

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 12-2/25 on December 25, 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	Floxalive	levofloxacin (levofloxacin hemihydrate)	tablets film-coated	500mg; (5/1x5) in blister	IBN AL-Haytham Pharma Industries Co., P.O. Box 16232, Al Mansura-Aleppo	Syria	IBN AL-Haytham Pharma Industries Co., P.O. Box 16232, Al Mansura-Aleppo	Syria	PoM	23790 25.12.2025
2	Floxalive	levofloxacin (levofloxacin hemihydrate)	tablets film-coated	750mg; (5/1x5) in blister	IBN AL-Haytham Pharma Industries Co., P.O. Box 16232, Al Mansura-Aleppo	Syria	IBN AL-Haytham Pharma Industries Co., P.O. Box 16232, Al Mansura-Aleppo	Syria	PoM	23791 25.12.2025
3	BIOVEINE CALCIUM G.M.C.	calcium gluconate, magnesium hexahydrate	solution for injection	25,04mg+52,96mg; plastic container 500ml	V.M.D. NV, Hoge Mauw 900, 2370 Arendonk- secondary packager, batch releaser, Laboratories Biove, 3 Rue Lorraine, 62510 Arques, France- bulk manufacturer, primary packager, quality control	Belgium	V.M.D. NV, Hoge Mauw 900, 2370 Arendonk	Belgium	PoM	23792 25.12.2025
4	M-Flox	moxifloxacin (moxifloxacin hydrochloride)	tablets film-coated	400mg; (5/1x5) in blister	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	PoM	23793 25.12.2025
5	M-Flox	moxifloxacin (moxifloxacin hydrochloride)	solution for infusion	400mg/250ml; glass vial 250ml	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	PoM	23794 25.12.2025
6	CinnaPoietin	erythropoietin beta	solution for injection	2000IU/0,3ml; (6) glass pre-filled syringes 0,3ml	CinnaGen Co., Plot No. 72, 74, 87, 88, 3rd Sq., Simin Dasht Non-Governmental Industrial Area, Fardis County, Alborz Province	Iran	CinnaGen Co., Plot No. 72, 74, 87, 88, 3rd Sq., Simin Dasht Non-Governmental Industrial Area, Fardis County, Alborz Province	Iran	PoM	23795 25.12.2025

7	Razo	rabeprazole (rabeprazole sodium)	tablets gastro-resistant coated	10mg; (15/1x15/) in blister, (30/2x15/) in blister	Dr. Reddy's Laboratories Ltd., FTO Unit 3, Survey No. 41, 42 part, 45 part & 46 part, Bachupally (Village), Bachupally (Mandal), Medchal-Malkajgiri (Dist.), Telangana	India	Dr. Reddy's Laboratories Ltd., 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana-500034	India	PoM	23796 25.12.2025
8	Razo	rabeprazole (rabeprazole sodium)	tablets gastro-resistant coated	20mg; (15/1x15/) in blister, (30/2x15/) in blister	Dr. Reddy's Laboratories Ltd., FTO Unit 3, Survey No. 41, 42 part, 45 part & 46 part, Bachupally (Village), Bachupally (Mandal), Medchal-Malkajgiri (Dist.), Telangana	India	Dr. Reddy's Laboratories Ltd., 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana-500034	India	PoM	23797 25.12.2025

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1	Brilinta	ticagrelor	tablets film-coated	90mg; (14/1x14) in blister, (56/4x14) in blister, (168/12x14) in blister	AstraZeneca AB Gartunavagen, Sodertalje, 152 57	Sweden	AstraZeneca AB, Sodertalje, SE-15185	Sweden	PoM	23773 (013059) 25.12.2025
2	Brilinta	ticagrelor	tablets film-coated	90mg; (14/1x14) in blister, (56/4x14) in blister, (168/12x14) in blister	AstraZeneca Industries LLC, 249020, Kaluga Region, Borovsky District, Dobrino village, 1st Vostochny proezd, estate 8	Russia	AstraZeneca AB, Sodertalje, SE-15185	Sweden	PoM	23774 (013059) 25.12.2025
3	Brilinta	ticagrelor	tablets film-coated	90mg; (14/1x14) in blister, (56/4x14) in blister, (168/12x14) in blister	AstraZeneca Industries LLC, 249020, Kaluga Region, Borovsky District, Dobrino village, 1st Vostochny proezd, estate 8- secondary packager, batch releaser, AstraZeneca AB Gartunavagen, Sodertalje, 152 57, Sweden- bulk manufacturer, primary packager, quality control	Russia	AstraZeneca AB, Sodertalje, SE-15185	Sweden	PoM	23775 (013059) 25.12.2025
4	Miladean	melatonin, memantine (memantine hydrochloride)	tablets orodispersible	3mg+5mg; (10/1x10) in blister, (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	23776 (003207) 25.12.2025

5	Forxiga	dapagliflozin	tablets film-coated	5mg; (14/1x14) in blister, (28/2x14) in blister, (30/3x10) in blister	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire SK10 2NA- packager, quality control, batch releaser, AstraZeneca Pharmaceuticals LP, 4601 Highway 62 East, Mount Vernon, Indiana, 47620, USA- bulk manufacturer	UK	AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge	UK	PoM	23777 (011122) 25.12.2025
6	Forxiga	dapagliflozin	tablets film-coated	10mg; (14/1x14) in blister, (28/2x14) in blister, (30/3x10) in blister	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire SK10 2NA- packager, quality control, batch releaser, AstraZeneca Pharmaceuticals LP, 4601 Highway 62 East, Mount Vernon, Indiana, 47620, USA- bulk manufacturer	UK	AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge	UK	PoM	23778 (011122) 25.12.2025
7	Forxiga	dapagliflozin	tablets film-coated	10mg; (28/2x14) in blister, (30/3x10) in blister	AstraZeneca Industries LLC, 249020, Kaluga Region, Borovsky District, Dobrino village, 1st Vostochny proezd, estate 8	Russia	AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge	UK	PoM	23779 (011122) 25.12.2025
8	Forxiga	dapagliflozin	tablets film-coated	10mg; (14/1x14) in blister, (28/2x14) in blister	Nobel Almaty Pharmaceutical Factory, 050008, Almaty city, Almaly district, 162E Shevchenko Street- secondary packager, quality control, batch releaser, AstraZeneca Pharmaceuticals LP, 4601 Highway 62 East, Mount Vernon, Indiana, 47620- bulk manufacturer, AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire SK10 2NA- primary packager	Kazakhstan	AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge	UK	PoM	23780 (011122) 25.12.2025

9	Forxiga	dapagliflozin	tablets film-coated	10mg; (30/3x10/) in blister, (90/9x10/) in blister	AstraZeneca Industries LLC, 249020, Kaluga Region, Borovsky District, Dobrino village, 1st Vostochny proezd, estate 8- secondary packager, quality control, batch releaser, AstraZeneca Pharmaceuticals LP, 4601 Highway 62 East, Mount Vernon, Indiana, 47620, USA- bulk manufacturer, AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire SK10 2NA- primary packager	Russia	AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge	UK	PoM	23781 (011122) 25.12.2025
10	Trimetazidine-AKOS MV	trimetazidine (trimetazidine dihydrochloride)	tablets coated modified-release	35mg; (10/1x10/) in blister, (20/2x10/) in blister, (30/3x10/) in blister, (40/4x10/) in blister, (50/5x10/) in blister, (60/6x10/) in blister, (120/12x10/) in blister	Biocom JSC, 54 Chapaevsky Cr., Stavropol, 355016	Russia	Biocom JSC, 54 Chapaevsky Cr., Stavropol, 355016	Russia	PoM	23782 (002888) 25.12.2025
11	Hemomycin	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3/) in blister	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	PoM	23783 (011149) 25.12.2025
12	Hemomycin	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3/) in blister	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb- packager, quality control (microbiological), batch releaser, Hemofarm d.o.o., Novakovici bb, Banja Luka 78000, Bosnia and Herzegovina- bulk manufacturer, quality control (physicochemical)	Serbia	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	PoM	23784 (011149) 25.12.2025
13	Hemomycin	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3/) in blister	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb- packager, quality control, batch releaser, Hemofarm d.o.o., Novakovici bb, Banja Luka 78000, Bosnia and Herzegovina- bulk manufacturer	Serbia	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	PoM	23785 (011149) 25.12.2025
14	CoPlavix	clopidogrel, acetylsalicylic acid	tablets film-coated	75mg+100mg; (7/1x7/) in blister, (14/2x7/) in blister, (28/4x7/) in blister, (100/10x10/) in blister	Sanofi Winthrop Industrie, 1, rue de la Vierge, Ambares et Lagrave, 33565 Carbon Blanc Cedex	France	Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly	France	PoM	23786 (000270) 25.12.2025

15	Magne B6	magnesium lactate dihydrate, pyridoxine hydrochloride	tablets coated	470mg+5mg: (50/5x10) in blister, (60/3x20) in blister, (100/5x20) in blister, (180/9x20) in blister	Sanofi Winthrop Industrie, 1, rue de la Vierge, Ambares et Lagrave, 33565 Carbon Blanc cedex	France	Opella Healthcare Commercial Ltd., 1138 Budapest, st. Vachi 133, b.E, floor 3	Hungary	OTC	23787 (004190) 25.12.2025
16	Magne B6	magnesium lactate dihydrate, pyridoxine hydrochloride	tablets coated	470mg+5mg: (50/5x10) in blister, (60/3x20) in blister, (100/5x20) in blister, (180/9x20) in blister	Opella Healthcare Hungary Limited Liability Company (Opella Healthcare Hungary Ltd.), Levai u. 5., Veresegyhaz, 2112- 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, Vaci ut 133. E. ep. 3 em.	Hungary	OTC	23788 (004190) 25.12.2025
17	Magne B6	magnesium lactate dihydrate, pyridoxine hydrochloride	tablets coated	470mg+5mg: (50/5x10) in blister, (60/3x20) in blister, (100/5x20) in blister, (180/9x20) 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	23789 (004190) 25.12.2025
18	Prevenar 13*	pneumococcal polysaccharide conjugate vaccine pneumococcal conjugate 1 (polysaccharide -CRM197)pneumococcal polysaccharide serotype 1, pneumococcal polysaccharide serotype 3, pneumococcal polysaccharide serotype 4, pneumococcal polysaccharide serotype 5, pneumococcal polysaccharide serotype 6A, pneumococcal polysaccharide serotype 6B, pneumococcal polysaccharide serotype 7F, pneumococcal polysaccharide serotype 9V, pneumococcal polysaccharide serotype 14, pneumococcal polysaccharide serotype 18C, pneumococcal polysaccharide serotype 19A, pneumococcal polysaccharide serotype 19F, pneumococcal polysaccharide serotype 23F	suspension for injection	2,2mcg/dose+2,2mcg/dose+2,2mcg/dose+2,2mcg/dose+2,2mcg/dose+4,4mcg/dose+2,2mcg/dose+2,2mcg/dose+2,2mcg/dose+2,2mcg/dose+2,2mcg/dose+2,2mcg/dose+2,2mcg/dose; (50) glass vials 0,5ml	Pfizer Manufacturing Belgium N.V., Rijksweg 12, Puurs-Sint-Amands, 2870	Belgium	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	PoM	23772 (02256) 25.12.2025

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 12-2/25 on December 25, 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	Kestine	ebastine	tablets film-coated	10mg; (5/1x5/) in blister, (10/1x10/) in blister	Industrias Farmaceuticas Almirall S.A., Ctra. De Martorell 41-61, 08740 Sant Andreu de la Barca, Barcelona	Spain	Almirall, S.A., Ronda General Mitre, 151, 08022 Barcelona	Spain	PoM	23764/25.12.2025

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 12-2/25 on December 25, 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	Actovegin	deproteinised haemoderivate of calf blood	tablets coated	200mg; (50) in glass container	Takeda Pharmaceuticals LLC, Yaroslavl city, 9 Technoparkovaya street	Russia	"Takeda Pharmaceuticals" LLC, Usacheva str 2 bld. 1, Moscow 119048	Russia	PoM	23765 25.12.2025
2	Actovegin	deproteinised haemoderivate of calf blood	solution for injection	40mg/ml; (25/5x5) ampoules 2ml in blister	Takeda Pharmaceuticals LLC, Yaroslavl city, 9 Technoparkovaya street	Russia	"Takeda Pharmaceuticals" LLC, Usacheva str 2 bld. 1, Moscow 119048	Russia	PoM	23766 25.12.2025
3	Actovegin	deproteinised haemoderivate of calf blood	solution for injection	40mg/ml; (5/1x5) ampoules 5ml in blister	Takeda Pharmaceuticals LLC, Yaroslavl city, 9 Technoparkovaya street	Russia	"Takeda Pharmaceuticals" LLC, Usacheva str 2 bld. 1, Moscow 119048	Russia	PoM	23767 25.12.2025
4	Actovegin	deproteinised haemoderivate of calf blood	solution for injection	40mg/ml; (5/1x5) ampoules 10ml in blister	Takeda Pharmaceuticals LLC, Yaroslavl city, 9 Technoparkovaya street	Russia	"Takeda Pharmaceuticals" LLC, Usacheva str 2 bld. 1, Moscow 119048	Russia	PoM	23768 25.12.2025
5	Sodium chloride solution 0.9%	sodium chloride	solution for infusion	9mg/ml; 50ml plastic pack, 100ml plastic pack, 200ml plastic pack, 250ml plastic pack, 400ml plastic pack, 500ml plastic pack, 1000ml plastic pack, 2000ml plastic pack, 3000ml plastic pack	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	23769 25.12.2025
6	Iodinol	iodine	solution for external use	1mg/ml; 100ml glass bottle, 100ml plastic bottle	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	OTC	23770 25.12.2025

7	Brovin syrup	levodropropizine	syrup	6mg/ml; 60ml glass bottle, 120ml glass bottle	Osoth Inter Laboratories Co. Ltd, 600/9 Sukhaphiban 8 Road, Moo 11, Nong Kham, Si Racha, Chonburi 20230	Thailand	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	23771 25.12.2025
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of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-2/25 on December 25, 2025

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1	Charcoal activated-Pharmstandard	charcoal activated	tablets	250mg; (10) in blister, (10/1x10/) in blister, (30/3x10) in blister, (50/5x10) in blister	Pharmstandard-Leksredstva OJSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	ARGO-PHARM LLC, 13/9 Sundukyan str., 0012 Yerevan	Republic of Armenia	OTC	22598/1/1 25.12.2025
2	Citramon-Pharmstandard	acetylsalicylic acid, paracetamol, caffeine (caffeine monohydrate)	tablets	240mg+180mg+30mg; (10) in blister, (10/1x10/) in blister, (20/2x10/) in blister	Pharmstandard-Leksredstva OJSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	ARGO-PHARM LLC, 13/9 Sundukyan str., 0012 Yerevan	Republic of Armenia	OTC	21203/2/2 25.12.2025
3	Zolomaks	alprazolam	tablets	0,25mg; (30/3x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	21518/1/1 25.12.2025
4	Zolomaks	alprazolam	tablets	0,5mg; (30/3x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	21519/1/1 25.12.2025
5	Zolomaks	alprazolam	tablets	1mg; (30/3x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	21520/1/1 25.12.2025
6	Diflucan	fluconazole	solution for i/v infusion	2mg/ml; glass vial 50ml	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	21956/1/1 25.12.2025
7	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	23202/1/1 25.12.2025

8	Trivate	betamethasone (betamethasone dipropionate), clotrimazole, gentamicin (gentamicin sulfate)	ointment	0,5mg/g+10mg/g+1mg/g; aluminium tube 15g	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	Belinda Laboratories LLP, Unit 18, 53 Norman road, Greenwich Centre Business park, SE10 9QF, London	UK	PoM	20204/1/1 25.12.2025
9	Relantan 100	progesterone	capsules soft	100mg; (30/3x10/) in blister	Aversi-Rational Ltd, 33 David Kobakhidze Str., 0198, Tbilisi- secondary packager, quality control, batch releaser, M/s.Steril-Gene Life Sciences (P) Ltd , No.45 Mangalam Main Road, Mangalam Village, Villianur Commune, Puducherry, 605110, India- bulk manufacturer, primary packager	Georgia	Aversi-Rational Ltd, 33 David Kobakhidze Str., 0198, Tbilisi	Georgia	PoM	21409/2/1 25.12.2025
10	Relantan 200	progesterone	capsules soft	200mg; (30/3x10/) in blister	Aversi-Rational Ltd, 33 David Kobakhidze Str., 0198, Tbilisi- secondary packager, quality control, batch releaser, M/s.Steril-Gene Life Sciences (P) Ltd , No.45 Mangalam Main Road, Mangalam Village, Villianur Commune, Puducherry, 605110, India- bulk manufacturer, primary packager	Georgia	Aversi-Rational Ltd, 33 David Kobakhidze Str., 0198, Tbilisi	Georgia	PoM	21410/3/1 25.12.2025
11	Shelsy	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	500mg+125mg; (14(2x7/1x7/)) blister in sachet	Aversi-Rational Ltd, 33 David Kobakhidze Str., 0198, Tbilisi- secondary packager, quality control, batch releaser, Reyoung Pharmaceutical Co. Ltd., No. 1 Ruiyang Road, Yiyuan County, Shandong Province, China- bulk manufacturer, primary packager for Aversi-Rational Ltd, 33 David Kobakhidze Str., 0198, Tbilisi, Georgia	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	21116/1/1 25.12.2025

12	Shelsy	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	875mg+125mg; (14(2x7/1x7/)) blister in sachet	Aversi-Rational Ltd, 33 David Kobakhidze Str., 0198, Tbilisi- secondary packager, quality control, batch releaser, Reyoung Pharmaceutical Co. Ltd., No. 1 Ruiyang Road, Yiyuan County, Shandong Province, China- bulk manufacturer, primary packager for Aversi-Rational Ltd, 33 David Kobakhidze Str., 0198, Tbilisi, Georgia	Georgia	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov str., 6, building 1, 238315	Russia	PoM	21117/1/1 25.12.2025
13	Inforin gel	ibuprofen, levomenthol (menthol)	gel for external use	50mg/g+30mg/g; 40g aluminum tube	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	Belinda Laboratories LLP, Unit 18, 53 Norman road, Greenwich Centre Business park, SE10 9QF, London	UK	OTC	20438/1/1 25.12.2025

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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

12-2/25 on December 25, 2025

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1	Allergostin	ebastine	tablets film-coated	10mg; (10/1x10) in blister	Scientific Technological Pharmaceutical Firm "POLYSAN" Ltd, lit. A, 2 building, 72 Salova st., Saint- Petersburg, 192102	Russia	Scientific Technological Pharmaceutical Firm "POLYSAN" Ltd, lit. A, 2 building, 72 Salova st., Saint- Petersburg, 192102	Russia	OTC	JITI-N°001179-ITI-AM 25.12.2025
2	Allergostin	ebastine	tablets film-coated	20mg; (10/1x10) in blister	Scientific Technological Pharmaceutical Firm "POLYSAN" Ltd, lit. A, 2 building, 72 Salova st., Saint- Petersburg, 192102	Russia	Scientific Technological Pharmaceutical Firm "POLYSAN" Ltd, lit. A, 2 building, 72 Salova st., Saint- Petersburg, 192102	Russia	OTC	JITI-N°001179-ITI-AM 25.12.2025
3	Myfortic	mycophenolic acid (mycophenolate sodium)	tablets gastro-resistant	180mg; (50/5x10) in blister, (60/6x10) in blister, (100/10x10) in blister, (120/12x10) in blister, (250/25x10) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr Baden Wurttemberg	Germany	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	JITI-N°000299-ITI-AM 25.12.2025
4	Myfortic	mycophenolic acid (mycophenolate sodium)	tablets gastro-resistant	180mg; (50/5x10) in blister, (60/6x10) in blister, (100/10x10) in blister, (120/12x10) in blister, (250/25x10) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, quality control, batch releaser, Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr, Germany- bulk manufacturer	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	JITI-N°000299-ITI-AM 25.12.2025
5	Myfortic	mycophenolic acid (mycophenolate sodium)	tablets gastro-resistant	180mg; (50/5x10) in blister, (60/6x10) in blister, (100/10x10) in blister, (120/12x10) in blister, (250/25x10) in blister	Novartis Neva LLC, Doroga v Kamenku Road to Kamenka, Building 40, Block 3, Letter A	Russia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	JITI-N°000299-ITI-AM 25.12.2025

6	Myfortic	mycophenolic acid (mycophenolate sodium)	tablets gastro- resistant	360mg; (50/5x10') in blister; (60/6x10') in blister; (100/10x10') in blister; (120/12x10') in blister; (250/25x10') in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr Baden Wurttemberg	Germany	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	JITI-N°000299-ITI- AM 25.12.2025
7	Myfortic	mycophenolic acid (mycophenolate sodium)	tablets gastro- resistant	360mg; (50/5x10') in blister; (60/6x10') in blister; (100/10x10') in blister; (120/12x10') in blister; (250/25x10') in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, quality control, batch releaser, Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr, Germany- bulk manufacturer	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	JITI-N°000299-ITI- AM 25.12.2025
8	Myfortic	mycophenolic acid (mycophenolate sodium)	tablets gastro- resistant	360mg; (50/5x10') in blister; (60/6x10') in blister; (100/10x10') in blister; (120/12x10') in blister; (250/25x10') in blister	Novartis Neva LLC, Doroga v Kamenku Road to Kamenka, Building 40, Block 3, Letter A	Russia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	JITI-N°000299-ITI- AM 25.12.2025

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of variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-2/25 on December 25, 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	Tadalafil Genericon	tadalafil	tablets film-coated	20mg; (4/1x4) in blister	Genericon Pharma Gesellschaft m.b.H., Hafnerstrasse 211, 8054, Graz, Styria- quality control (physicochemical), batch releaser, Humanis Saglik JSC, Cerkezkoy Organize Sanayi Bolgesi Karaagac, Mah. Fatih Bulv. N32, Kapakli, Tekirdag, Turkey- bulk manufacturer, packager, AGES Graz IMED, Beethovenstrasse 6, Graz, 8010, Austria- quality control (microbiological)	Austria	Genericon Pharma Gesellschaft m.b.H., Hafnerstrasse 211, 8054, Graz, Styria	Austria	PoM	21272/3/2 25.12.2025
2	On.setron-Denk 8mg ODT	ondansetron	tablets orodispersible	8mg; (6/1x6) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, packager, quality control (physicochemical), batch releaser, 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	19982/1 25.12.2025
3	Tribux	trimebutine (trimebutine maleate)	tablets	100mg; (30/3x10) in blister	Biofarm Sp. z o.o., 13, Walbrzyska Str., 60-198, Poznan	Poland	Biofarm Sp. z o.o., 13, Walbrzyska Str., 60-198, Poznan	Poland	PoM	19839/2 25.12.2025
4	Dibase 10,000IU/ml oral drops, solution	colecalfiferol (vitamin D3)	drops oral, solution	10000IU/ml; glass bottle 10ml and dropper	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	PoM	22178/2 25.12.2025
5	Dibase 25,000IU/2,5ml oral solution	colecalfiferol (vitamin D3)	solution oral	25000IU/2,5ml; glass bottle 2,5ml	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	PoM	22179/1 25.12.2025

6	Dibase 50,000IU/2,5ml oral solution	colecalfiferol (vitamin D3)	solution oral	50000IU/2,5ml; glass bottle 2,5ml	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	PoM	22180/1 25.12.2025
7	Dibase 100,000IU/ml solution for injection	colecalfiferol (vitamin D3)	solution for injection/oral	100000IU/ml; (6) ampoules 1ml	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	PoM	22181/1 25.12.2025
8	Cosopt PF	timolol (timolol maleate), dorzolamide (dorzolamide hydrochloride)	drops eye (solution)	5mg/ml+20mg/ml; plastic vial 10ml	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	19865/4 25.12.2025
9	DEKXETON	dexketoprofen (dexketoprofen trometamol)	tablets film- coated	25mg; (20/2x10) in blister	Mash for Pharmaceutical Industries & Cosmetic (Mash Premiere), Third industrial zone-part No.54/2-Badr city for Mash	Egypt	Pharmaceutical Industries & Cosmetic (Mash Premiere), S6-3 Region 6, Second District, 90 st., Fifth Settlement, New Cairo City	Egypt	PoM	23271/1 25.12.2025
10	Omnipaque	iohexol	solution for injection	350mg iodine/ml; (10) plastic vials 200ml	GE Healthcare Ireland Limited, IDA Business Park, Carrigtohill, Cork, T45 AV60	Ireland	GE Healthcare AS, P.O. Box 4220, Nydalén, 0401 Oslo	Norway	PoM	23204/1 25.12.2025
11	Omnipaque	iohexol	solution for injection	350mg iodine/ml; (10) plastic vials 500ml	GE Healthcare Ireland Limited, IDA Business Park, Carrigtohill, Cork, T45 AV60	Ireland	GE Healthcare AS, P.O. Box 4220, Nydalén, 0401 Oslo	Norway	PoM	23205/1 25.12.2025
12	RIVAROXABAN- ASTERIA	rivaroxaban	tablets film- coated	10mg; (30/3x10) in blister	Yuyu Pharma. Inc., 94 Bio valley 1-ro, Jecheon-si, Chungcheongbuk-do	Republic of Korea	ASTERIA LLC, 72/3 Nairi Zaryan str., 0051 Yerevan	Republic of Armenia	PoM	23268/1 25.12.2025
13	RIVAROXABAN- ASTERIA	rivaroxaban	tablets film- coated	15mg; (30/3x10) in blister	Yuyu Pharma. Inc., 94 Bio valley 1-ro, Jecheon-si, Chungcheongbuk-do	Republic of Korea	ASTERIA LLC, 72/3 Nairi Zaryan str., 0051 Yerevan	Republic of Armenia	PoM	23269/1 25.12.2025
14	RIVAROXABAN- ASTERIA	rivaroxaban	tablets film- coated	20mg; (30/3x10) in blister	Yuyu Pharma. Inc., 94 Bio valley 1-ro, Jecheon-si, Chungcheongbuk-do	Republic of Korea	ASTERIA LLC, 72/3 Nairi Zaryan str., 0051 Yerevan	Republic of Armenia	PoM	23270/1 25.12.2025

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of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 12-2/25 on December 25, 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	Trittico	trazodone (trazodone hydrochloride)	tablets prolonged-release	150mg; (20/2x10/) in blister; (60/6x10/) in blister; (90/6x15/) in blister	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. Via Vecchia Del Pinocchio, 22, 60131 Ancona	Italy	Angelini Pharma Sp.A., Viale, Amelia 70, 00181, Rome	Italy	PoM	JITI-N°001171-ITI-AM 25.12.2025