

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 05-1/26 on May 15, 2026

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	Eloira	levonorgestrel	system intrauterine	52mg; (1) in blister	Pregna International Limited, Survey No. 342/3 plot no.29, Bharat Industrial Estate, Village Bhimpore, Daman-396 210	India	Pregna International Limited, 13 Suryoday estate, 136 Tardeo Road, Mumbai, Maharashtra, 400034	India	PoM	24103 15.05.2026
2	Cetrine	cetirizine	tablets film-coated	10mg; (20/2x10) in blister, (30/3x10) in blister	DR. REDDY'S LABORATORIES LTD., Formulations Unit - 6, Vill. Khol, Nalagarh Road, Baddi, Distt. Solan H.P 173205	India	Dr. Reddy's Laboratories Ltd., 8-2-337, Road No. 3, Banjara Hills, Hyderabad-500 034 Telangana	India	OTC	24104 15.05.2026
3	Cetrine	cetirizine	tablets film-coated	10mg; (20/2x10) in blister, (30/3x10) in blister	Dr. Reddy's Laboratories Limited, Formulations Tech Ops II, Survey No. 42p, 43, 44p, 45p, 46p, 53, 54 & 83, Bachupally Village, Bachupally Mandal, Medchal Malkajiril district - 500 090, Telengana state	India	Dr. Reddy's Laboratories Ltd., 8-2-337, Road No. 3, Banjara Hills, Hyderabad-500 034 Telangana	India	OTC	24105 15.05.2026
4	Arylia	denosumab	solution for injection	60mg/ml; (1) pre-filled syringe 1ml	AryoGen Pharmed, No. 140, 24th km Karaj Makhsoos Road, Garmdareh City, Karaj County, Alborz Province	Iran	AryoGen Pharmed, No. 140, 24th km Karaj Makhsoos Road, Garmdareh City, Karaj County, Alborz Province	Iran	PoM	24106 15.05.2026

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1	Atorvastatin Alkaloid	atorvastatin (atorvastatin calcium trihydrate)	tablets film-coated	10mg; (30/3x10) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	24119 (015902) 15.05.2026
2	Atorvastatin Alkaloid	atorvastatin (atorvastatin calcium trihydrate)	tablets film-coated	20mg; (30/3x10) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	24120 (015902) 15.05.2026
3	Atorvastatin Alkaloid	atorvastatin (atorvastatin calcium trihydrate)	tablets film-coated	40mg; (30/2x15) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	24121 (015902) 15.05.2026
4	Atorvastatin Alkaloid	atorvastatin (atorvastatin calcium trihydrate)	tablets film-coated	80mg; (30/3x10) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	24122 (015902) 15.05.2026
5	Bepanthen	dexpanthenol	cream	50mg/g; aluminium tube 3,5g aluminium tube 30g, aluminium tube 50g, aluminium tube 100g	GP Grenzach Produktions GmbH, Emil-Barell-Strasse 7, D-79639 Grenzach-Wyhlen	Germany	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	24123 (012147) 15.05.2026

6	Tibsovo	ivosidenib	tablets film-coated	250mg; (60) in plastic container	Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy- batch releaser, Rottendorf Pharma GmbH, Ostenfelder Strasse 51-61, Ennigerloh, 59320, Germany- bulk manufacturer, quality control (physicochemical), Almac Pharma Services Limited, Seagoe Industrial Estate, Portadaun, Creigavon, BT63 5UA, United Kingdom- packager, Eurofins BioPharma Product Testing Munich GmbH, Robert-Koch-Strasse 3a, Planegg, Bavaria, Germany- quality control (microbiological)	France	Laboratoires Servier, 50, rue Carno, 92284 Suresnes cedex	France	PoM	24124 (018983) 15.05.2026
7	Tibsovo	ivosidenib	tablets film-coated	250mg; (60) in plastic container	Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy- batch releaser, Patheon Inc., 2100 Syntex Court, Mississauga, Ontario, L5N 7K9, Canada- bulk manufacturer, quality control, Almac Pharma Services Limited, Seagoe Industrial Estate, Portadaun, Creigavon, BT63 5UA, United Kingdom- packager	France	Laboratoires Servier, 50, rue Carno, 92284 Suresnes cedex	France	PoM	24125 (018983) 15.05.2026
8	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	5mg; (56/4x14) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24126 (007278) 15.05.2026
9	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	15mg; (56/4x14) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24127 (007278) 15.05.2026
10	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	20mg; (56/4x14) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24128 (007278) 15.05.2026

11	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	5mg; (56/4x14) in blister	SKOPINPHARM LTD, Zdanie 1, Promyshlennaya Zona No 1, Skopinsky Rayon, Ryazan Oblast, 391800- secondary packager, batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland- bulk manufacturer, primary packager, quality control	Russia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24129 (007278) 15.05.2026
12	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	15mg; (56/4x14) in blister	SKOPINPHARM LTD, Zdanie 1, Promyshlennaya Zona No 1, Skopinsky Rayon, Ryazan Oblast, 391800- secondary packager, batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland- bulk manufacturer, primary packager, quality control	Russia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24130 (007278) 15.05.2026
13	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	20mg; (56/4x14) in blister	SKOPINPHARM LTD, Zdanie 1, Promyshlennaya Zona No 1, Skopinsky Rayon, Ryazan Oblast, 391800- secondary packager, batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland- bulk manufacturer, primary packager, quality control	Russia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24131 (007278) 15.05.2026
14	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	5mg; (56/4x14) in blister	SKOPINPHARM LTD, Zdanie 1, Promyshlennaya Zona No 1, Skopinsky Rayon, Ryazan Oblast, 391800- secondary packager, quality control (physicochemical), batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland- bulk manufacturer, primary packager, quality control (microbiological)	Russia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24132 (007278) 15.05.2026

15	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	15mg; (56/4x14) in blister	SKOPINPHARM LTD, Zdanie 1, Promyshlennaya Zona No 1, Skopinsky Rayon, Ryazan Oblast, 391800- secondary packager, quality control (physicochemical), batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland- bulk manufacturer, primary packager, quality control (microbiological)	Russia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24133 (007278) 15.05.2026
16	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	20mg; (56/4x14) in blister	SKOPINPHARM LTD, Zdanie 1, Promyshlennaya Zona No 1, Skopinsky Rayon, Ryazan Oblast, 391800- secondary packager, quality control (physicochemical), batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland- bulk manufacturer, primary packager, quality control (microbiological)	Russia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24134 (007278) 15.05.2026
17	Torvazin Plus	atorvastatin (atorvastatin calcium trihydrate), ezetimibe	capsules	10mg+10mg; (30/3x10) in blister, (90/9x10) in blister	EGIS Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65	Hungary	EGIS Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	24135 (000738) 15.05.2026
18	Torvazin Plus	atorvastatin (atorvastatin calcium trihydrate), ezetimibe	capsules	20mg+10mg; (30/3x10) in blister, (90/9x10) in blister	EGIS Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65	Hungary	EGIS Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	24136 (000738) 15.05.2026
19	Torvazin Plus	atorvastatin (atorvastatin calcium trihydrate), ezetimibe	capsules	40mg+10mg; (30/3x10) in blister, (90/9x10) in blister	EGIS Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65	Hungary	EGIS Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	24137 (000738) 15.05.2026
20	Torvazin Plus	atorvastatin (atorvastatin calcium trihydrate), ezetimibe	capsules	10mg+10mg; (30/3x10) in blister, (90/9x10) in blister	EGIS Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, batch releaser, EGIS Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65, Hungary- bulk manufacturer, quality control	Hungary	EGIS Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	24138 (000738) 15.05.2026

21	Torvazin Plus	atorvastatin (atorvastatin calcium trihydrate), ezetimibe	capsules	20mg+10mg; (30/3x10) in blister, (90/9x10) in blister	EGIS Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, batch releaser, EGIS Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65, Hungary- bulk manufacturer, quality control	Hungary	EGIS Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	24139 (000738) 15.05.2026
22	Torvazin Plus	atorvastatin (atorvastatin calcium trihydrate), ezetimibe	capsules	40mg+10mg; (30/3x10) in blister, (90/9x10) in blister	EGIS Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, batch releaser, EGIS Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65, Hungary- bulk manufacturer, quality control	Hungary	EGIS Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	24140 (000738) 15.05.2026
23	Naziloc	oxymetazoline (oxymetazoline hydrochloride)	drops nasal	0,25mg/ml; 5ml plastic bottle-dropper, 10ml plastic bottle-dropper	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	OTC	24108 (018169) 15.05.2026
24	Naziloc	oxymetazoline (oxymetazoline hydrochloride)	drops nasal	0,5mg/ml, 5ml plastic bottle-dropper, 10ml plastic bottle-dropper	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	OTC	24109 (018169) 15.05.2026
25	Naziloc Baby	oxymetazoline (oxymetazoline hydrochloride)	drops nasal	0,1mg/ml; 5ml plastic bottle-dropper, 10ml plastic bottle-dropper	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	OTC	24110 (018169) 15.05.2026
26	Naziloc	oxymetazoline (oxymetazoline hydrochloride)	spray nasal	0,25mg/ml; 10ml plastic bottle	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	OTC	24111 (018169) 15.05.2026
27	Naziloc	oxymetazoline (oxymetazoline hydrochloride)	spray nasal	0,5mg/ml; 10ml plastic bottle	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	OTC	24112 (018169) 15.05.2026
28	Brimoptic-N	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	24107 (020680) 15.05.2026

29	Nonpres	eplerenone	tablets film-coated	25mg; (20/2x10/) in blister, (30/3x10/) in blister	Adamed Pharma S.A., 5 Marszalka J. Pilsudskiego Str., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza St., 05-152 Czosnow	Poland	PoM	24114 (021968) 15.05.2026
30	Nonpres	eplerenone	tablets film-coated	50mg; (20/2x10/) in blister, (30/3x10/) in blister	Adamed Pharma S.A., 5 Marszalka J. Pilsudskiego Str., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza St., 05-152 Czosnow	Poland	PoM	24115 (021968) 15.05.2026
31	ORLOBIN-NEO	amikacin (amikacin sulfate)	solution for injection/infusion	500mg/2ml; (1) glass vial, (5) ampoules 2ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Medicus S.A., 10 Valaoritou str., 144 52, Metamorfofi	Greece	PoM	24116 (028719) 15.05.2026
32	Dimex	diphenhydramine (diphenhydramine hydrochloride), ammonium chloride	syrup	9,96mg/5ml+99,6mg/5ml; 125ml plastic bottle and measuring cup	Sopharma AD, str. Iliensko shosse 16, 1220 Sofia- batch releaser, Sopharma AD, Vrabevo vlg. 5660, district of Lovetch, Bulgaria- bulk manufacturer, packager, quality control	Bulgaria	Sopharma AD, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	24117 (030988) 15.05.2026
33	Pelethrocin Plus	diosmin, hesperidin	tablets film-coated	450mg+50mg; (30/2x15/) in blister, (60/4x15/) in blister	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., 14452 Metamorfofi	Greece	OTC	24118 (036187) 15.05.2026
34	Moxicin	moxifloxacin (moxifloxacin hydrochloride)	drops eye	5mg/ml; plastic 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	24113 (028831) 15.05.2026

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of the medicines recommended for re-registration under the EAEU procedure by the Center according to the meeting decision N 05-1/26 on May 15,
2026

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1	Midazem	midazolam	solution for injection	5mg/ml; (5) ampoules 3ml	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	PoM	24141 (041279) 15.05.2026

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of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 05-1/26 on May 15, 2026

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Tyzine Classic	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	JTNL LLC, 121614, Moscow, Krylatskaya intercity municipal district, Krylatskaya str., 17, bld. 3	Russia	OTC	22969/2/2 15.05.2026
2	Tyzine Classic	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	JTNL LLC, 121614, Moscow, Krylatskaya intercity municipal district, Krylatskaya str., 17, bld. 3	Russia	OTC	22970/2/2 15.05.2026
3	Teraligen retard	alimemazine (alimemazine tartrate)	tablets sustained-release film-coated	20mg; (30/3x10) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	PoM	20201/2/2 15.05.2026

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of variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting decision N

05-1/26 on May 15, 2026

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1	Fungoderil	naftifine (naftifine hydrochloride)	solution for external use	10mg/ml; 15ml glass vial with dropper, 25ml glass vial with dropper	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, s.1- quality control, batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia- bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	JITI-N*000609-ITI-AM 15.05.2026
2	MabThera	rituximab	concentrate for solution for infusion	10mg/ml; (2) glass vials 10ml	F. Hoffmann-La Roche Ltd., Wurmisweg, 4303 Kaiseraugst- secondary packager, batch releaser, Roche Diagnostics GmbH, Sandhofer strasse 116, 68305 Mannheim, Germany- bulk manufacturer, primary packager, quality control	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4058 Basel	Switzerland	PoM	JITI-N*004365-ITI-AM 15.05.2026
3	MabThera	rituximab	concentrate for solution for infusion	10mg/ml; (2) glass vials 10ml	F. Hoffmann-La Roche Ltd., Wurmisweg, 4303 Kaiseraugst- secondary packager, quality control, batch releaser, Roche Diagnostics GmbH, Sandhofer strasse 116, 68305 Mannheim, Germany- bulk manufacturer, primary packager	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4058 Basel	Switzerland	PoM	JITI-N*004365-ITI-AM 15.05.2026
4	MabThera	rituximab	concentrate for solution for infusion	10mg/ml; (2) glass vials 10ml	F. Hoffmann-La Roche Ltd., Wurmisweg, 4303 Kaiseraugst- secondary packager, quality control, batch releaser, Genentech Inc., 4625 NE Brookwood Parkway, Hillsboro, OR 97124, USA- bulk manufacturer, primary packager	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4058 Basel	Switzerland	PoM	JITI-N*004365-ITI-AM 15.05.2026

5	MabThera	rituximab	concentrate for solution for infusion	10mg/ml; (2) glass vials 10ml	F. Hoffmann-La Roche Ltd., Wurmisweg, 4303 Kaiseraugst- secondary packager, batch releaser, Genentech Inc., 4625 NE Brookwood Parkway, Hillsboro, OR 97124, USA- bulk manufacturer, primary packager, Roche Diagnostics GmbH, Sandhofer strasse 116, 68305 Mannheim, Germany- quality control	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4058 Basel	Switzerland	PoM	JITI-N°004365-ITI-AM 15.05.2026
6	MabThera	rituximab	concentrate for solution for infusion	10mg/ml; (1) glass vial 50ml	F. Hoffmann-La Roche Ltd., Wurmisweg, 4303 Kaiseraugst- secondary packager, batch releaser, Roche Diagnostics GmbH, Sandhofer strasse 116, 68305 Mannheim, Germany- bulk manufacturer, primary packager, quality control	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4058 Basel	Switzerland	PoM	JITI-N°004365-ITI-AM 15.05.2026
7	MabThera	rituximab	concentrate for solution for infusion	10mg/ml; (1) glass vial 50ml	F. Hoffmann-La Roche Ltd., Wurmisweg, 4303 Kaiseraugst- secondary packager, quality control, batch releaser, Roche Diagnostics GmbH, Sandhofer strasse 116, 68305 Mannheim, Germany- bulk manufacturer, primary packager	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4058 Basel	Switzerland	PoM	JITI-N°004365-ITI-AM 15.05.2026
8	MabThera	rituximab	concentrate for solution for infusion	10mg/ml; (1) glass vial 50ml	F. Hoffmann-La Roche Ltd., Wurmisweg, 4303 Kaiseraugst- secondary packager, batch releaser, Genentech Inc., 4625 NE Brookwood Parkway, Hillsboro, OR 97124, USA- bulk manufacturer, primary packager, Roche Diagnostics GmbH, Sandhofer strasse 116, 68305 Mannheim, Germany- quality control	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4058 Basel	Switzerland	PoM	JITI-N°004365-ITI-AM 15.05.2026
9	MabThera	rituximab	concentrate for solution for infusion	10mg/ml; (1) glass vial 50ml	F. Hoffmann-La Roche Ltd., Wurmisweg, 4303 Kaiseraugst- secondary packager, quality control, batch releaser, Genentech Inc., 4625 NE Brookwood Parkway, Hillsboro, OR 97124, USA- bulk manufacturer, primary packager	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4058 Basel	Switzerland	PoM	JITI-N°004365-ITI-AM 15.05.2026

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of variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 05-1/26 on May 15,
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1	Codelac Neo-Oticipharm	butamirate (butamirate citrate)	drops oral	5mg/ml; 20ml glass vial-dropper	Pharmstandard-Leksredstva JSC, 305022, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, flr.12, apartment II, 29, Moscow 123112	Russia	OTC	20806/3/1 15.05.2026
2	Letrozole Denk 2.5	letrozole	tablets film-coated	2,5mg; (30/3x10) in blister	Haupt Pharma Munster GmbH, Schleebruggenkamp 15, 48159 Munster, Nordrhein-Westfalen- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Umweltlabor ACB GmbH, Albrecht-Thaer-Strasse 14, 48147 Muenster, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	PoM	24054/1 15.05.2026
3	Purified tuberculosis allergen in the standard dilution (purified tuberculin in the standard dilution)	tuberculoprotein allergen	solution for intradermal injection	2TU/0,1 ml; (1) ampoule 1ml and (5) syringes, (10) ampoules 1ml	FSUE SPbSRIVS FMBA of Russia, Saint Petersburg, Krasnoe Selo, Svobody St., 52	Russia	FSUE SPbSRIVS FMBA of Russia, Saint Petersburg, Krasnoe Selo, Svobody St., 52	Russia	PoM	22532/1 15.05.2026
4	Simdax	levosimendan	concentrate for solution for infusion	2,5mg/ml; glass vial 5ml	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	PoM	21693/1 15.05.2026

5	Demitex	dexketoprofen (dexketoprofen trometamol)	granules for oral solution	25mg; (10) sachets	FORTEX NUTRACEUTICALS LTD. 10, Prohladen kat street, Suhodol district, 1362 Sofia- bulk manufacturer, quality control, batch releaser, FORTEX NUTRACEUTICALS LTD. 8, Prohladen kat street, Suhodol district, 1362 Sofia, Bulgaria- packager	Bulgaria	Demi Pharm LLC, Griboyedovi 12, ap. 25, Sevan 1501	Republic of Armenia	PoM	23202/2/1 15.05.2026
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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 05-1/26 on May 15, 2026

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	Arduan	pipecuronium bromide	powder lyophilized and solvent for solution for injection	4mg; (50/5x10(5 glass vials 10ml+5 ampoules 2ml with solvent)) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JИT-N*004052-ITI-AM 15.05.2026
2	Arduan	pipecuronium bromide	powder lyophilized and solvent for solution for injection	4mg; (50/5x10(5 glass vials 10ml+5 ampoules 2ml with solvent)) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- powder manufacturer, secondary packager, quality control, batch releaser, Hemofarm A.D., 26300, Vrsac, Beogradski put b.b., Serbia- solvent bulk manufacturer, primary packager	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JИT-N*004052-ITI-AM 15.05.2026
3	Preductal 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	JИT-N*000215-ITI-AM 15.05.2026
4	Preductal 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	JИT-N*000215-ITI-AM 15.05.2026

5	Efeira	netakimab	solution for subcutaneous injection	60mg/ml; (2/2x1) glass syringes 1 ml in blister, (2/2x1) glass syringes 1 ml in blister and N2 alcohol swabs, (2/1x2) plastic autoinjector 1ml in blister, (2/1x2) plastic autoinjector 1ml in blister and (2) alcohol swabs	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	JITI-Nº005293-ITI-AM 15.05.2026
6	Efeira	netakimab	solution for subcutaneous injection	60mg/ml; (2/2x1) glass syringes 1 ml in blister, (2/2x1) glass syringes 1 ml in blister and N2 alcohol swabs, (2/1x2) plastic autoinjector 1ml in blister, (2/1x2) plastic autoinjector 1ml in blister and (2) alcohol swabs	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422- quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422, Russia- bulk manufacturer, packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeschch. 89, Saint Petersburg, 198515	Russia	PoM	JITI-Nº005293-ITI-AM 15.05.2026
7	Tantum Verde	benzydamine (benzydamine hydrochloride)	spray for local use	0,255mg/dose; 30ml (176 doses) plastic container with pump dispenser	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. Via Vecchia Del Pinocchio, 22, 60131 Ancona	Italy	Angelini Pharma Sp.A., Viale, Amelia 70, 00181, Rome	Italy	OTC	JITI-Nº000747-ITI-AM 15.05.2026
8	Thiogamma	thioctic acid	solution for infusion	12mg/ml; (1) glass vial 50ml, (5) glass vials 50ml, (10) glass vials 50ml	Solpharm Pharmazeutische Erzeugnisse GmbH, Industriestrasse 3, 34212 Melsungen	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boblingen	Germany	PoM	JITI-Nº001968-ITI-AM 15.05.2026
9	Mydocalm Long	tolperisone (tolperisone hydrochloride)	tablets film-coated prolonged release	450mg; (10/1x10) in blister, (30/3x10) in blister, (bag) 10,5-18,5 kg x 1(box	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Polska Spz 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	JITI-Nº000314-ITI-AM 15.05.2026

10	Mydocalm Long	tolperisone (tolperisone hydrochloride)	tablets film-coated prolonged release	450mg; (10/1x10) in blister, (30/3x10) in blister, (bag) 10,5-18,5 kg x 1(box)	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	JIT-N°000314-ITI-AM 15.05.2026
11	Mydocalm Long	tolperisone (tolperisone hydrochloride)	tablets film-coated prolonged release	450mg; (10/1x10) in blister, (30/3x10) in blister, (bag) 10,5-18,5 kg x 1(box)	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JIT-N°000314-ITI-AM 15.05.2026
12	Tantum Verde	benzydamine (benzydamine hydrochloride)	spray for local use	0,255mg/dose; 30ml (176 doses) plastic container with pump dispenser	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. Via Vecchia Del Pinocchio, 22, 60131 Ancona	Italy	Angelini Pharma S.p.A., Viale, Amelia 70, 00181, Rome	Italy	OTC	JIT-N°000704-ITI-AM 15.05.2026

13	Thiogamma	thioctic acid	tablets film-coated	600mg; (30/3x10/) in blister, (60/6x10/) in blister, (100/10x10/) in blister	Dragenopharm Apotheker Puschl GmbH, Gollstrasse 1, 84529 Tittmoning- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LSSE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological)	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen	Germany	PoM	JITI-N°000229-TTI-AM 15.05.2026
14	Thiogamma	thioctic acid	tablets film-coated	600mg; (30/3x10/) in blister, (60/6x10/) in blister, (100/10x10/) in blister	Worwag Pharma Operations Sp. z o.o., Ul. Gen. Mariana Langiewiczza 58, Konstantynow Lodzki, 95-050- bulk manufacturer, packager, quality control (physicochemical), batch releaser, MIKROLAB Spotka z ograniczona odpowiedzialnoscia, ul. Lubelska 5/7, 03-802 Warszawa, Poland- quality control (microbiological)	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen	Germany	PoM	JITI-N°000229-TTI-AM 15.05.2026
15	Warfarin STADA	warfarin (warfarin sodium)	tablets	2,5mg; (50) in plastic container, (100) in plastic container, (50/1x50) in plastic container, (100/1x100) in plastic container	Orifarm Manufacturing Poland Sp.z o.o., 12 Ksiewta Lowickiego st., 99-420 Lyszkowice	Poland	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	PoM	JITI-N°005887-TTI-AM 15.05.2026