

## LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 02-1/25 on February 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	Levo-Denk 500	levofloxacin (levofloxacin hemihydrate)	tablets film-coated	500mg; (10/1x10) in blister	Allphamed PHARBIL Arzneimittel GmbH, Hildebrandstr. 10-12, 37081 Gottingen	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	22694 14.02.2025
2	Lornoxicam	lornoxicam	powder lyophilized for solution for i/v and i/m injection	8mg; (5) glass vials	Moscow Endocrine Plant FSUE, 25, bld 1, Novokhokhlovskaya st., Moscow, 109052- quality control, batch releaser, «Moscow Endocrine Plant FSUE», 25, bld 2, Novokhokhlovskaya st., Moscow, 109052, Russia- bulk manufacturer, packager	Russia	«Moscow Endocrine Plant FSUE», 25, Novokhokhlovskaya st., Moscow 109052	Russia	PoM	22695 14.02.2025

## LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 02-1/25 on February 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	Singlon	montelukast (montelukast sodium)	tablets film-coated	10mg; (14/2x7) in blister, (28/4x7) in blister, (56/8x7) in blister	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Poland Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22729 (007715) 14.02.2025
2	Singlon	montelukast (montelukast sodium)	tablets film-coated	10mg; (14/2x7) in blister, (28/4x7) in blister, (56/8x7) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- quality control, batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22730 (007715) 14.02.2025
3	Chondroxid Artra	chondroitin sulfate (chondroitin sulfate sodium)	gel for external use	50mg/g; 30g aluminium or plastic tube	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, s.1- quality control, batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia- bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	22731 (006630) 14.02.2025
4	Afrin	oxymetazoline (oxymetazoline hydrochloride)	spray nasal	0,5mg/ml; 15ml plastic vial with pump dispenser	Delpharm Montreal Inc., 3535, Route Transcanadienne, Pointe-Claire, Quebec H9R 1B4	Canada	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	22732 (001398) 14.02.2025
5	Azopt	brinzolamide	drops eye	10mg/ml; plastic vial 5ml	S.A. Alcon-Couvreur N.V., Rijksweg 14, 2870 Puurs	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22733 (010145) 14.02.2025

6	Piracezine	piracetam, cinnarizine	capsules	400mg+25mg: (10/1x10/) in blister, (60/6x10/) in blister	Minskintercaps U.E., 26/3, Inzhenernaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.E., 26, Inzhenernaya str., 220075, Minsk	Republic of Belarus	PoM	22734 (005288) 14.02.2025
7	Caffetin Lady	ibuprofen (ibuprofen lysinate)	tablets film-coated	200mg: (10/1x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	OTC	22735 (006649) 14.02.2025
8	Mycosyst	fluconazole	capsules	150mg: (1/1x1/) in blister, (2/2x1/) in blister, (4/4x1/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22736 (011633) 14.02.2025
9	Mycosyst	fluconazole	capsules	150mg: (1/1x1/) in blister, (2/2x1/) in blister, (4/4x1/) 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	22737 (011633) 14.02.2025

10	Mycosyst	fluconazole	capsules	150mg; (1/1x1) in blister, (2/2x1) in blister, (4/4x1) 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	22738 (011633) 14.02.2025
11	Nitromint	nitroglycerin	spray sublingual dosed	0,4mg/dose; 10g (180 doses) aluminium container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	22739 (010096) 14.02.2025
12	Yarina	drospirenone, ethinylestradiol	tablets film- coated	3mg+0,03mg; (21/1x21) in blister	Bayer AG, Muellerstrasse 178, 13353, Berlin- packager, quality control, batch releaser, Bayer Weimar GmbH und Co. KG, Doebereinerstrasse 20, Weimar, Thueringen, 99427, Germany- bulk manufacturer	Germany	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	PoM	22740 (008706) 14.02.2025
13	Urorec	silodosin	capsules hard	4mg; (30/3x10) in blister	Recordati Industria Chimica e Farmaceutica S.p.A., Via Civitali, 1-20148 Milano	Italy	Recordati Ireland Ltd., Raheens East, Ringaskiddy, Co Cork	Ireland	PoM	22741 (006292) 14.02.2025
14	Urorec	silodosin	capsules hard	8mg; (30/3x10) in blister, (90/9x10) in blister	Recordati Industria Chimica e Farmaceutica S.p.A., Via Civitali, 1-20148 Milano	Italy	Recordati Ireland Ltd., Raheens East, Ringaskiddy, Co Cork	Ireland	PoM	22742 (006292) 14.02.2025
15	Valsacor	valsartan	tablets film- coated	80mg; (28/4x7) 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	22743 (005826) 14.02.2025

16	Valsacor	valsartan	tablets film-coated	80mg; (28/4x7) 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	22744 (005826) 14.02.2025
17	Valsacor	valsartan	tablets film-coated	80mg; (28/4x7) 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	22745 (005826) 14.02.2025
18	Valsacor	valsartan	tablets film-coated	80mg; (28/4x7) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500- bulk manufacturer, packager, batch releaser, Chemilab d.o.o, Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22746 (005826) 14.02.2025
19	Valsacor	valsartan	tablets film-coated	160mg; (28/4x7) 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	22747 (005826) 14.02.2025
20	Valsacor	valsartan	tablets film-coated	160mg; (28/4x7) 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	22748 (005826) 14.02.2025
21	Valsacor	valsartan	tablets film-coated	160mg; (28/4x7) 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	22749 (005826) 14.02.2025
22	Valsacor	valsartan	tablets film-coated	160mg; (28/4x7) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500- bulk manufacturer, packager, batch releaser, Chemilab d.o.o, Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22750 (005826) 14.02.2025
23	Norvasc	amlodipine (amlodipine besilate)	tablets	5mg; (30/3x10) in blister, (40/4x10) in blister, (90/9x10) in blister, (14/1x14) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieburg Im Breisgau- packager, quality control, batch releaser, Viatris 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	22751 (007725) 14.02.2025

24	Norvasc	amlodipine (amlodipine besilate)	tablets	10mg; (30/3x10/) in blister, (40/4x10/) in blister, (90/9x10) in blister, (14/1x14) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau- packager, quality control, batch releaser, Viatris 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	22752 (007725) 14.02.2025
25	Essentiale N	phospholipids (essential)-EPL	solution for i/v injection	50mg/ml; (5) ampoules 5ml	Famar Health Care Services Madrid, S.A.U., Avenida de Leganes, 62, 28923 Alcorcon (Madrid)	Spain	Opella Healthcare LLC, Tverskaya str. 22, Moscow	Russia	PoM	22753 (003980) 14.02.2025
26	Aspirin Cardio	acetylsalicylic acid	tablets gastro-resistant	100mg; (28/2x14/) in blister	Bayer Bitterfeld GmbH, Ortsteil Greppin, Salegaster Chaussee 1, 06803 Bitterfeld-Wolfen- packager, quality control, batch releaser, Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen, Germany- bulk manufacturer	Germany	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	OTC	22754 (009311) 14.02.2025
27	Aspirin Cardio	acetylsalicylic acid	tablets gastro-resistant	100mg; (28/2x14/) in blister	Bayer Bitterfeld GmbH, Ortsteil Greppin Salegaster Chaussee 1, 06803 Bitterfeld-Wolfen	Germany	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	OTC	22755 (009311) 14.02.2025
28	ESCITAM ACINO	escitalopram (escitalopram oxalate)	tablets film-coated	10mg; (30/3x10) 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	22727 (013389) 14.02.2025
29	ESCITAM ACINO	escitalopram (escitalopram oxalate)	tablets film-coated	20mg; (30/3x10) 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	22728 (013389) 14.02.2025

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of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 02-1/25 on  
February 14, 2025

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1	CLOLAX	tadalafil	tablets film-coated	2,5mg; (30) in plastic container	Amneal Pharmaceuticals Pvt. Ltd., Oral Solid Unit, Plot No-16 & 17, Pharmez SEZ, Sarkhej-Bavla Highway, Vil. Matoda, TA-Sanand, Dist. Ahmedabad, 382213, Gujarat State	India	Amneal EU Limited, Cahir Road, Cashel, Co. Tipperary E25 XD51	Ireland	PoM	22718 14.02.2025
2	CLOLAX	tadalafil	tablets film-coated	5mg; (30) in plastic container	Amneal Pharmaceuticals Pvt. Ltd., Oral Solid Unit, Plot No-16 & 17, Pharmez SEZ, Sarkhej-Bavla Highway, Vil. Matoda, TA-Sanand, Dist. Ahmedabad, 382213, Gujarat State	India	Amneal EU Limited, Cahir Road, Cashel, Co. Tipperary E25 XD51	Ireland	PoM	22719 14.02.2025
3	CLOLAX	tadalafil	tablets film-coated	10mg; (30/1x30) in blister	Amneal Pharmaceuticals Pvt. Ltd., Oral Solid Unit, Plot No-16 & 17, Pharmez SEZ, Sarkhej-Bavla Highway, Vil. Matoda, TA-Sanand, Dist. Ahmedabad, 382213, Gujarat State	India	Amneal EU Limited, Cahir Road, Cashel, Co. Tipperary E25 XD51	Ireland	PoM	22720 14.02.2025
4	CLOLAX	tadalafil	tablets film-coated	20mg; (30/1x30) in blister	Amneal Pharmaceuticals Pvt. Ltd., Oral Solid Unit, Plot No-16 & 17, Pharmez SEZ, Sarkhej-Bavla Highway, Vil. Matoda, TA-Sanand, Dist. Ahmedabad, 382213, Gujarat State	India	Amneal EU Limited, Cahir Road, Cashel, Co. Tipperary E25 XD51	Ireland	PoM	22721 14.02.2025
5	Neyoba	abiraterone (abiraterone acetate)	tablets	250mg; (120) in 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	22722 14.02.2025

6	Neyoba	abiraterone (abiraterone acetate)	tablets film-coated	500mg; (60) in 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	22723 14.02.2025
7	Ponicton	spironolactone	tablets film-coated	25mg; (100) in 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	22724 14.02.2025
8	Ponicton	spironolactone	tablets film-coated	50mg; (100) in 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 EU Limited, Cahir Road, Cashel, Co. Tipperary E25 XD51	Ireland	PoM	22725 14.02.2025
9	Ponicton	spironolactone	tablets film-coated	100mg; (100) in 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 EU Limited, Cahir Road, Cashel, Co. Tipperary E25 XD51	Ireland	PoM	22726 14.02.2025



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of the medicines recommended for the re-registration by the Center according to the meeting decision N 02-1/25 on February 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	CERTICAN	everolimus	tablets	0,25mg; (60/6x10) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	22696 14.02.2025
2	CERTICAN	everolimus	tablets	0,75mg; (60/6x10) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	22697 14.02.2025
3	Corvitin	quercetine, povidon	lyophilisate for solution for injection	0,05g+0,45g; (5) glass vials	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	22698 14.02.2025
4	Allochol	cattle bile dried, dried garlic, charcoal activated, nettle leaves	tablets coated	80mg+40mg+25mg+5mg; (10/1x10) in blister; (50) plastic container	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	22699 14.02.2025
5	PRIMAFUNGIN	natamycin	suppositories vaginal	100mg; (3/1x3)	Farmaprim LTD, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Laboratory for Quality Control of Medicines and Medical Devices Agency 2/1, Korolenko street, Chisinau, MD-2028, Moldova- quality control (microbiological)	Moldova	Farmaprim LTD, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	PoM	22700 14.02.2025

6	CLOMEZOLE	metronidazole, neomycin (neomycin sulfate), clotrimazole	suppositories vaginal	500mg+200mg+150mg; (10/2x5/)	Farmaprim LTD, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Laboratory for Quality Control of Medicines and Medical Devices Agency 2/1, Korolenko street, Chisinau, MD-2028, Moldova- quality control (microbiological)	Moldova	Farmaprim LTD, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	PoM	22701 14.02.2025
7	Fraxiparine	nadroparin calcium	solution for injection	2850IU AXa/0,3ml; (10) pre-filled syringes 0,3ml	Aspen Notre Dame de Bondeville, 1 rue de l' Abbaye, 76960 Notre Dame de Bondeville	France	Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24	Ireland	PoM	22702 14.02.2025
8	Fraxiparine	nadroparin calcium	solution for injection	5700IU AXa/0,6ml; (10) pre-filled syringes 0,6ml	Aspen Notre Dame de Bondeville, 1 rue de l' Abbaye, 76960 Notre Dame de Bondeville	France	Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24	Ireland	PoM	22703 14.02.2025
9	Ascorutin	rutoside, ascorbic acid	tablets	50mg+50mg; (50) in plastic container	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	OTC	22704 14.02.2025
10	Klyntopic	clindamycin (clindamycin phosphate), benzoyl peroxide	gel	10mg/g+50mg/g; aluminium tube 15g	Farmaprim LTD, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Laboratory for Quality Control of Medicines and Medical Devices Agency 2/1, Korolenko street, Chisinau, MD-2028, Moldova- quality control (microbiological)	Moldova	Farmaprim LTD, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	PoM	22705 14.02.2025
11	Visipaque	iodixanol	solution for injection	320mg iodine/ml; (10) plastic vials 50ml	GE Healthcare Ireland Limited, IDA Business Park, Carrigtwohill, Cork, T45 AV60	Ireland	GE Healthcare AS, P.O. Box 4220, Nydalen, 0401 Oslo	Norway	PoM	22706 14.02.2025
12	Visipaque	iodixanol	solution for injection	320mg iodine/ml; (10) plastic vials 100ml	GE Healthcare Ireland Limited, IDA Business Park, Carrigtwohill, Cork, T45 AV60	Ireland	GE Healthcare AS, P.O. Box 4220, Nydalen, 0401 Oslo	Norway	PoM	22707 14.02.2025
13	Emcor 2.5	bisoprolol (bisoprolol fumarate)	coated tablets	2,5mg; (30/3x10) in blister	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	22708 14.02.2025
14	Emcor 5	bisoprolol (bisoprolol fumarate)	coated tablets	5mg; (30/3x10) in blister	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	22709 14.02.2025

15	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, Vardodara-390016, India- bulk manufacturer, primary packager	Republic of Armenia	A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan	Republic of Armenia	PoM	22710 14.02.2025
16	Tiamox	amoxicillin (amoxicillin trihydrate)	capsules	500mg; (10/1x10) 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, Vardodara-390016, India- bulk manufacturer, primary packager	Republic of Armenia	A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan	Republic of Armenia	PoM	22711 14.02.2025
17	Oftan Dexamethason	dexamethasone (dexamethasone sodium phosphate)	drops eye	1mg/ml; 5ml plastic bottle-dropper	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, NextPharma Oy, Niittyhaankatu 20, 33720 Tampere, Finland- bulk manufacturer, primary packager, quality control, Manufacturing Packaging Farmaca (MPF) B.V., Neptunus 12, HEERENVEEN, 8448 CN, the Netherlands- secondary packager	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	PoM	22712 14.02.2025
18	AMOROLFINE MOOSMANN Medicated Nail Laquer 5%	amorolfine (amorolfine hydrochloride)	medicated nail laquer	50mg/ml; 3ml glass vial, (10) spatulas, (30) nail files, (30) alcohol swabs	Poul W. Beyvers GmbH, Schaffhausener Strasse 26-34, Tempelhof, Berlin, 12099- bulk manufacturer, packager, quality control (physicochemical), batch releaser, ifp Privates Institut fur Produktqualitat GmbH, Wagner-Regeny-Strasse 8, 12489 Berlin, Germany- quality control (microbiological)	Germany	Moosmann Pharmaceuticals LLC, Vanahovit 8, Proshyan v., Ashtarak Ave., Kotayk Marz 2413	Republic of Armenia	OTC	22713 14.02.2025

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of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 02-1/25 on February 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	Fastum gel	ketoprofen	gel	25mg/g; aluminum tube 30g, aluminum tube 50g, aluminum tube 100g	A. Menarini Manufacturing Logistics and Services S.r.l., Via Sette Santi, 3 50131 Firenze	Russia	A. Menarini Industrie Farmaceutiche Riunite S.r.l., Via Sette Santi, 3 50131 Firenze	Italy	PoM	22714 14.02.2025
2	Nasonex	mometasone (mometasone furoate)	spray nasal (suspension)	50mcg/dose; 18g (140 dose) plastic bottle with spray pump 18g (140 dose)	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	the Netherlands	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	22715 14.02.2025
3	Dexamethasone	dexamethasone (dexamethasone sodium phosphate)	solution for injection	4mg/ml; (10) ampoules 1ml, (25) ampoules 1ml, (100) ampoules 1ml	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	the Netherlands	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	the Netherlands	PoM	22716 14.02.2025
4	ERYTHROMYCIN OINTMENT	erythromycin	ointment	10mg/g; aluminium tube 20g, aluminium tube 25g	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	22717 14.02.2025

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of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 02-1/25 on February 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	Elidel	pimecrolimus	cream for external use	10mg/g; aluminium tube 15g	MEDA Manufacturing, Avenue JF Kennedy, 33700 Merignac	France	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg	Germany	PoM	19383/4/1 14.02.2025
2	Trimedat forte	trimebutine (trimebutine maleate)	tablets prolonged-release film-coated	300mg; (20/2x10) in blister, (60/6x10) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2.	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2.	Russia	PoM	19333/4/2 14.02.2025

3	Acetylsalicylic acid	acetylsalicylic acid	tablets	500mg; (10/1x10) tablets in paper/carton strip, (10/1x10) tablets in paper/polimer strip	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	20509/1/1 14.02.2025
4	Rinza	paracetamol, caffeine, phenylephrine (phenylephrine hydrochloride), chlorphenamine (chlorphenamine maleate)	tablets	500mg+30mg+10mg+2mg; (4/1x4) in blister, (10/1x10) in blister, (20/2x10) in blister	Unique Pharmaceutical Laboratories (a division of J. B. Chemicals & Pharmaceuticals Ltd.), Survey No. 101/2 & 102/1, Daman Industrial Estate, Kadaiya, Daman-396 210	India	JTNL LLC, 121614, Moscow, Krylatskaya intercity municipal district, Krylatskaya str., 17, bld. 3	Russia	OTC	21367/1/1 14.02.2025
5	Aquadetrim Vitamin D3 Medana	colecalfiferol	drops oral	15000IU/ml; 10ml glass bottle, 30ml glass bottle	Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 10 Wladyslawa Lokietka St. 98-200 Sieradz-batch releaser, Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 57 Polskiej Organizacji Wojskowej st. 98-200 Sieradz, Poland- bulk manufacturer, packager, quality control	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	PoM	20675/2/1 14.02.2025

6	Fenkarol	quiifenadine (quiifenadine hydrochloride)	tablets	10mg; (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	OTC	19971/1/1 14.02.2025
7	Fenkarol	quiifenadine (quiifenadine hydrochloride)	tablets	25mg; (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	OTC	19972/1/1 14.02.2025
8	Fenkarol	quiifenadine (quiifenadine hydrochloride)	tablets	50mg; (15/1x15) in blister, (30/2x15) in blister	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	Olpha AS, 5 Rupnicu Str., Olaine, Olaines region, LV-2114	Latvia	OTC	19973/2/1 14.02.2025
9	Iburodem 600	ibuprofen	tablets film-coated	600mg; (20/2x10) in blister, (30/3x10) in blister, (60/6x10) in blister	Medinfar Manufacturing S.A, Parque Industrial Armando Martins Tavares, Rua Outeiro Da Armada No 5, Condeixa-A-Nova, 3150-194 Sebal	Portugal	Demi Pharm Griboyedovi 12, ap. 25, Sevan 1501	Republic of Armenia	OTC	19241/1/1 14.02.2025

10	Gliclazide Canon	gliclazide	tablets prolonged- release	60mg; (30/3x10) in blister, (30/2x15) in blister	CJSC Canonpharma production, 105B bldg. 11, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region- quality control, batch releaser, CJSC Canonpharma production, 105B, bldg. 16, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, Russia- bulk manufacturer, primary and secondary packager	Russia	CJSC Canonpharma production, 105 Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, 141100	Russia	OTC	22085/1/1 14.02.2025
11	Contractubex	extract cepae, heparin (heparin sodium), allantoin	gel for external use	100mg/g+50IU/g+10mg/g; 20g aluminium tube	Merz Pharma GmbH & Co. KGaA, Lud- wigstrasse 22, Reinheim, Hessen, 64354	Germany	Merz Pharmaceuticals GmbH, Eckenheimer Landstrasse 100, 60318 Frankfurt/Main	Germany	PoM	21081/2/1 14.02.2025



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of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 02-1/25 on February 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	AMOROLFINE MOOSMANN Medicated Nail Laquer 5%	amorolfine (amorolfine hydrochloride)	medicated nail laquer	50mg/ml; 3ml glass vial, (10) spatulas, (30) nail files, (30) alcohol swabs	Poul W. Beyvers GmbH, Schaffhausener Strasse 26-34, Tempelhof, Berlin, 12099- bulk manufacturer, packager, quality control (physicochemical), batch releaser, ifp Privates Institut fur Produktqualitat GmbH, Wagner-Regeny-Strasse 8, 12489 Berlin, Germany- quality control (microbiological)	Germany	Moosmann Pharmaceuticals LLC, Vanahovit 8, Proshyan v., Ashtarak Ave., Kotayk Marz 2413	Republic of Armenia	OTC	17943/5/1 14.02.2025
2	Ascorutin	rutoside, ascorbic acid	tablets	50mg+50mg; (50) in plastic container	Pharmstandard-Ufa VITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	Pharmstandard-Ufa VITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	OTC	18993/2 14.02.2025
3	Benzylpenicillin	benzylpenicillin (benzylpenicillin sodium)	powder for solution for injection	1000000IU; (40) glass vial	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	20627/2 14.02.2025
4	Mirolute	misoprostol	tablets	200mcg; (4) in blister, (4) in plastic container	Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 3a/3- batch releaser, Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 107, Russia- bulk manufacturer, packager, quality control	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	21025/2/1 14.02.2025

5	Mecol	chloramphenicol, methyluracil	ointment for external use	7,5mg/g+40mg/g; aluminium tube 40g	Open joint stock company «Borisovskiy zavod medicinskih preparatov» 64, Chapaev str., Borisov 222518, Minsk region	Belarus	Open joint stock company «Borisovskiy zavod medicinskih preparatov» 64, Chapaev str., Borisov 222518, Minsk region	Belarus	OTC	19878/2 14.02.2025
6	Phlogenzym	bromelain, trypsin, rutin	tablets gastro-resistant	450FIP-U+1440FIP-U(24mck-at)+100mg; (40/2x20) in blister, (100/5x20) in blister, (200/10x20) in blister, (800) in plastic container	Mucos Emulsions GmbH, Miraustrasse 17, D-13509 Berlin	Germany	Mucos Pharma GmbH & Co. KG, Miraustrasse 17, D-13509 Berlin	Germany	OTC	18978/6/1 14.02.2025
7	ATRIUM	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	17011/2/1 14.02.2025
8	Actrapid	insulin human (recombinant DNA)	solution for injection	100IU/ml; glass vial 10ml	Novo Nordisk Production SAS, 45 avenue d' Orleans, F-28000, Chartres	France	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	21316/3 14.02.2025
9	Isoflurane	isoflurane	liquid for inhalation	100%; 250ml glass bottle	Piramal Pharma Limited, Sy. No.7-70, 70/1 & 70/2, Digwal Village, Kohir Mandal, Sangareddy District- 502 321, Telangana	India	Piramal Pharma Limited, Piramal Ananta, Agastya Corporate Park, Opposite Fire Brigade, Kamani Junction, LBS Marg, Kurla (West), Mumbai-400070, Maharashtra	India	PoM	21544/2 14.02.2025
10	CERTICAN	everolimus	tablets	0,25mg; (60/6x10) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	18513/3 14.02.2025
11	CERTICAN	everolimus	tablets	0,75mg; (60/6x10) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	18514/3 14.02.2025
12	Bronchobos	carbocisteine	syrup	125mg/5ml; 250ml glass bottle (200ml syrup) and measuring spoon	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	19988/4 14.02.2025
13	Bronchobos	carbocisteine	syrup	250mg/5ml; 250ml glass bottle (200ml syrup) and measuring spoon	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	19989/4 14.02.2025

14	Gardasil	human papillomavirus type 6 L1 protein, human papillomavirus type 11 L1 protein, human papillomavirus type 16 L1 protein, human papillomavirus type 18 L1 protein	suspension for i/m injection	20mcg/dose+40mcg/dose+40mcg/dose+20mcg/dose; 0,5ml/dose glass vial	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem- secondary packager, batch releaser, Merck Sharp & Dohme LLC, 770 Sumneytown Pike, West Point, Pennsylvania (PA) 19486, USA- bulk manufacturer, primary packager, quality control	the Netherlands	Merck Sharp & Dohme IDEA GmbH, Tribschenstrasse 60, 6005 Luzern	Switzerland	PoM	20189/6/3 14.02.2025
15	Gardasil	human papillomavirus type 6 L1 protein, human papillomavirus type 11 L1 protein, human papillomavirus type 16 L1 protein, human papillomavirus type 18 L1 protein	suspension for i/m injection	20mcg/dose+40mcg/dose+40mcg/dose+20mcg/dose; 0,5ml/dose pre-filled syringe and (1) needle, 0,5ml/dose pre-filled syringe and (2) needles	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem- secondary packager, batch releaser, Merck Sharp & Dohme LLC, 770 Sumneytown Pike, West Point, Pennsylvania (PA) 19486, USA- bulk manufacturer, primary packager, quality control	the Netherlands	Merck Sharp & Dohme IDEA GmbH, Tribschenstrasse 60, 6005 Luzern	Switzerland	PoM	20190/6/3 14.02.2025
16	Thioctacid 600 HR	alfa-lipoic acid	tablets film-coated	600mg; (30) in glass container, (100) in glass container	Rottapharm Ltd., Damastown Industrial Park, Mulhuddart, Dublin 15	Ireland	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg	Germany	PoM	20469/2 14.02.2025
17	Thioctacid 600 T	thioctic acid (alfa-lipoic acid)	solution for injection	25mg/ml; (5) ampoules 24ml	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg- batch releaser, Siegfried Hameln GmbH, Langes Feld 13, Hameln, Niedersachsen, 31789, Germany- bulk manufacturer, packager, quality control	Germany	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg	Germany	PoM	21205/2 14.02.2025
18	Elidel	pimecrolimus	cream for external use	10mg/g; aluminium tube 15g	MEDA Manufacturing, Avenue JF Kennedy, 33700 Merignac	France	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg	Germany	PoM	19383/3 14.02.2025
19	Rexetin	paroxetine (paroxetine hydrochloride hemihydrate)	tablets film-coated	20mg; (30/3x10) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	20214/3 14.02.2025
20	Corvitin	quercetine, povidon	lyophilisate for solution for injection	0,05g+0,45g; (5) glass vial	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	18756/1 14.02.2025

21	PRIMAFUNGIN	natamycin	suppositories vaginal	100mg; (3/1x3/)	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Laboratory for Quality Control of Medicines and Medical Devices Agency 2/1, Korolenko street, Chisinau, 11MD-2028, Moldova- quality control (microbiological)	Moldova	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	PoM	18693/1 14.02.2025
22	Tiamox	amoxicillin (amoxicillin trihydrate)	capsules	500mg; (10/1x10) 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	18953/3/1 14.02.2025
23	CLOMEZOLE	metronidazole, neomycin (neomycin sulfate), clotrimazole	suppositories vaginal	500mg+200mg+150mg; (10/2x5/)	Farmaprim LTD, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829- bulk manufacturer, packager, quality control(physicochemical), batch releaser, Laboratory for Quality Control of Medicines and Medical Devices Agency 2/1, Korolenko street, Chisinau, MD-2028, Moldova- quality control (microbiological)	Moldova	Farmaprim LTD, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	PoM	18816/1 14.02.2025
24	Nidol Gel	nimesulide	gel	20mg/g; aluminium tube 30g	Polipharm Co., Ltd., 109 Bangna-Trad Road, Bang Phli District, Samut Prakan 10540	Thailand	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	22088/1 14.02.2025
25	Dexamethasone	dexamethasone (dexamethasone sodium phosphate)	solution for injection	4mg/ml; (10) ampoules 1ml, (25) ampoules 1ml, (100) ampoules 1ml	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	PoM	19191/2 14.02.2025
26	Ambroxol	ambroxol (ambroxol hydrochloride)	tablets	30mg; (20/2x10) in blister	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	OTC	21184/2 14.02.2025

27	Fevarin	fluvoxamine (fluvoxamine maleate)	tablets film-coated	50mg; (15/1x15) in blister	Mylan Laboratories SAS, Route de Belleville, Lieu-dit Maillard, 01400 Chatillon sur Chalaronne	France	Abbott Healthcare Products B.V., C.J. van Houtenlaan 36, 1381 CP Weesp	the Netherlands	PoM	22169/1 14.02.2025
28	Fevarin	fluvoxamine (fluvoxamine maleate)	tablets film-coated	100mg; (15/1x15) in blister	Mylan Laboratories SAS, Route de Belleville, Lieu-dit Maillard, 01400 Chatillon sur Chalaronne	France	Abbott Healthcare Products B.V., C.J. van Houtenlaan 36, 1381 CP Weesp	the Netherlands	PoM	22170/1 14.02.2025
29	Viburcol	atropa bella-donna D2, calcium carbonicum Hahnemanni D8, matricaria recutita D1, plantago major D3, pulsatilla pratensis D2	suppositories rectal	1,1mg+4,4mg+1,1mg+1,1mg+2,2mg; (12/2x6)	Biologische Heilmittel Heel GmbH, Dr.-Reckeweg-Strasse 2-4, 76532 Baden-Baden	Germany	Biologische Heilmittel Heel GmbH, Dr.-Reckeweg-Strasse 2-4, 76532 Baden-Baden	Germany	OTC	21794/1 14.02.2025
30	Bronchobos	carbocisteine	capsules	375mg; (30/3x10) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	19990/6 14.02.2025
31	ERYTHROMYCIN OINTMENT	erythromycin	ointment	10mg/g; aluminium tube 20g, aluminium tube 25g	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	18972/1 14.02.2025
32	Clariscan	gadoteric acid	solution for injection	0,5mmol/ml; (10) glass vials 10ml	GE Healthcare AS-Oslo Plant, Nycoveien 1, NO-0485 Oslo	Norway	GE Healthcare AS, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	PoM	20610/4 14.02.2025
33	Clariscan	gadoteric acid	solution for injection	0,5mmol/ml; (10) glass vials 15ml	GE Healthcare AS-Oslo Plant, Nycoveien 1, NO-0485 Oslo	Norway	GE Healthcare AS, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	PoM	20611/4 14.02.2025
34	Clariscan	gadoteric acid	solution for injection	0,5mmol/ml; (10) glass vials 20ml	GE Healthcare AS-Oslo Plant, Nycoveien 1, NO-0485 Oslo	Norway	GE Healthcare AS, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	PoM	20612/4 14.02.2025
35	Clariscan	gadoteric acid	solution for injection	0,5mmol/ml; (10) plastic bottles 50ml	GE Healthcare AS-Oslo Plant, Nycoveien 1, NO-0485 Oslo	Norway	GE Healthcare AS, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	PoM	20613/4 14.02.2025

36	Clariscan	gadoteric acid	solution for injection	0,5mmol/ml, (10) plastic bottles 100ml	GE Healthcare AS-Oslo Plant, Nycoveien 1, NO-0485 Oslo	Norway	GE Healthcare AS, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	PoM	20615/4 14.02.2025
37	Ducressa	dexamethasone (dexamethasone sodium phosphate), levofloxacin (levofloxacin hemihydrate)	drops eye	1mg/ml+5mg/ml; 5ml plastic vial-dropper	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, Tubilux Pharma S.p.A., Via Costarica, 20/22, 00071 Pomezia/Rome, Italy- bulk manufacturer, packager, quality control	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere,	Finland	PoM	20402/5/1 14.02.2025
38	Diflucan	fluconazole	capsules	50mg; (7/1x7) in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	Pfizer H.C.P. Corporation, 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	21731/2/1 14.02.2025
39	Diflucan	fluconazole	capsules	150mg; (1/1x1) in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	Pfizer H.C.P. Corporation, 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	21732/2/1 14.02.2025
40	Duphaston	dydrogesterone	tablets film-coated	10mg; (20/1x20) in blister	ABBOTT Biologicals B.V., Veerweg 12, 8121 AA Olst	the Netherlands	ABBOTT Healthcare Products B.V., C.J. van Houtenlaan 36, NL-1381 CP Weesp	the Netherlands	PoM	19642/2 14.02.2025
41	Allochol	cattle bile dried, dried garlic, charcoal activated, nettle leaves	tablets coated	80mg+40mg+25mg+5mg; (10/1x10) in blister, (50) plastic container	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	19109/2 14.02.2025
42	Oftaquix	levofloxacin (levofloxacin hemihydrate)	drops eye	5mg/ml; 5ml plastic bottle-dropper	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, NextPharma Oy, Niittyhaankatu 20, 33720 Tampere, Finland- bulk manufacturer, primary packager, quality control, Manufacturing Packaging Farmaca (MPF) B.V., Neptunus 12, HEERENVEEN, 8448 CN, the Netherlands- secondary packager	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	PoM	19335/3 14.02.2025

43	Wobenzym	pancreatin, trypsin, chymotrypsin, bromelain, papain, amylase, lipase, rutoside trihydrate	tablets gastro-resistant	300 prot.UA+360FIP-U+300FIP-U+225FIP-U+90FIP-U+50FIP-U+34FIP-U+50mg (40/2x20) and (200/10x20) in blister, (800) in plastic container	Mucos Emulsionsgesellschaft mbH, Mirastrasse 17, D-13509 Berlin	Germany	Mucos Pharma GmbH & Co. KG, Mirastrasse 17, D-13509 Berlin	Germany	OTC	21258/3 14.02.2025
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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 02-1/25 on February 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	Predictal OD	trimetazidine (trimetazidine dihydrochloride)	capsules prolonged-release	80mg; (30/3x10) in blister, (60/6x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, quality control, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65, Hungary- bulk manufacturer	Hungary	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000215 14.02.2025
2	Predictal OD	trimetazidine (trimetazidine dihydrochloride)	capsules prolonged-release	80mg; (30/3x10) in blister, (60/6x10) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000215 14.02.2025
3	Oncaspar	Pegaspargase	lyophilizate for solution for i/m injection and infusion	750IU/ml; glass vial 5ml	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy- quality control, batch releaser, Lyophilization Services of New England, Inc (LSNE), 25 Commerce Drive, Bedford, New Hampshire (NH) 03110, USA- bulk manufacturer, primary packager, Exelead Inc., 6925 Guion Road, Indianapolis, Indiana (IN) 46268, USA- secondary packager	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000545 14.02.2025
4	Brimoptic	timolol (timolol maleate), brimonidine (brimonidine tartrate)	drops eye	5mg/ml+2mg/ml; vial-dropper 10ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	007496 14.02.2025
5	Arifam	amlodipine (amlodipine besilate), indapamide	tablets film-coated modified-release	5mg+1,5mg; (30/2x15) in blister, (90/6x15) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	001627 14.02.2025
6	Arifam	amlodipine (amlodipine besilate), indapamide	tablets film-coated modified-release	10mg+1,5mg; (30/2x15) in blister, (90/6x15) in blister	Les Laboratoires Servier Industrie, 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot 92284 Suresnes cedex	France	PoM	001627 14.02.2025



7	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	5mg+5mg; (29) in plastic container, (30) in plastic container, (90/3x30/) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000575 14.02.2025
8	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	5mg+10mg; (29) in plastic container, (30) in plastic container, (90/3x30/) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000575 14.02.2025
9	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	10mg+5mg; (29) in plastic container, (30) in plastic container, (90/3x30/) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000575 14.02.2025
10	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	10mg+10mg; (29) in plastic container, (30) in plastic container, (90/3x30/) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000575 14.02.2025
11	Noliprel A Forte	perindopril arginine, indapamide	tablets film-coated	5mg+1,25mg; (14) in plastic container, (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000175 14.02.2025
12	Noliprel A Forte	perindopril arginine, indapamide	tablets film-coated	5mg+1,25mg; (14) in plastic container, (30) in plastic container, (90) in plastic container	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	000175 14.02.2025
13	Noliprel A Forte	perindopril arginine, indapamide	tablets film-coated	5mg+1,25mg; (14) in plastic container, (29) in plastic container, (30) in plastic container, (90) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000175 14.02.2025
14	Noliprel A Forte	perindopril arginine, indapamide	tablets film-coated	5mg+1,25mg; (14) in plastic container, (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284- batch releaser, packager, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000175 14.02.2025