1 14.03.2025

19	Ascorbic acid with glucose	ascorbic acid, glucose (glucose monohydrate)	tablets	100mg+877mg; (10) in strip, (20/2x10) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 24, Stroiteley str., Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	OTC	21103/1 14.03.2025
20	Helmintox	pyrantel (pyrantel embonate)	tablets film-coated	125mg; (6/1x6) 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	19959/1 14.03.2025
21	Helmintox	pyrantel (pyrantel embonate)	tablets film-coated	250mg; (3/1x3) 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	19960/1 14.03.2025
22	Pantoprazole Canon	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	20mg; (28/4x7) in blister	CJSC Canonpharma production, 105B bldg., 11, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100- quality control, batch releaser, CJSC Canonpharma production, 105B bldg., 16, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100, Russia- bulk manufacturer, packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100	Russia	OTC	18741/3/2 14.03.2025
23	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	18740/3/2 14.03.2025
24	Indometacin	indometacin	ointment for external use	100mg/g; aluminium tube 40g	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, No2, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	OTC	21820/2 14.03.2025

25	Eligard	leuprorelin (leuprorelin acetate)	powder lyophilized and solvent for solution for s/c injection	7,5mg; I- syringe A- 343mg solvent and plunger for syringe B in plastic pack, II- syringe B- 10,6mg lyophilized powder and needle in plastic pack	Astellas Pharma Europe B.V., Hogemaat 2, 7942 JG Meppel- secondary packager, quality control (physicochemical), batch releaser, Tolmar Inc., 701 Centre Avenue, Ft. Collins, CO 80526, USA- bulk manufacturer, primary packager (syringe A and syringe B), Nelson Laboratories LLC, 6280 South Redwood Road, Salt Lake City, Utah (UT) 84123, USA- quality control (microbiological)	the Netherlands	Recordati Industria Chimica e Farmaceutica S.p.A., Via Matteo Civitali, 1-20148 Milano	Italy	PoM	20071/2/1 14.03.2025
26	Eligard	leuprorelin (leuprorelin acetate)	powder lyophilized and solvent for solution for s/c injection	22,5mg; I- syringe A- 457mg solvent and plunger for syringe B in plastic pack, II- syringe B- 29,2mg lyophilized powder and needle in plastic pack	Astellas Pharma Europe B.V., Hogemaat 2, 7942 JG Meppel- secondary packager, quality control (physicochemical), batch releaser, Tolmar Inc., 701 Centre Avenue, Ft. Collins, CO 80526, USA- bulk manufacturer, primary packager (syringe A and syringe B), Nelson Laboratories LLC, 6280 South Redwood Road, Salt Lake City, Utah (UT) 84123, USA- quality control (microbiological)	the Netherlands	Recordati Industria Chimica e Farmaceutica S.p.A., Via Matteo Civitali, 1-20148 Milano	Italy	PoM	20072/2/1 14.03.2025
27	Eligard	leuprorelin (leuprorelin acetate)	powder lyophilized and solvent for solution for s/c injection	45mg; I- syringe A- 434mg solvent and plunger for syringe B in plastic pack, II- syringe B- 59,2mg lyophilized powder and needle in plastic pack	Astellas Pharma Europe B.V., Hogemaat 2, 7942 JG Meppel- secondary packager, quality control (physicochemical), batch releaser, Tolmar Inc., 701 Centre Avenue, Ft. Collins, CO 80526, USA- bulk manufacturer, primary packager (syringe A and syringe B), Nelson Laboratories LLC, 6280 South Redwood Road, Salt Lake City, Utah (UT) 84123, USA- quality control (microbiological)	the Netherlands	Recordati Industria Chimica e Farmaceutica S.p.A., Via Matteo Civitali, 1-20148 Milano	Italy	PoM	20073/2/1 14.03.2025
28	Gangleron	ganglefene	solution for injection	15mg/ml; (10) ampoules 2ml	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	19181/2 14.03.2025

29	Sedpor	ibandronic acid (ibandronic acid sodium monohydrate)	tablets film-coated	150mg; (1/1x1/) in blister	Pharmathen S.A., Dervenakion 6, 15351 Pallini, Attiki	Greece	Pharmathen S.A., Dervenakion 6, 15351 Pallini, Attiki	Greece	PoM	21760/2 14.03.2025
30	Cardiomagnyl	acetylsalicylic acid, magnesium hydroxide	tablets film-coated	75mg+15,2mg; (30) in glass container, (100) in glass container	Takeda GmbH, Lehnitzstrasse 70-98, Oranienburg 16515	Germany	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	21154/1 14.03.2025
31	Cardiomagnyl	acetylsalicylic acid, magnesium hydroxide	tablets film-coated	150mg+30,39mg; (30) in glass container, (100) in glass container	Takeda GmbH, Lehnitzstrasse 70-98, Oranienburg 16515	Germany	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	21155/1 14.03.2025
32	Kameton	chlorobutanol (chlorobutanol hydrate), camphora, L-menthol, eucalyptus oil	aerosol for local use	6,67mg/g+6,67mg/g+6,67mg/ g+6,67mg/g; 30g aluminium container with vertical pump dispenser; 45g aluminium container with vertical pump dispenser, 30g aluminium container with vertical pump dispenser and horizontal pump dispenser, 45g aluminium container with vertical pump dispenser and horizontal pump dispenser	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard- Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	22287/1 14.03.2025
33	Ketorolac	ketorolac (ketorolac trometamol)	tablets film-coated	10mg; (10), (20/2x10) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64A, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	PoM	19964/2/1 14.03.2025
34	Bisacodyl	bisacodyl	tablets gastro- resistant film- coated	5mg; (30/3x10) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 24, Stroiteley str., Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	OTC	21473/1 14.03.2025
35	Drotaverine	drotaverine (drotaverine hydrochloride)	solution for i/v and i/m injection	20mg/ml; (10) ampoules 2ml, (10) ampoules 2ml label banderol, (10) ampoules 2ml dividella	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	21060/3 14.03.2025

36	Meteospasmyl	alverine (alverine citrate), simeticone	capsules	60mg+300mg (20/2x10) in blister, (30/3x10) in blister	Laboratoires MAYOLY SPINDLER, 6 avenue de l' Europe, 78400 Chatou- packager, quality control (physicochemical), batch releaser, Laboratoires GALENIQUES VERNIN, 20 rue Louis-Charles Vernin, 77190 Dammarie-Les-Lys, France- bulk manufacturer, quality control (microbiological)	France	Laboratoires MAYOLY SPINDLER, 6 avenue de l' Europe, 78400 Chatou	France	OTC	19602/2 14.03.2025
37	Valerianae tincture	valerianae extract	tincture	200mg/ml; glass vial 30ml	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	OTC	19644/3/1 14.03.2025
38	Alka-Seltzer	acetylsalicylic acid, citric acid, sodium bicarbonate	tablets effervescent	324mg+965mg+1625mg; (10/5x2) in strip	Bayer Bitterfeld GmbH, Ortsteil Greppin, Salegaster Chaussee 1, 06803 Bitterfeld-Wolfen	Germany	JSC BAYER, 3rd Rybinskaya st., 18, build. 2, 107113 Moscow	Russia	OTC	21821/1 14.03.2025
39	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, Weystrasse 20, 6006 Luzern	Switzerland	PoM	22669/1 14.03.2025
40	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, Weystrasse 20, 6006 Luzern	Switzerland	PoM	22670/1 14.03.2025

41	Zometa	zoledronic acid (zoledronic acid monohydrate)	solution for infusion	0,04mg/ml; plastic vial 100ml	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- secondary packager, batch releaser, Fresenius Kabi Austria GmbH, Hafnerstrasse 36, Graz, 8055, Austria- bulk manufacturer, primary packager, Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland- quality control (physicochemical), AGES GmbH IMED, Beethovenstrasse 6, Graz, 8010, Austria- quality control (microbiological)	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22200/1 14.03.2025
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LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 03-1/25 on March 14, 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	Diabeton MR	gliclazide	tablets modified-release	60mg; (30/1x30/) in blister, (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	ЛПТ-№000531-ITI-AM 14.03.2025
2	Diabeton MR	gliclazide	tablets modified-release	60mg; (28/2x14/) in blister, (30/2x15/) in blister, (60/4x15/) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№000531-ITI-AM 14.03.2025
3	Diabeton MR	gliclazide	tablets modified-release	60mg; (28/2x14/) in blister, (30/2x15/) in blister, (30/1x30/) in blister, (60/2x30/) in blister, (60/4x15/) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№000531-ITI-AM 14.03.2025
4	Dicloberl N 75	diclofenac (diclofenac sodium)	solution for injection	25mg/ml; (5) ampoules 3ml	A. Menarini Manufacturing Logistics and Services S.r.l, Via Sette Santi, 3-50131 Florence	Italy	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	PoM	ЛПТ-№000476-PI-AM 14.03.2025
5	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	ЛПТ-№002311-ITI-AM 14.03.2025

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	ЛПТ-№002311-ITI-AM 14.03.2025
7	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	ЛПТ-№002311-ITI-AM 14.03.2025
8	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	ЛПТ-№002311-ITI-AM 14.03.2025
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	ЛПТ-№002311-ITI-AM 14.03.2025
10	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	ЛПТ-№002311-ITI-AM 14.03.2025
11	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	ЛПТ-№002311-ITI-AM 14.03.2025
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	ЛПТ-№002311-ITI-AM 14.03.2025

13	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	ЛПТ-№002311-ITI-AM 14.03.2025
14	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	ЛПТ-№002311-ITI-AM 14.03.2025
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	ЛПТ-№002311-ITI-AM 14.03.2025
16	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	ЛПТ-№002311-ITI-AM 14.03.2025