

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 07-1/25 on July 24, 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	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 24.07.2025
2	Bonexime	cefixime (cefixime trihydrate)	tablets film-coated	400mg; (10/2x5) in blister	ACS DOBFAR S.p.A, Via Laurentina Km 24.730, 00071 Pomezia (Rome)	Italy	Bon Pharm LLC, Artsakh str., bld. 4, apt. 22, 0005, Yerevan	Republic of Armenia	PoM	23203 24.07.2025
3	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, Nydalen, 0401 Oslo	Norway	PoM	23204 24.07.2025
4	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, Nydalen, 0401 Oslo	Norway	PoM	23205 24.07.2025
5	Baneocin	bacitracin zinc, neomycin (neomycine sulfate)	ointment for external use	250IU/g+5000IU/g; aluminum tube 20g	Salutas Pharma GmbH, Lange Goehren 3, 39171 Osterweddingen- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben, Germany- quality control (microbiological)	Germany	Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl	Austria	OTC	23206 24.07.2025

6	Varicella Vaccine, Live	varicella zoster virus (Ok strain)	powder lyophilized for suspension for injection with solvent	10 ⁶ 3,3 PFU/0,5ml; glass vial 2ml and solvent in ampoule 0,5ml	Sinovac (Dalian) Vaccine Technology Co., Ltd., No. 36, 2nd Life Road, DD Port, Economic and Technical Development Zone, Dalian- powder bulk manufacturer, packager, quality control, batch releaser, Sinovac (Dalian) Vaccine Technology Co., Ltd., No. 36, 2nd Life road, DD Port, Economic and Technical Development Zone, Dalian, China- solvent bulk manufacturer, primary packager	China	Sinovac (Dalian) Vaccine Technology Co., Ltd., No. 36, 2nd Life road, DD Port, Economic and Technical Development Zone, Dalian, Liaoning province, 116620	China	PoM	23207 24.07.2025
7	ReciGen 44	interferon beta-1 a 44	solution for injection	44mcg(12 milion IU); (12(4x3/1x3)) glass syringes 0,5 ml in blister	CinnaGen Co., Plot No. 72, 74, 87, 88, 3rd Sq., Simin Dasht Non-Governmental Industrial Area, Fardis Country, Alborz Province	Iran	CinnaGen Co., Plot No. 72, 74, 87, 88, 3rd Sq., Simin Dasht Non-Governmental Industrial Area, Fardis Country, Alborz Province	Iran	PoM	23208 24.07.2025
8	Demicef	ceftriaxone	powder for solution for injection or infusion	1000mg; (10) glass vials	Shin Poong Pharm. Co., Ltd., 41-15, Osongsaengmyeong 5-ro, Osongseup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do	Korea North	DEMI PHARM LLC, Griboyedovi 12, ap. 25, Sevan 1501	Republic of Armenia	PoM	23209 24.07.2025
9	DexketoNor	dexketoprofen (dexketoprofen trometamol)	granules for oral solution	25mg; (20) sachets	Laboratorios Normon S.A., Ronda de Valdecarrizo 6, 28760 Tres Cantos, Madrid	Spain	Laboratorios Normon S.A., Ronda de Valdecarrizo 6, 28760 Tres Cantos, Madrid	Spain	PoM	23210 24.07.2025
10	Levocetirizine Pharmproect	levocetirizine (levocetirizine dihydrochloride)	tablets film-coated	5mg; (10/1x10) in blister	MEDIZANT LIFECARE PRIVATE LIMITED C/o HEALTH CARE FORMULATIONS PVT. LTD., C/8, SARDAR ESTATE, AJWA ROAD, VADODARA -390 019, DIST.- VADODARA	India	Pharmproject LLC, G. Maharu St., 133/5, 0020, Yerevan	Republic of Armenia	OTC	23211 24.07.2025
11	Desloratadine Normon	desloratadine	tablets film-coated	5mg; (20/2x10) in blister	LABORATORIOS NORMON S.A., Ronda de Valdecarrizo 6, 28760 Tres Cantos, Madrid	Spain	LABORATORIOS NORMON S.A., Ronda de Valdecarrizo 6, 28760 Tres Cantos, Madrid	Spain	PoM	23212 24.07.2025
12	Diampa	empagliflozin	tablets film-coated	10mg; (14/2x7) 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	23213 24.07.2025

13	Diampa	empagliflozin	tablets film-coated	25mg; (14/2x7/) 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	23214 24.07.2025
14	Prolutex	progesterone	solution for injection	25mg/1,112ml; (7) glass vials 1,112ml	IBSA Institut Biochimique S.A., Via Pian Scairolo 49, 6912 Pazzallo- quality control, batch releaser, IBSA Institut Biochimique S.A., Via Serta 12, 6814 Lamone, Switzerland- bulk manufacturer, packager	Switzerland	IBSA Institut Biochimique S.A., Via Pian Scairolo 49, 6912 Pazzallo	Switzerland	PoM	23215 24.07.2025
15	Prolutex	progesterone	solution for injection	25mg/1,112ml; (7) glass vials 1,112ml	IBSA Institut Biochimique SA, Via Pian Scairolo 49, 6912 Pazzallo- quality control, batch releaser, Alfisigma S.p.A. Pescara, Via Enrico Fermi, 1, Alanno, 65020, Italy- bulk manufacturer, primary packager, IBSA Institut Biochimique S.A., Via Serta 12, Lamone, 6814, Switzerland- secondary packager	Switzerland	IBSA Institut Biochimique S.A., Via Pian Scairolo 49, 6912 Pazzallo	Switzerland	PoM	23216 24.07.2025
16	Axaban-Denk 2.5mg	apixaban	tablets film-coated	2,5mg; (60/3x20) in blister	COMBINO PHARM MALTA, LTD., HF60, Hal Far Industrial Estate Hal Far BBG3000- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Biodna Laboratory Services Limited, Is2.1.1 and Is2.1.2, Malta Life Sciences Park, San Gwann Industrial Estate, San Gwann SGN3000, Malta- quality control (microbiological)	Malta	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	23217 24.07.2025
17	Axaban-Denk 5mg	apixaban	tablets film-coated	5mg; (60/3x20) in blister	COMBINO PHARM MALTA, LTD., HF60, Hal Far Industrial Estate Hal Far BBG3000- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Biodna Laboratory Services Limited, Is2.1.1 and Is2.1.2, Malta Life Sciences Park, San Gwann Industrial Estate, San Gwann SGN3000, Malta- quality control (microbiological)	Malta	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	23218 24.07.2025
18	Rehydron Optim	sodium chloride, potassium chloride, sodium citrate dihydrate, glucose	powder for oral solution	1,300g+0,750g+1,450g+6,750g; (20) sachets 10,7g	Recipharm Parets S.L.U, C/R Ramon and Cajal 2, 08150 Parets del Valles Barcelona	Spain	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	OTC	23219 24.07.2025

19	Cefyaps	cefuroxime (cefuroxime sodium)	powder for solution for injection/ infusion	750mg; glass vial 10ml	ACS Dobfar S.p.A., Via Alessandro Fleming 2, 37135 Verona	Italy	SPEY MEDICAL LTD, Lynton house 7-12 Tavistock square, London, WC1H9LT	UK	PoM	23220 24.07.2025
20	Verabez	rabeprazole (rabeprazole sodium)	tablets film-coated	10mg; (14/1x14) in blister	Laboratorios Liconsa S.A., Avda. Miralcampo, 7, Pol. Ind. Miralcampo, Azuqueca de Henares, 19200, Guadalajara- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Laboratorio Echevarne, S.A., C/ Provenca, No 312, Bajos, Barcelona, 08037, Spain- quality control (microbiological)	Spain	VEGAPHARM LLP, Unit 18, 53 Norman Road, Greenwich Centre Business Park, SE10 9QF	UK	PoM	23221 24.07.2025
21	Verabez	rabeprazole (rabeprazole sodium)	tablets film-coated	20mg; (14/1x14) in blister	Laboratorios Liconsa S.A., Avda. Miralcampo, 7, Pol. Ind. Miralcampo, Azuqueca de Henares, 19200, Guadalajara- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Laboratorio Echevarne, S.A., C/ Provenca, No 312, Bajos, Barcelona, 08037, Spain- quality control (microbiological)	Spain	VEGAPHARM LLP, Unit 18, 53 Norman Road, Greenwich Centre Business Park, SE10 9QF	UK	PoM	23222 24.07.2025
22	Anastrozole Theo	anastrozole	tablets film-coated	1mg; (28/2x14) in blister	Synthon Hispania, S.L., C/Castello, N1, 08830, Sant Boi de Llobregat, Barcelona	Spain	Theopharma" LLC, David Bek 1 Tim / B / 5, Erebuni, 0008 Yerevan	Republic of Armenia	PoM	23223 24.07.2025
23	Allereyes	olopatadine hydrochloride	drops eye	1mg/ml; plastic vial-dropper 5ml	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	Belinda Laboratories LLP, Unit 18, 53 Norman road, London	UK	PoM	23224 24.07.2025
24	Azithromycin Normon 500mg film-coated tablets	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3) in blister	Laboratorios Normon S.A., Ronda de Valdecarrizo 6, 28760 Tres Cantos, Madrid	Spain	Laboratorios Normon S.A., Ronda de Valdecarrizo 6, 28760 Tres Cantos, Madrid	Spain	OTC	23225 24.07.2025
25	Solidagoren	liquid extract of mixture of goldenrod herb, silverweed herb and horsetail herb	drops oral	0,79ml/ml; 20ml glass bottle, 50ml glass bottle, 100ml glass bottle	Dr. Gustav Klein GmbH & Co. KG, Steinenfeld 3, 77736 Zell am Harmersbach	Germany	Alpen Pharma GmbH, Steinenfeld 3, 77736 Zell am Harmersbach	Germany	PoM	23226 24.07.2025

26	Toras-Denk 10	torasemide	tablets	10mg; (30/3x10') in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning, Bavaria- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4-6, Grossenbrach, Bad Bocklet, Bavaria, 97708, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	23227 24.07.2025
27	Rocuroniumbromid-Hameln	rocuronium bromide	solution for I.V. injection/ infusion	50mg; (5) glass vials	Sunny Pharmaceutical, Parts no. 37, 38 industrial zone, 100 Fadan shark El roubaky, Badr city Cairo	Egypt	Sunny Pharmaceutical, Parts no. 37, 38 industrial zone, 100 Fadan shark El roubaky, Badr city Cairo	Egypt	PoM	23228 24.07.2025
28	Daflozin 10	dapagliflozin	tablets flim-coated	10mg; (28/2x14') in blister	Santa Farma Ilac San. A.S., Kocaeli, Gebze, V (Kimya) Ihtisas OSB Erol Kiresepi Cad. No. 8, Dilovasi, Kocaeli	Turkey	Aversi-Rational Ltd, David Kobakhidze Str. 33, 0198 Tbilisi	Georgia	PoM	23229 24.07.2025
29	ASPIRIN-ASTERIA 100mg tablets	acetylsalicylic acid	tablets	100mg; (60/6x10') in blister	Medinfar Manufacturing S.A, Parque Industrial Armando Martins Tavares, Rua Outeiro Da Armada No 5, Coimbra, Condeixa-A-Nova, 3150-194, Sebal	Portugal	Asteria LLC, 72/3 Nairi Zaryan, 0051 Yerevan	Republic of Armenia	PoM	23230 24.07.2025
30	Dexketoprofen Normon	dexketoprofen (dexketoprofen trometamol)	tablets film-coated	25mg; (20/1x20') in blister	LABORATORIOS NORMON S.A., Ronda de Valdecarrizo 6, 28760 Tres Cantos, Madrid	Spain	LABORATORIOS NORMON S.A., Ronda de Valdecarrizo 6, 28760 Tres Cantos, Madrid	Spain	OTC	23231 24.07.2025
31	NITRONAL	nifuroxazide	capsules	200mg; (20/2x10') in blister	Aversi-Rational Ltd, 33, David Kobakhidze Str., 0198 Tbilisi- secondary packager, quality control, batch releaser, Alkaloid AD Skopje, Aleksandar Makedonski 12, 1000, Skopje, Republic of North Macedonia- bulk manufacturer, primary packager	Georgia	Aversi-Rational Ltd, 33, David Kobakhidze Str., 0198 Tbilisi	Georgia	PoM	23232 24.07.2025
32	NITRONAL	nifuroxazide	suspension oral	200mg/5ml; 90ml glass bottle and measuring cup	Aversi-Rational Ltd, 33, David Kobakhidze Str., 0198 Tbilisi- secondary packager, quality control, batch releaser, Alkaloid AD Skopje, Aleksandar Makedonski 12, 1000, Skopje, Republic of North Macedonia- bulk manufacturer, primary packager	Georgia	Aversi-Rational Ltd, 33, David Kobakhidze Str., 0198 Tbilisi	Georgia	PoM	23233 24.07.2025

33	IbuNor 400 mg film-coated tablets	ibuprofen	tablets film-coated	400mg; (30/3x10') in blister	Laboratorios Normon S.A., Ronda de Valdecarrizo 6, 28760 Tres Cantos, Madrid	Spain	Laboratorios Normon S.A., Ronda de Valdecarrizo 6, 28760 Tres Cantos, Madrid	Spain	PoM	23234 24.07.2025
34	IbuNor 600 mg film-coated tablets	ibuprofen	tablets film-coated	600mg; (40/4x10') in blister	Laboratorios Normon S.A., Ronda de Valdecarrizo 6, 28760 Tres Cantos, Madrid	Spain	Laboratorios Normon S.A., Ronda de Valdecarrizo 6, 28760 Tres Cantos, Madrid	Spain	PoM	23235 24.07.2025
35	Belifrin	phenylephrine (phenylephrine hydrochloride)	drops eye	25mg/ml; plastic vial 5ml	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd., 7200 Razgrad	Bulgaria	BELINDA LABORATORIES LLP, Unit 18, Norman road 53, Greenwich Centre Business park, SE10 9QF, London	UK	PoM	23236 24.07.2025
36	Ibuprofen Denk 600	ibuprofen	tablets film-coated	600mg; (20/2x10') in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning, Bavaria- bulk manufacturer, quality control (physicochemical), batch releaser, Swiss Caps GmbH, Grassinger Str. 9, 83043 Bad Aibling, Bavaria, Germany- packager, Labor LS SE & Co. KG, Mangelsfeld 4-6, Grossenbrach, Bad Bocklet, Bavaria, 97708, Germany- quality control (microbiological)	Germany	DENK PHARMA GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	23237 24.07.2025
37	Sevoflurane-Sunny Pharmaceutical	sevoflurane	liquid for inhalation volatile	100%; 250ml glass bottle	Sunny Pharmaceutical Parts no. 37, 38 Industrial zone (100 Fadan shark el roubaky)- Badr City-Cairo 11829	Egypt	Sunny Pharmaceutical Parts no. 37, 38 Industrial zone (100 Fadan shark el roubaky)- Badr City-Cairo 11829	Egypt	PoM	23238 24.07.2025
38	Amoxi-Denk 500	amoxicillin (amoxicillin trihydrate)	tablets	500mg; (20/2x10') in blister	PenCef Pharma GmbH, Breitenbachstr. 13-14, D-13509 Berlin- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Allphamed PHARBIL Arzneimittel GmbH, Hildebrandstr. 10-12, 37081 Gottingen, Lower Saxony, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen, Bavaria	Germany	PoM	23239 24.07.2025

39	Amoxi-Denk 1000	amoxicillin (amoxicillin trihydrate)	tablets	1000mg; (10/1x10/) in blister	PenCef Pharma GmbH, Breitenbachstr. 13-14, D-13509 Berlin- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Allphamed PHARBIL Arzneimittel GmbH, Hildebrandstr. 10-12, 37081 Göttingen, Lower Saxony, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 München, Bavaria	Germany	PoM	23240 24.07.2025
40	Xymelin Eco	xylometazoline (xylometazoline hydrochloride)	spray nasal	140mcg/dose; 10ml (60 dose) plastic container with pump dispenser	Curida AS, Solbaervegen 5, Elverum, NO-2409	Norway	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	OTC	23241 24.07.2025
41	Xymelin Eco with menthol	xylometazoline (xylometazoline hydrochloride)	spray nasal	140mcg/dose; 10ml (60 dose) plastic container with pump dispenser	Curida AS, Solbaervegen 5, Elverum, NO-2409, Norway	Norway	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	OTC	23242 24.07.2025
42	M-ISOFLU	isoflurane	liquid for inhalation	100%; 250ml glass bottle with cup	PharmaTech CJSC, 111 Raffi str., 0064, Yerevan- batch releaser, Lunan Better Pharmaceutical Co., Ltd. N243, Yinqueshan Road, Linyi City, Shandong, China- bulk manufacturer, packager, quality control	Republic of Armenia	PharmaTech CJSC, 111 Raffi str., 0064, Yerevan	Republic of Armenia	PoM	23243 24.07.2025
43	Pemetrexed EVER Pharma 25mg/ml	pemetrexed (pemetrexed disodium heptahydrate)	concentrate for solution for infusion	25mg/ml; (1) glass vial 4ml, (1) glass vial 20ml, (1) glass vial 40ml	EVER Pharma Jena GmbH, Bruesseler Strasse 18, 07747 Jena	Germany	EVER Valinject GmbH, Oberburgau 3, 4866 Unterach am Attersee	Austria	PoM	23244 24.07.2025
44	MELOXICAM- ASTERIA	meloxicam	tablets	15mg; (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	Asteria LLC, 72/3 Nairi Zaryan, 0051 Yerevan	Republic of Armenia	PoM	23245 24.07.2025
45	AqVitecan	irinotecan	concentrate for solution for infusion	300mg/15ml; (1) glass vial 15ml	AqVida GmbH, Kaiser- Wilhelm-Str. 89, Neustadt, Hamburg, 20355- batch releaser, AqVida GmbH, Werkstrasse 21, Dassow, 23942, Germany- bulk manufacturer, packager, quality control	Germany	Aversi-Rational Ltd, David Kobakhidze Str. 33, 0198, Tbilisi	Georgia	PoM	23246 24.07.2025
46	Omeprazole Gobens 20mg hard gastro-resistant capsules	omeprazole	capsules gastro-resistant hard	20mg; (14/1x14) in blister	LABORATORIOS NORMON S.A., Ronda de Valdecarrizo 6, 28760 Tres Cantos, Madrid	Spain	LABORATORIOS NORMON S.A., Ronda de Valdecarrizo 6, 28760 Tres Cantos, Madrid	Spain	PoM	23247 24.07.2025

47	SURRICOX 400mg/ ml	amprolium (amprolium hydrochloride)	solution oral	400mg/ml; 1l plastic bottle, 5l plastic container	V.M.D. NV, Hoge Mauw 900, 2370 Arendonk- secondary packager, batch releaser, Laboratories Biove, Rue de Lorraine, 62510 Arques, France- bulk manufacturer, primary packager, quality control	Belgium	V.M.D. NV, Hoge Mauw 900, 2370 Arendonk	Belgium	OTC	23248 24.07.2025
48	Nizoral	ketoconazole	shampoo medicinal	20mg/g; plastic bottle 60ml, plastic bottle 120ml	Hemofarm A.D., 26300, Vrsac, Beogradski put b.b.- batch releaser, Hemofarm A.D., 15000, Vrsac, Hajduk (plant Sabac), Veljkova b.b., Sabac, Serbia- bulk manufacturer, packager, quality control	Serbia	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	OTC	23249 24.07.2025
49	Tonoxib	etoricoxib	tablets film- coated	90mg; (30/3x10') in blister	Mash for Pharmaceutical Industries & Cosmetic (Mash Premiere)- pharmaceuticals, Third industrial zone- part No.54/2-Badr city	Egypt	Mash for Pharmaceutical Industries & Cosmetic (Mash Premiere), S6-3 Region 6, Second District 90 st., Fifth Settlement, New Cairo City	Egypt	PoM	23250 24.07.2025
50	Rivaroxaban STADA	rivaroxaban	tablets film- coated	10mg; (30/2x15') in blister	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel- batch releaser, Hemofarm A.D., 26300 Vrsac, Beogradskii put bb, Serbia- bulk manufacturer, packager, STADA Hemofarm S.R.L., Calea Torontalului Km 6, Timisoara, 300633, Romania- quality control (physicochemical), Allphamed Pharbil Arzneimittel GmbH, Hildebrandstrasse 12, Goettingen, Lower Saxony, 37081, Germany- quality control (microbiological)	Germany	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	PoM	23251 24.07.2025

51	Rivaroxaban STADA	rivaroxaban	tablets film-coated	15mg; (28/2x14) in blister	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel- batch releaser, Hemofarm A.D., 26300 Vrsac, Beogradskii put bb, Serbia- bulk manufacturer, packager, STADA Hemofarm S.R.L., Calea Torontalului Km 6, Timisoara, 300633, Romania- quality control (physicochemical), Allphamed Pharbil Arzneimittel GmbH, Hildebrandstrasse 12, Goettingen, Lower Saxony, 37081, Germany- quality control (microbiological)	Germany	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	PoM	23252 24.07.2025
52	Rivaroxaban STADA	rivaroxaban	tablets film-coated	20mg; (28/2x14) in blister	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel- batch releaser, Hemofarm A.D., 26300 Vrsac, Beogradskii put bb, Serbia- bulk manufacturer, packager, STADA Hemofarm S.R.L., Calea Torontalului Km 6, Timisoara, 300633, Romania- quality control (physicochemical), Allphamed Pharbil Arzneimittel GmbH, Hildebrandstrasse 12, Goettingen, Lower Saxony, 37081, Germany- quality control (microbiological)	Germany	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	PoM	23253 24.07.2025
53	Dutams	dutasteride, tamsulosin	capsules hard	0,5mg+0,4mg; (30) in plastic bottle	Laboratorios Leon Farma S.A., Poligono Industrial Navatejera, C/ La Vallina s/n, Villaquilambre, 24008, Leon- bulk manufacturer, packager, quality control (physicochemical), batch releaser, LABORATORIO ECHEVARNE, S.A., Avenida Can Bellet 61-65, Sant Cugat Del Valles, 08174, Barcelona, Spain- quality control (microbiological)	Spain	Spey Medical Ltd, Lynton House 7-12 Tavistock square, WC1H 9LT, London	UK	PoM	23254 24.07.2025
54	ESAFOSFINA	D-fructose-1,6-diphosphate	powder and solvent for solution for infusion	0,5g/10ml; (4) glass vials and (4) ampoules 10ml with solvent	Biomedica Foscama Industria Chimico-Farmaceutica S.p.A., Via Morolense 87, Ferentino, 03013	Italy	Biomedica Foscama Industria Chimico-Farmaceutica S.p.A., Via Morolense 87, Ferentino, 03013	Italy	PoM	23255 24.07.2025

55	ESAFOSFINA	D-fructose-1,6-diphosphate	powder and solvent for solution for infusion	5g/50ml; (1) glass vial and (1) glass vial 50ml with solvent	Biomedica Foscama Industria Chimico-Farmaceutica S.p.A., Via Morolense 87, Ferentino, 03013	Italy	Biomedica Foscama Industria Chimico-Farmaceutica S.p.A., Via Morolense 87, Ferentino, 03013	Italy	PoM	23256 24.07.2025
56	Diocor CH	sacubitril, valsartan (valsartan sodium)	tablets film-coated	24,3mg+25,7mg; (28/4x7/) in blister	ELPEN Pharmaceutical Co. Inc. Marathonos Avenue 95, Pikermi, 19009	Greece	Acino AG, Leopoldstrasse 115, 80804 Munich	Germany	PoM	23257 24.07.2025
57	Diocor CH	sacubitril, valsartan (valsartan sodium)	tablets film-coated	48,6mg+51,4mg; (28/4x7/) in blister	ELPEN Pharmaceutical Co. Inc. Marathonos Avenue 95, Pikermi, 19009	Greece	Acino AG, Leopoldstrasse 115, 80804 Munich	Germany	PoM	23258 24.07.2025
58	Diocor CH	sacubitril, valsartan (valsartan sodium)	tablets film-coated	97,2mg+102,8mg; (28/4x7/) in blister, 56(8x7) in blister	ELPEN Pharmaceutical Co. Inc. Marathonos Avenue 95, Pikermi, 19009	Greece	Acino AG, Leopoldstrasse 115, 80804 Munich	Germany	PoM	23259 24.07.2025
59	Propofol-Sunny Pharmaceutical 1%	Propofol	emulsion for i/v injection/infusion	200mg/20ml; (10) glass vials 50ml, (20) glass vials 20ml, (50) glass vials 20ml	Sunny Pharmaceutical Parts no. 37,38 Industrial zone 100 Fadan shark el roubaky Badr City	Egypt	Sunny Pharmaceutical Parts no. 37,38 Industrial zone 100 Fadan shark el roubaky Badr City	Egypt	PoM	23260 24.07.2025
60	Rovalang	citicoline (citicoline sodium)	solution for injection	500mg/3ml; (5) ampoules 3ml	LABORATORIO FARMACEUTICO C.T. S.R.L., VIA DANTE ALIGHIERI, 71, 18038 SANREMO (IM)- bulk manufacturer, packager, batch releaser, LABORATORIO FARMACEUTICO C.T. S.R.L., VIA DANTE ALIGHIERI, 71, SANREMO, 18038, Italy- quality control	UK	Spey Medical Ltd, Lynton House 7-12 Tavistock square, WC1H 9LT, London	UK	PoM	23261 24.07.2025
61	Rovalang	citicoline (citicoline sodium)	solution for injection	1000mg/4ml; (5) ampoules 4ml	LABORATORIO FARMACEUTICO C.T. S.R.L., VIA DANTE ALIGHIERI, 71, 18038 SANREMO (IM)- bulk manufacturer, packager, batch releaser, LABORATORIO FARMACEUTICO C.T. S.R.L., VIA DANTE ALIGHIERI, 71, SANREMO, 18038, Italy- quality control	UK	Spey Medical Ltd, Lynton House 7-12 Tavistock square, WC1H 9LT, London	UK	PoM	23262 24.07.2025
62	Sugammadex	rocuronium bromide	solution for i/v injection	100mg/ml; (1) glass vial 2ml, (5) glass vials 2ml	Sunny Pharmaceutical, Parts no. 37, 38 industrial zone, 100 Fadan shark El roubaky, Badr city Cairo	Egypt	Sunny Pharmaceutical, Parts no. 37, 38 industrial zone, 100 Fadan shark El roubaky, Badr city Cairo	Egypt	PoM	23263 24.07.2025

63	ZETOR PLUS	rosuvastatin (rosuvastatin calcium), Ezetimibe	tablets film-coated	5mg/10mg; (30/3x10) in blister	ELPEN Pharmaceutical CO., INC, Marathonos Avenue 95, Pikermi, 19009-bulk manufacturer, packager, quality control (microbiological), batch releaser, Qualimetrix S.A., 579, Mesogeion Ave., Agia Paraskevi 15343 Athens, Greece-quality control (physicochemical)	Greece	GM Pharmaceuticals Ltd, Rustavi Highway 52,Tbilisi	Georgia	PoM	23264 24.07.2025
64	ZETOR PLUS	rosuvastatin (rosuvastatin calcium), ezetimib	tablets film-coated	10mg/10mg; (30/3x10) in blister	ELPEN Pharmaceutical CO., INC, Marathonos Avenue 95, Pikermi, 19009-bulk manufacturer, packager, quality control (microbiological), batch releaser, Qualimetrix S.A., 579, Mesogeion Ave., Agia Paraskevi 15343 Athens, Greece-quality control (physicochemical)	Greece	GM Pharmaceuticals Ltd, Rustavi Highway 52,Tbilisi	Georgia	PoM	23265 24.07.2025
65	ZETOR PLUS	rosuvastatin (rosuvastatin calcium), ezetimib	tablets film-coated	20mg/10mg; (30/3x10) in blister	ELPEN Pharmaceutical CO., INC, Marathonos Avenue 95, Pikermi, 19009-bulk manufacturer, packager, quality control (microbiological), batch releaser, Qualimetrix S.A., 579, Mesogeion Ave., Agia Paraskevi 15343 Athens, Greece-quality control (physicochemical)	Greece	GM Pharmaceuticals Ltd, Rustavi Highway 52,Tbilisi	Georgia	PoM	23266 24.07.2025
66	Bortezomib	bortezomib	powder lyophilized for solution for injection	3,5mg; (1) glass vial 10ml	Dr.Reddy's Laboratories Limited Formulation Unit-VII, Plot Nos. P1 to P9, Phase III, VSEZ, Duvvada, Visakhapatnam District 530046, Andhra Pradesh	India	Dr.Reddy's Laboratories Limited Formulation Unit-VII, Plot Nos. P1 to P9, Phase III, VSEZ, Duvvada, Visakhapatnam District 530046, Andhra Pradesh	India	PoM	23267 24.07.2025
67	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 24.07.2025
68	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 24.07.2025
69	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 24.07.2025

70	DEXKETON	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	Egypt	Mash for Pharmaceutical Industries & Cosmetic (Mash Premiere), S6-3 Region 6, Second District, 90 st., Fifth Settlement, New Cairo City	Egypt	PoM	23271 24.07.2025
71	TAD 600mg/4ml	glutathione (glutathione sodium)	powder and solvent for injection	150mg/ml; (10) glass vials and (10) ampoules 4ml with solvent	BIOMEDICA FOSCAMA INDUSTRIA CHIMICO-FARMACEUTICA S.p.A., Via Morolense 87, Ferentino 03013	Italy	BIOMEDICA FOSCAMA INDUSTRIA CHIMICO- FARMACEUTICA S.p.A., Via Morolense 87, Ferentino 03013	Italy	PoM	23272 24.07.2025
72	Mildronat	meldonium	solution for injection	100mg/ml; (10/2x5) ampoules 10ml in blister	Grindeks JSC, Krustpils street 53, LV- 1057, Riga- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680, Martin, Slovak Republic- bulk manufacturer, packager, quality control	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	23273 24.07.2025

LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 07-1/25 on July 24, 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	Rissar	risperidone	tablets film-coated	1mg; (20/2x10) 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	23275 (008286) 24.07.2025
2	Rissar	risperidone	tablets film-coated	2mg; (20/2x10) 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	23276 (008286) 24.07.2025
3	Rissar	risperidone	tablets film-coated	3mg; (20/2x10) 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	23277 (008286) 24.07.2025
4	Nevanac	nepafenac	drops eye	1mg/ml; plastic vial-dropper 5ml	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	23278 (009615) 24.07.2025
5	Hydrocortison-Richter	hydrocortisone (hydrocortisone acetate), lidocaine (lidocaine hydrochloride)	suspension for injection	25mg/ml+5mg/ml; (1) glass vial 5ml	Gedeon Richter PLC, Gyomroi st. 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi st. 19-21, 1103 Budapest	Hungary	PoM	23279 (005500) 24.07.2025
6	Vancoter	vancomycin	powder for concentrate for solution for infusion or oral solution	500mg; (1) glass vial, (5) glass vials	TriplePharm JLLC, house 2B, st. Minskaya, Logoisk, Minsk region, 223141	Republic of Belarus	Alpharma LLC, office 4541R4, bld.100-2, Dmitrovskoe Ave., ext. ter.city municipal district Vostochnoe Degunino, Moscow, 127247	Russia	PoM	23280 (003683) 24.07.2025

7	Vancoter	vancomycin	powder for concentrate for solution for infusion or solution oral	750mg; (1) glass vial, (5) glass vials	TriplePharm JLLC, house 2B, st. Minskaya, Logoisk, Minsk region, 223141	Republic of Belarus	Alpharma LLC, office 4541R4, bld.100-2, Dmitrovskoe Ave., ext. ter.city municipal district Vostochnoe Degunino, Moscow, 127247	Russia	PoM	23281 (003683) 24.07.2025
8	Vancoter	vancomycin	powder for concentrate for solution for infusion or solution oral	1000mg; (1) glass vial, (5) glass vials	TriplePharm JLLC, house 2B, st. Minskaya, Logoisk, Minsk region, 223141	Republic of Belarus	Alpharma LLC, office 4541R4, bld.100-2, Dmitrovskoe Ave., ext. ter.city municipal district Vostochnoe Degunino, Moscow, 127247	Russia	PoM	23282 (003683) 24.07.2025
9	Vancoter	Vancomycin	powder for concentrate for solution for infusion or solution oral	500mg; (1) glass vial, (5) glass vials	ALTEGRA JSC, building 33, Science Avenue, Dubna, Dubna district, Moscow region, 141983- secondary packager, quality control, batch releaser, TriplePharm JLLC, house 2B, st. Minskaya, Logoisk, Minsk region, 223141, Republic of Belarus- bulk manufacturer, primary packager	Russia	Alpharma LLC, office 4541R4, bld.100-2, Dmitrovskoe Ave., ext. ter.city municipal district Vostochnoe Degunino, Moscow, 127247	Russia	PoM	23283 (003683) 24.07.2025
10	Vancoter	Vancomycin	powder for concentrate for solution for infusion or solution oral	750mg; (1) glass vial, (5) glass vials	ALTEGRA JSC, building 33, Science Avenue, Dubna, Dubna district, Moscow region, 141983- secondary packager, quality control, batch releaser, TriplePharm JLLC, house 2B, st. Minskaya, Logoisk, Minsk region, 223141, Republic of Belarus- bulk manufacturer, primary packager	Russia	Alpharma LLC, office 4541R4, bld.100-2, Dmitrovskoe Ave., ext. ter.city municipal district Vostochnoe Degunino, Moscow, 127247	Russia	PoM	23284 (003683) 24.07.2025
11	Vancoter	Vancomycin	powder for concentrate for solution for infusion or solution oral	1000mg; (1) glass vial, (5) glass vials	ALTEGRA JSC, building 33, Science Avenue, Dubna, Dubna district, Moscow region, 141983- secondary packager, quality control, batch releaser, TriplePharm JLLC, house 2B, st. Minskaya, Logoisk, Minsk region, 223141, Republic of Belarus- bulk manufacturer, primary packager	Russia	Alpharma LLC, office 4541R4, bld.100-2, Dmitrovskoe Ave., ext. ter.city municipal district Vostochnoe Degunino, Moscow, 127247	Russia	PoM	23285 (003683) 24.07.2025

12	Solpadeine Active	paracetamol, caffeine	tablets soluble	500mg+65mg; (12/3x4) in strip, (24/6x4) in strip	GlaxoSmithKline Dungarvan Limited, Knockbrack, Dungarvan X35 RY76	Ireland	JSC "Haleon Rus", Presnenskaya Naberezhnaya, 10, unit III, room 9, 6 floor, Moscow, 123112	Russia	OTC	23286 (017112) 24.07.2025
13	Bonspri	ofatumumab	solution for subcutaneous injection	20mg/0,4ml; glass pre-filled syringe 0,4ml in blister	Novartis Pharma Stein, Schaffhauserstrasse, Stein AG, 4332	Switzerland	Novartis Overseas Investments AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	23287 (000474) 24.07.2025
14	Macmiror Complex	nifuratel, nystatin	capsules vaginal	500mg+200 000IU; (8/1x8) in blister	Doppel Farmaceutici S.r.l., Via Martiri delle Foibe, 1 - 29016 Cortemaggiore (PC)	Italy	Polichem S.r.l., Via Giuseppe Marcora, 11 - 20121 Milan	Italy	PoM	23288 (006543) 24.07.2025
15	Macmiror Complex	nifuratel, nystatin	capsules vaginal	500mg+200 000IU; (8/1x8) in blister	Doppel Farmaceutici S.r.l., Via Martiri delle Foibe, 1 - 29016 Cortemaggiore (PC)- bulk manufacturer, quality control, batch releaser, Doppel Farmaceutici S.r.l., Via Volturmo, 48 - Quinto De` Stampi - 20089 Rozzano (MI), Italy- packager	Italy	Polichem S.r.l., Via Giuseppe Marcora, 11 - 20121 Milan	Italy	PoM	23289 (006543) 24.07.2025
16	Galazolin Polpharma 0,1%	xylometazoline (xylometazoline hydrochloride)	drops nasal	1mg/ml; 10ml plastic vial-dropper, 15ml plastic vial-dropper	Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 10 Wladyslawa Lokietka St. 98-200 Sieradz- batch releaser, Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 57 Polskiej Organizacji Wojskowej st. 98-200 Sieradz, Poland- bulk manufacturer, packager, quality control	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	OTC	23290 (000523) 24.07.2025
17	Analgin	metamizole (metamizole sodium)	solution for i/v and i/m injection	500mg/ml; (10) ampules 2ml CAMA, (10) ampules 2ml label banderol, (10) ampules 2ml dividella	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	PoM	23291 (001537) 24.07.2025
18	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	23292 (000750) 24.07.2025

19	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	23293 (000750) 24.07.2025
20	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	23294 (000750) 24.07.2025
21	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 Wuerttemberg	Germany	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	23295 (000750) 24.07.2025
22	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	23296 (000750) 24.07.2025
23	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	23297 (000750) 24.07.2025
24	Duotam	dutasteride, tamsulosin (tamsulosin hydrochloride)	capsules hard	0,5mg+0,4mg; (30) in plastic container	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- batch releaser, Laboratorios Leon Farma S.A., Poligono Industrial Navatejera, C/ La Vallina s/n, Villaquilambre, 24008, Leon, Spain- bulk manufacturer, packager, Netpharmalab Consulting Services S.L., Carretera De Fuencarral 22, Poligono Vereda De Los Pobres, Alcobendas, 28108, Spain- quality control (physicochemical), LABORATORIO ECHEVARNE, S.A., Avinguda De Can Bellet 61-65, Sant Cugat Del Valles, 08174, Spain- quality control (microbiological)	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	23274 (010993) 24.07.2025

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of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 07-1/25 on July 24, 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	TURBOCAINA	articaine (articaine hydrochloride), epinephrine	solution for injection	40mg/ml+10mcg/ml; (50/5x10) glass or plastic cartridges 1,8ml in blister	LABORATORIOS ZEYCO, S.A. DE C.V., Camino a Santa Ana Tepetitlan No. 2230-C Col. Santa Ana Tepetitlan C.P. 45230, Zapopan, Jalisco	Mexico	LABORATORIOS ZEYCO, S.A. DE C.V., Camino a Santa Ana Tepetitlan No. 2230-C Col. Santa Ana Tepetitlan C.P. 45230, Zapopan, Jalisco	Mexico	PoM	23176 24.07.2025

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 07-1/25 on July 24, 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	Valcivir	valaciclovir (valaciclovir hydrochloride)	tablets film-coated	500mg; (20/2x10/) in blister	Eva pharma for pharmaceuticals and medical appliances, Kafr El-Gabal, 176 El Sadat str., El-Haram, 12561	Egypt	Eva pharma for pharmaceuticals and medical appliances, Kafr El-Gabal, 176 El Sadat str., El-Haram, 12561	Egypt	PoM	23177 24.07.2025
2	KHONDRA-JECT	chondroitin sulfate (chondroitin sulfate sodium)	solution for injection	100mg/ml; (10/2x5/) ampoules 1ml in blister	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region- quality control, batch releaser, "Sotex"PharmFirm" CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, Russia- bulk manufacturer, packager	Russia	"Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	PoM	23178 24.07.2025
3	KHONDRA-JECT	chondroitin sulfate (chondroitin sulfate sodium)	solution for injection	100mg/ml; (10/2x5/) ampoules 2ml in blister	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, rural settlement Bereznjakovskoe, Sergiev-Posad municipal district, Moscow Region, 141345- quality control, batch releaser, "Sotex"PharmFirm" CJSC, Bld. 10, village Belikovo, rural settlement Bereznjakovskoe, Sergiev-Posad municipal district, Moscow Region, 141345, Russia- bulk manufacturer, packager f	Russia	"Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, rural settlement Bereznjakovskoe, Sergiev-Posad municipal district, Moscow Region, 141345	Russia	PoM	23179 24.07.2025
4	Tro-xime 750mg powder for solution for injection/infusion	cefuroxime (cefuroxime sodium)	powder for solution for injection/infusion	750mg; (1) glass vial 10ml, (50) glass vials 10ml	Reyoung Pharmaceutical Co. Ltd., No1 Ruiyang Road, Yiyuan County, Shandong Province- packager, quality control, batch releaser, Titan Pharmaceutical Co., Ltd (Guangdong), Lantang Town, Zijin County, Heyuan City, China- bulk manufacturer	China	Troge Medical GmbH, Milchstrasse 19, 20148 Hamburg	Germany	PoM	23180 24.07.2025

5	Roxera Plus	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets film-coated	10mg+10mg; (30/3x10/) in blister; (60/6x10/) in blister; (90/9x10/) 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	23181 24.07.2025
6	Roxera Plus	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets film-coated	20mg+10mg; (30/3x10/) in blister; (60/6x10/) in blister; (90/9x10/) 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	23182 24.07.2025
7	Loranex	desloratadine	tablets film-coated	5mg; (10/1x10/) in blister	GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi	Georgia	PoM	23183 24.07.2025
8	CETAMOL	paracetamol	syrup with cherry flavour	24mg/ml; glass bottle 100ml	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	OTC	23184 24.07.2025
9	Aerius	desloratadine	syrup	0,5mg/ml; glass bottle 60ml and measuring spoon	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	PoM	23185 24.07.2025
10	Herbion Iceland moss syrup	iceland moss soft extract	syrup	6mg/ml; 150ml glass bottle and measuring spoon	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- quality control (microbiological), batch releaser, KRKA d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia- bulk manufacturer, packager, 1. KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto, Slovenia, 2. Nacionalni laboratorij za zdravje, okolje in hrano (NLZOH), Dalmatinova ulica 3, Novo mesto, 8000, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	23186 24.07.2025
11	Avamys	fluticasone (fluticasone furoate)	spray nasal (suspension)	27,5mcg/dose; (1) glass bottle with metering pump (120 dose)	Glaxo Operations UK Ltd., Harmire Road Barnard Castle Co Durham, DL12 8DT	UK	GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24	Ireland	PoM	23187 24.07.2025
12	Tonofungyn	fluconazole	capsules hard	150mg; (2/2x1/) in strip	Egyptian International Pharmaceutical Industries Company (EIPICO), 10th of Ramadan City, Industrial Area B1, P.O. box 149, Tenth	Egypt	Egyptian International Pharmaceutical Industries Company (EIPICO), 10th of Ramadan City, Industrial Area B1, P.O. box 149, Tenth	Egypt	PoM	23188 24.07.2025

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 07-12/25 on July 24, 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	SOLUFERR	iron (III)-hydroxide sucrose complex	solution for i/v injection or concentrate for solution for infusion	20mg/ml; (5) ampoules 5ml	Help S.A. Pedini, Ioanninon, Ioannina, 45500	Greece	Moosmann Pharmaceuticals LLC, Vanahovit 8, Proshyan v., Ashtarak Ave., Kotayk Marz 2413	Republic of Armenia	PoM	23189 24.07.2025
2	Vametal	ondansetron (ondansetron hydrochloride dihydrate)	solution for i/v and i/m injection	2mg/ml; glass vial 2ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Medicus S.A., 10 Valaoritou str., GR 144 52, Metamorphosis, Attica	Greece	PoM	23190 24.07.2025
3	Vametal	ondansetron (ondansetron hydrochloride dihydrate)	solution for i/v and i/m injection	2mg/ml; glass vial 4ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Medicus S.A., 10 Valaoritou str., GR 144 52, Metamorphosis, Attica	Greece	PoM	23191 24.07.2025
4	Aremed	anastrozole	tablets film-coated	1mg; (28/2x14) in blister	Remedica Ltd, Aharnon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	Remedica Ltd, Aharnon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	PoM	23192 24.07.2025
5	CLAVOTON 1g	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	875mg+125mg (14/2x7) in blister	Medochemie Ltd- Factory B, 48 Iapetou street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupolis street, 3011 Limassol	Cyprus	PoM	23193 24.07.2025

6	DICLTON 75mg/3ml	diclofenac (diclofenac sodium)	solution for injection/infusion	25mg/ml; (5) ampoules 3ml	Medochemie Ltd. (Ampoule Injectable Facility) 48 Iapetou street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd.,1-10 Constantinoupoleos street, 3011 Limassol,	Cyprus	PoM	23194 24.07.2025
7	LEVOFLOXACIN 0.5%	levofloxacin (levofloxacin hemihydrate)	solution for infusion	5mg/ml; 50ml plastic pack, 100ml plastic pack	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	23195 24.07.2025
8	Folic Acid	folic acid	tablets	5mg; (48/2x24) in blister; (50/5x10) in blister	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	23196 24.07.2025
9	Ketonal DUO	ketoprofen	capsules modified-release	150mg; (20/2x10) in blister, (30/3x10) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- quality control (microbiological), batch releaser, Novartis Pharmaceuticals Manufacturing LLC, Verovskova Ulica 57, 1000, Ljubljana, Slovenia- bulk manufacturer, packager, quality control (physicochemical)	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	23197 24.07.2025
10	Upsarin Upsa with vitamin C	acetylsalicylic acid, ascorbic acid	tablets effervescent	330mg+200mg; (20/2x10) in plastic container	UPSA SAS, 979, avenue des Pyrenees, 47520 Le Passage	France	UPSA SAS, 3, rue Joseph Monier- 92500 Rueil-Malmaison	France	OTC	23198 24.07.2025
11	Artrum	ketoprofen	solution for i/v and i/m injection	50mg/ml; (10/2x5) ampoules 2ml in blister	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	PoM	23199 24.07.2025
12	Gonadotropin chorionic	gonadotrophin chorionic	powder lyophilized for solution for i/m injection	500IU; (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	23200 24.07.2025

13	Gonadotropin chorionic	gonadotrophin chorionic	powder lyophilized for solution for i/m injection	1000IU; (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	23201 24.07.2025
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of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 07-1/25 on July 24, 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	Amoksiklav powder for solution for injection 500mg/100mg	amoxicillin (amoxicillin sodium), clavulanic acid (potassium clavulanate)	powder for solution for injection	500mg+100mg; (5) glass vials, (10) glass vials	Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl	Austria	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19966/3/1 24.07.2025
2	Amoksiklav powder for solution for injection 1000mg /200mg	amoxicillin (amoxicillin sodium), clavulanic acid (potassium clavulanate)	powder for solution for injection	1000mg+200mg; (5) glass vials, (10) glass vials	Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl	Austria	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19967/3/1 24.07.2025
3	Essliver Forte	essential phospholipids, thiamine (thiamine mononitrate), riboflavin, pyridoxine (pyridoxine hydrochloride), alpha-tocopherol acetate, nicotinamide, cyanocobalamin	capsules	300mg+6mg+6mg+6mg+6mg+30mg+6mcg; (30/3x10) in blister, (50/5x10) in blister	Nabros Pharma Pvt. Ltd., Survey No110/A/2 Amit Farm, Jain Upasrya, N.H. No. 8 Kajipura, Kheda, 387411, Gujarat	India	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	20047/1/1 24.07.2025
4	Essliver Forte	essential phospholipids, thiamine (thiamine mononitrate), riboflavin, pyridoxine (pyridoxine hydrochloride), alpha-tocopherol acetate, nicotinamide, cyanocobalamin	capsules	300mg+6mg+6mg+6mg+6mg+30mg+6mcg; (30/3x10) in blister, (50/5x10) in blister	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7- secondary packager, quality control, batch releaser, Nabros Pharma Pvt. Ltd., Survey No110/A/2 Amit Farm, Jain Upasrya, N.H. No. 8 Kajipura, Kheda, 387411, Gujarat, India- bulk manufacturer, primary packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	20632/1/1 24.07.2025

5	Codelac Neo-Otcpharm	butamirate (butamirate citrate)	solution oral	1,5mg/ml; 100ml glass bottle and measuring spoon, 200ml glass bottle and measuring spoon	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	20799/2/2 24.07.2025
6	Ceftriaxone-Primus	ceftriaxone (ceftriaxone sodium)	powder for solution for and injection/infusion	1000mg; (1) vial 10ml, (50) vials 10ml	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111 - batch releaser, Reyoung Pharmaceutical Co. Ltd., No1 Ruiyang Road, Yiyuan County, Shandong Province, China- bulk manufacturer, packager, quality control	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	20711/1/1 24.07.2025
7	Otrivin	xylometazoline (xylometazoline hydrochloride)	drops nasal	0,5mg/ml; plastic bottle-dropper 10ml	Haleon CH SARL, Route de l' Etraz, Nyon, 1260	Switzerland	JSC "Haleon Rus", Presnenskaya Naberezhnaya, 10, unit III, room 9, 6 floor, Moscow, 123112	Russia	OTC	21756/1/1 24.07.2025
8	Enerzair Breezhaler	indacaterol (indacaterol acetate), glycopyrronium bromide, mometasone fuora	powder for inhalation, capsules hard	150mcg+50mcg+160mcg; (30/3x10/) in blister and inhaler	Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona- packager, batch releaser, Novartis Pharma Stein AG Novartis Technical Operations Schweiz, Stein Solids, Schaffhauserstrasse, 4332 Stein AG, Switzerland- bulk manufacturer, quality control (microbial/ biological), 1.Novartis Pharma Stein AG Novartis Technical Operations Schweiz, Stein Solids, Schaffhauserstrasse, 4332 Stein AG, Switzerland; 2.Solvias AG, Romerpark 2, 4303 Kaiseraugst 4303, Switzerland; 3.Pharmanalytica SA., Via Balestra, Locarno, 6600, Switzerland- quality control (physicochemical)	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20652/1/1 24.07.2025
9	Enerzair Breezhaler	indacaterol (indacaterol acetate), glycopyrronium bromide, mometasone fuora	powder for inhalation, capsules hard	150mcg+50mcg+160mcg; (30/3x10/) in blister and inhaler	Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	21683/1/1 24.07.2025
10	Codelac Neo-Otcpharm	butamirate (butamirate citrate)	solution oral	1,5mg/ml; 100ml glass bottle and measuring spoon, 200ml glass bottle and measuring spoon	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	20806/1/1 24.07.2025

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of the variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 07-1/25 on July 24, 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	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	50mg; (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	ЛПТ-№002602-ІТІ-АМ 24.07.2025
2	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	50mg; (30/3x10) 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	ЛПТ-№002602-ІТІ-АМ 24.07.2025

3	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	50mg; (30/3x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest, Hungary- bulk manufacturer, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛПТ-№002602-ИТИ-AM 24.07.2025
4	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	50mg; (30/3x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, packager, batch releaser, 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	ЛПТ-№002602-ИТИ-AM 24.07.2025
5	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	150mg; (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	ЛПТ-№002602-ИТИ-AM 24.07.2025

6	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	150mg; (30/3x10') 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	ЛПТ-№002602-ІТІ- AM 24.07.2025
7	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	150mg; (30/3x10') in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest, Hungary- bulk manufacturer, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛПТ-№002602-ІТІ- AM 24.07.2025

8	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	150mg; (30/3x10') in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, packager, batch releaser, 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	ЛПТ-№002602-ЛПТ- AM 24.07.2025
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of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 07-1/25 on July 24, 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	Valcivir	valaciclovir (valaciclovir hydrochloride)	tablets film-coated	500mg; (20/2x10/) in blister	Eva pharma for pharmaceuticals and medical appliances, Kafr El-Gabal, 176 El Sadat str., El-Haram, 12561	Egypt	Eva pharma for pharmaceuticals and medical appliances, Kafr El-Gabal, 176 El Sadat str., El-Haram, 12561	Egypt	PoM	18217/1 24.07.2025
2	KHONDRA-JECT	chondroitin sulfate (chondroitin sulfate sodium)	solution for injection	100mg/ml; (10/2x5) ampoules 1ml in blister	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, rural settlement Bereznjakovskoe, Sergiev-Posad municipal district, Moscow Region, 141345- quality control, batch releaser, "Sotex"PharmFirm" CJSC, Bld. 10, village Belikovo, rural settlement Bereznjakovskoe, Sergiev-Posad municipal district, Moscow Region, 141345, Russia- bulk manufacturer, packager	Russia	"Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, rural settlement Bereznjakovskoe, Sergiev-Posad municipal district, Moscow Region, 141345	Russia	PoM	19244/1 24.07.2025
3	KHONDRA-JECT	chondroitin sulfate (chondroitin sulfate sodium)	solution for injection	100mg/ml; (10/2x5) ampoules 2ml in blister	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, rural settlement Bereznjakovskoe, Sergiev-Posad municipal district, Moscow Region, 141345- quality control, batch releaser, "Sotex"PharmFirm" CJSC, Bld. 10, village Belikovo, rural settlement Bereznjakovskoe, Sergiev-Posad municipal district, Moscow Region, 141345, Russia- bulk manufacturer, packager	Russia	"Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, rural settlement Bereznjakovskoe, Sergiev-Posad municipal district, Moscow Region, 141345	Russia	PoM	19245/1 24.07.2025

4	Hexalyse	biclotymol, lysozyme (lysozyme hydrochloride), enoxolone	tablets orodispersible	5mg+5mg+5mg (30/3x10) in blister	Laboratoires Bouchara-Recordati, Parc Mecatronic 03410 Saint Victor	France	Laboratoires Bouchara- Recordati, Immeuble le Wilson, 70 avenue du General de Gaulle, 92800 Puteaux	France	OTC	19457/5 24.07.2025
5	Tro-xime 750mg powder for solution for injection/infusion	cefuroxime (cefuroxime sodium)	powder for solution for injection/infusion	750mg; (1) glass vial 10ml, (50) glass vials 10ml	Reyoung Pharmaceutical Co. Ltd., No1 Ruiyang Road, Yiyuan County, Shandong Province- packager, quality control, batch releaser, Titan Pharmaceutical Co., Ltd (Guangdong), Lantang Town, Zijin County, Heyuan City, China- bulk manufacturer	China	Troge Medical GmbH, Milchstrasse 19, 20148 Hamburg	Germany	PoM	19125/1 24.07.2025
6	Soluferr	iron (III)-hydroxide sucrose complex	solution for i/v injection or concentrate for solution for infusion	20mg/ml; (5) ampoules 5ml	Help S.A. Pedini, Ioanninon, Ioannina, 45500	Greece	Moosmann Pharmaceuticals LLC, Vanahovit 8, Proshyan v., Ashtarak Ave., Kotayk Marz 2413	Republic of Armenia	PoM	19139/4/1 24.07.2025
7	Inforin Active	ibuprofen, levomenthol(menthol)	gel for external use	50mg/g+30mg/g; 40g aluminum tube	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	Spey Medical Ltd, Lynton House 7-12 Tavistock square, WC1H 9LT, London	UK	OTC	21842/1 24.07.2025
8	Exforge	amlodipine (amlodipine besilate), valsartan	tablets film-coated	5mg+160mg; (14/1x14) in PVC/ PVDC blister, (28/2x14) in PVC/PVDC blister, (14/1x14) in PA/AL/PVC(Alu-Alu) blister, (28/2x14) in PA/AL/PVC(Alu- Alu) blister	Novartis Farma S.p.A, Via Provinciale Schito 131, 80058 Torre Annunziata(NA)	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	21841/1 24.07.2025
9	Exforge	amlodipine (amlodipine besilate), valsartan	tablets film-coated	10mg+160mg; (14/1x14) in PVC/PVDC blister, (28/2x14) in PVC/PVDC blister, (14/1x14) in PA/AL/PVC(Alu-Alu) blister, (28/2x14) in PA/AL/PVC(Alu- Alu) blister	Novartis Farma S.p.A, Via Provinciale Schito 131, 80058 Torre Annunziata(NA)	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	21842/1 24.07.2025
10	Dicloton 75mg/3ml	diclofenac (diclofenac sodium)	solution for injection/infusion	25mg/ml (5) ampoules 3ml	Medochemie Ltd. (Ampoule Injectable Facility) 48 Iapetou street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd.,1-10 Constantinoupoleos street, 3011 Limassol	Cyprus	PoM	19403/2 24.07.2025

11	Folic Acid	folic acid	tablets	5mg; (48/2x24) in blister; (50/5x10) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	19238/1 24.07.2025
12	Noradrenaline	noradrenaline (noradrenaline tartrate)	concentrate for solution for infusion	1mg/ml; (5/1x5) ampoules 2ml in plastic liner, (10/2x5) ampoules 2ml in plastic liner	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, 1. HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia 2.Grindeks JSC, Krustpils street 53, LV-1057, Riga, Latvia- quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	19568/3/1 24.07.2025
13	Noradrenaline	noradrenaline tartrate	concentrate for solution for infusion	1mg/ml; (5/1x5) ampoules 4ml in plastic liner, (10/2x5) ampoules 4ml in plastic liner	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, 1. HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia 2.Grindeks JSC, Krustpils street 53, LV-1057, Riga, Latvia- quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	19569/3/2 24.07.2025
14	Marion	ceftriaxone (ceftriaxone sodium)	powder for solution for injection/infusion	1000mg; glass vial	Anfarm Hellas S.A., 61st Km National Road Athens-Lamia, Sximatari Viotias, 32009	Greece	J&P Pharma UK LTD, 7 Becket Wood, Newdigate, Dorking RH5 5AQ	UK	PoM	20595/2 24.07.2025
15	Marion	ceftriaxone (ceftriaxone sodium)	powder and solvent for solution for i/m injection	1000mg; glass vial and solvent in ampoule 3.5ml	Anfarm Hellas S.A., 61st Km National Road Athens-Lamia, Sximatari Viotias, 32009	Greece	J&P Pharma UK LTD, 7 Becket Wood, Newdigate, Dorking RH5 5AQ	UK	PoM	20596/2 24.07.2025
16	Letiram	levetiracetam	tablets coated	250mg; (30/3x10) in blister, (60/6x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, PharOS MT Ltd, HF62X, Hal Far Industrial Estate, Birzebbugia BBG, 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22295/1 24.07.2025

17	Letiram	levetiracetam	tablets coated	500mg; (30/3x10/) in blister, (60/6x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, PharOS MT Ltd, HF62X, Hal Far Industrial Estate, Birzebbugia BBG, 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22296/1 24.07.2025
18	Letiram	levetiracetam	tablets coated	750mg; (30/3x10/) in blister, (60/6x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, PharOS MT Ltd, HF62X, Hal Far Industrial Estate, Birzebbugia BBG, 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22297/1 24.07.2025
19	Letiram	levetiracetam	tablets coated	1000mg; (30/3x10/) in blister, (60/6x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, PharOS MT Ltd, HF62X, Hal Far Industrial Estate, Birzebbugia BBG, 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22298/1 24.07.2025
20	Espumisan	simeticone	capsules soft	40mg; (25/1x25/) in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, quality control, batch releaser, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany- bulk manufacturer	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	OTC	22361/1 24.07.2025
21	Lasolvan	ambroxol (ambroxol hydrochloride)	tablets	30mg; (20/2x10/) in blister	Delpharm Reims, 10 rue Colonel Charbonneaux, Reims, 51100	France	A. Nattermann & Cie. GmbH, Industriepark Hoechst, Bruningstrasse 50, D-65926, Frankfurt am Main	Germany	OTC	20868/2/1 24.07.2025
22	Diprosalic	betamethasone (betamethasone dipropionate), salicylic acid	ointment	0,5mg/g+30mg/g; 30g aluminium tube	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	21575/2/1 24.07.2025

23	Triderm	betamethasone (betamethasone dipropionate), clotrimazole, gentamicin (gentamicin sulfate)	ointment	0,5mg/g+10mg/g+1mg/g; aluminium tube 15g	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	21143/4/1 24.07.2025
24	Triderm	betamethasone (betamethasone dipropionate), clotrimazole, gentamicin (gentamicin sulfate)	cream	0,5mg/g+10mg/g+1mg/g; aluminium tube 15g	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	21887/2 24.07.2025
25	Clivas Plus	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets film-coated	10mg+10mg; (30/3x10') in blister	ELPEN Pharmaceutical CO., INC, Marathonos Ave. 95, Pikermi Attiki, 19009	Greece	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, Kiev	Ukraine	PoM	22665/1 24.07.2025
26	Clivas Plus	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets film-coated	20mg+10mg; (30/3x10') in blister	ELPEN Pharmaceutical CO., INC, Marathonos Ave. 95, Pikermi Attiki, 19009	Greece	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, Kiev	Ukraine	PoM	22666/1 24.07.2025
27	Clivas Plus	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets film-coated	40mg+10mg; (30/3x10') in blister	ELPEN Pharmaceutical CO., INC, Marathonos Ave. 95, Pikermi Attiki, 19009	Greece	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, Kiev	Ukraine	PoM	22667/1 24.07.2025
28	Rexocef	cefpodoxime (cefpodoxime proxetil)	powder for oral suspension	40mg/5ml; 64,8g powder in 100ml plastic vial with measuring cup and dosing syringe	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- quality control, batch releaser, Lupin Limited, 198-202, New Industrial Estate Area No.2 Mandideep-462046 district- Raisen M.P, India- bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	21692/3 24.07.2025
29	Vametal	ondansetron (ondansetron hydrochloride dihydrate)	solution for i/v and i/m injection	2mg/ml; glass vial 2ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Medicus S.A., 10 Valaoritou str., GR 144 52, Metamorphosis, Attika	Greece	PoM	19056/1 24.07.2025
30	Vametal	ondansetron (ondansetron hydrochloride dihydrate)	solution for i/v and i/m injection	2mg/ml; glass vial 4ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Medicus S.A., 10 Valaoritou str., GR 144 52, Metamorphosis, Attika	Greece	PoM	19057/1 24.07.2025

31	Berlipril 10	enalapril (enalapril maleate)	tablets	10mg; (30/3x10) in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, quality control(microbiological), batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1) Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin,Germany, 2) Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin, Germany - quality control (phisicochemical)	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	20484/1 24.07.2025
32	Berlipril 20	enalapril (enalapril maleate)	tablets	20mg; (30/3x10) in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, quality control(microbiological), batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1) Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin,Germany, 2) Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin, Germany- quality control(phisicochemical)	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	20473/1 24.07.2025
33	Paracetamol	paracetamol	tablets	500mg; (20/2x10) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64A, Chapaeva str., Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapaeva str., Borisov 222518, Minsk region	Republic of Belarus	OTC	21868/2 24.07.2025
34	Paracetamol	paracetamol	tablets	500mg; (10) in strip, (20/2x10) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 24, Stroiteley str., Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	OTC	20459/2/1 24.07.2025
35	Tamsu Genericon retard 0,4mg capsules	tamsulosin (tamsulosin hydrochloride)	capsules controlled-release hard	0,4mg; (10/1x10) in blister, (30/3x10) in blisters	Synthon Hispania,S.L., C/ Castello, N 1, Sant Boi de Llobregat, Barcelona, 08830	Spain	Genericon Pharma Gesellschaft m.b.H, 8054 Graz	Austria	PoM	22802/2 24.07.2025

36	Omeprazole	omeprazole	capsules	20mg; (30/3x10) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64A, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	PoM	20015/2/1 24.07.2025
37	Herbion Iceland moss syrup	iceland moss thick extract	syrup	6mg/ml 150ml glass bottle and measuring spoon	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- quality control (physical/chemical, microbiological), batch releaser, KRKA d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia- bulk manufacturer, packager, Nacionalni laboratorij za zdravje, okolje in hrano (NLZOH), Dalmatinova ulica 3, Novo mesto, 8000, Slovenia- quality control (physical/chemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	19448/1 24.07.2025
38	Roxera Plus	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets film-coated	10mg+10mg; (30/3x10) in blister, (60/6x10) in blister, (90/9x10) 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	19363/3/1 24.07.2025
39	Roxera Plus	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets film-coated	20mg+10mg; (30/3x10) in blister, (60/6x10) in blister, (90/9x10) 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	19420/3/1 24.07.2025
40	Kinezia	fampridine	tablets film-coated prolonged-release	10mg; (27/3x9) in blister, (54/6x9) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2- bulk manufacturer, packager, batch releaser, Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 1, Russia- quality control (physicochemical), Centemo LTD, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2.	Russia	PoM	21808/1 24.07.2025

41	Balzac liniment of Vishnevsky	birch tar, xeroform	liniment	30mg/g+30mg/g; aluminium tube 40g	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, No2, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	OTC	21837/2 24.07.2025
42	Oftan Catachrom	cytochrome C, adenosine, nicotinamide	drops eye	0,675mg/ml+2mg/ml+20mg/ml; plastic bottle-dropper 10ml	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, NextPharma Oy, Niittyhaankatu 20, Tampere, 33720, 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	19804/3 24.07.2025
43	9 months Folic acid	folic acid	tablets film-coated	400mcg; (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	20077/4/1 24.07.2025
44	CLAVOTON 1g	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	875mg+125mg; (14/2x7/) in blister	Medochemie Ltd- Factory B, 48 Iapetou street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupoleos street, 3011 Limassol	Cyprus	PoM	19466/3 24.07.2025
45	CETAMOL	paracetamol	syrup with cherry flavour	24mg/ml; glass bottle 100ml	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	OTC	18457/1 24.07.2025
46	Gonadotropin chorionic	gonadotrophin chorionic	powder lyophilized for solution for i/m injection	500IU; (5) glass vials	Moscow Endocrine Plant FSUE, 25, bld. 1, Novokhokhlovskaya st., Moscow, 109052- quality control (physicochemical and microbiological), batch releaser, "Moscow Endocrine Plant FSUE", 25, bld. 2, Novokhokhlovskaya st., Moscow, 109052, Russia- bulk manufacturer, packager (powder and solvent)	Russia	"Moscow Endocrine Plant FSUE", 25, Novokhokhlovskaya st., Moscow 109052	Russia	PoM	19522/3/1 24.07.2025

47	Gonadotropin chorionic	gonadotrophin chorionic	powder lyophilized for solution for i/m injection	1000IU; (5) glass vials	Moscow Endocrine Plant FSUE, 25, bld. 1, Novokhokhlovskaya st., Moscow, 109052- quality control (physicochemical and microbiological), batch releaser, "Moscow Endocrine Plant FSUE", 25, bld. 2, Novokhokhlovskaya st., Moscow, 109052, Russia- bulk manufacturer, packager (powder and solvent)	Russia	"Moscow Endocrine Plant FSUE", 25, Novokhokhlovskaya st., Moscow 109052	Russia	PoM	19521/3/1 24.07.2025
48	Aerius	desloratadine	syrup	0,5mg/ml; glass bottle 60ml and measuring spoon	Schering-Plough Labo N.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	PoM	19138/3 24.07.2025
49	Avamys	fluticasone (fluticasone furoate)	spray nasal (suspension)	27,5mcg/dose; (1) glass bottle with metering pump (120 dose)	Glaxo Operations UK Ltd., Harmire Road Barnard Castle Co Durham, DL12 8DT	UK	GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24	Ireland	PoM	19111/1 24.07.2025
50	Tonofungyn	fluconazole	capsules hard	150mg; (2/2x1/) in strip	Egyptian International Pharmaceutical Industries Company (EIPICO), 10th of Ramadan City, Industrial Area B1,P.O. box 149,Tenth	Egypt	Egyptian International Pharmaceutical Industries Company (EIPICO), 10th of Ramadan City, Industrial Area B1,P.O. box 149,Tenth	Egypt	PoM	18732/1 24.07.2025
51	Trimedat	trimebutine	tablets	100mg; (10/1x10) 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	19737/5/1 24.07.2025
52	Trimedat	trimebutine	tablets	200mg; (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	19738/5/1 24.07.2025
53	Azitrox	azithromycin (azithromycin dihydrate)	capsules	250mg; (6/1x6) in blister	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTCPharm JSC, 123317, Moscow, Testovskaya str., 10	Russia	PoM	19212/3/1 24.07.2025

54	Tonopenem	meropenem (meropenem trihydrate)	powder for solution for i/v injection	500mg; (36) glass vials 10ml	Tonus-Les LLC, N1 Laboratory complex, 6th str., v. Nor Gyugh, com. Akunk, Kotayk marz- batch releaser, TriplePharm, Minsk Region, Logoisk, Minskaya str., house 2B, Republic of Belarus- bulk manufacturer, packager, quality control	Republic of Armenia	Tonus-Les LLC, Yerevan, 1 Yervand Kochar str., 0070	Republic of Armenia	PoM	21677/3/1 24.07.2025
55	Vakunis	cefuroxime (cefuroxime sodium)	powder for solution for injection/infusion	750mg; glass vial 10ml	Anfarm Hellas S.A., 61st Km National Road Athens-Lamia, Schimatari Viotias, 32009	Greece	J&P Pharma UK LTD, 7 Becket Wood, Newdigate, Dorking RH5 5AQ	UK	PoM	21742/1 24.07.2025
56	Vakunis	cefuroxime (cefuroxime sodium)	powder for solution for injection/infusion	1500mg; glass vial 50ml	Anfarm Hellas S.A., 61st Km National Road Athens-Lamia, Schimatari Viotias, 32009	Greece	J&P Pharma UK LTD, 7 Becket Wood, Newdigate, Dorking RH5 5AQ	UK	PoM	21743/1 24.07.2025
57	Tingora	ticagrelor	tablets film-coated	60mg; (56/4x14) in blister	ALKALOID AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- batch releaser, Elpen Pharmaceutical Co. Inc., Marathonos Avenue 95, Pikermi Attiki, 19009, Greece- bulk manufacturer, packager, quality control	Republic of North Macedonia	ALKALOID AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	22881/2 24.07.2025
58	Tingora	ticagrelor	tablets film-coated	90mg; (56/4x14) in blister	ALKALOID AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- batch releaser, Elpen Pharmaceutical Co. Inc., Marathonos Avenue 95, Pikermi Attiki, 19009, Greece- bulk manufacturer, packager, quality control	Republic of North Macedonia	ALKALOID AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	22882/2 24.07.2025

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 07-1/25 on July 24, 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	Detralex	diosmin, hesperidin	tablets film-coated	450mg+50mg; (28/2x14/) in blister, (30/2x15/) in blister, (36/3x12/) in blister, (56/4x14/) in blister, (60/4x15/) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	OTC	ЛПТ-№000822-ITI-AM 24.07.2025
2	Detralex	diosmin, hesperidin	tablets film-coated	450mg+50mg; (28/2x14/) in blister, (30/2x15/) in blister, (36/3x12/) in blister, (56/4x14/) in blister, (60/4x15/) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	OTC	ЛПТ-№000822-ITI-AM 24.07.2025
3	Detralex	diosmin, hesperidin	tablets film-coated	450mg+50mg; (30/2x15/) in blister, (36/3x12/) in blister, (60/4x15/) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, quality control, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	OTC	ЛПТ-№000822-ITI-AM 24.07.2025
4	Detralex	diosmin, hesperidin	tablets film-coated	900mg+100mg; (18/2x9/) in blister, (27/3x9/) in blister, (30/3x10/) in blister, (60/6x10/) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	OTC	ЛПТ-№000880-ITI-AM 24.07.2025
5	Detralex	diosmin, hesperidin	tablets film-coated	900mg+100mg; (18/2x9/) in blister, (27/3x9/) in blister, (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	OTC	ЛПТ-№000880-ITI-AM 24.07.2025

6	ARIFON Retard	indapamide	tablets film-coated prolonged-release	1,5mg; (30/1x30/) in blister, (90/3x30/) 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	ЛІП-№000156- ІТІ-AM 24.07.2025
7	Alzepil	donepezil (donepezil hydrochloride)	tablets film-coated	5mg; (28/2x14/) in blister, (56/4x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	ЛІП-№000397- ІТІ-AM 24.07.2025
8	Alzepil	donepezil (donepezil hydrochloride)	tablets film-coated	10mg; (28/2x14/) in blister, (56/4x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	ЛІП-№000397- ІТІ-AM 24.07.2025
9	Sedistress	dry extract of passiflora, ethyl ester of alpha-bromisovaleric acid	tablets	300mg+10,2mg; (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	OTC	ЛІП-№004871- ПГ-AM 24.07.2025
10	Xarelto	rivaroxaban	tablets film-coated	15mg; (28/2x14/) in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen- bulk manufacturer, primary packager, quality control, batch releaser, Stegemann GmbH & Co. KG Up' n Nien Esch 14, 48268 Greven, Germany- secondary packager	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	ЛІП-№ 005279-ІТІ- AM 24.07.2025
11	Xarelto	rivaroxaban	tablets film-coated	15mg; (28/2x14/) in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	ЛІП-№ 005279-ІТІ- AM 24.07.2025
12	Xarelto	rivaroxaban	tablets film-coated	20mg; (28/2x14/) in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen- bulk manufacturer, primary packager, quality control, batch releaser, Stegemann GmbH & Co. KG Up' n Nien Esch 14, 48268 Greven, Germany- secondary packager	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	ЛІП-№ 005279-ІТІ- AM 24.07.2025
13	Xarelto	rivaroxaban	tablets film-coated	20mg; (28/2x14/) in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	ЛІП-№ 005279-ІТІ- AM 24.07.2025
14	Artmelok	meloxicam	tablets	15mg; (20/2x10/) in PVC/Alu blister, (20/2x10/) in hard PVC/ Alu blister	Pharmtechnology LLC, Korzhenevskogo str., 22, 220024, Minsk	Republic of Belarus	Giga Farm LLC, Gogunca str.3/5, Gyumri	Republic of Armenia	PoM	ЛІП-№001600- ПГ-AM 24.07.2025

15	Escapelle	levonorgestrel	tablets	1,5mg; (1) in blister	Gedeon Richter Plc., Gyomroi st. 19-21, 1103 Budapest- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Gedeon Richter Plc., 2510 Dorog, Esztergomi st. 27, Hungary- quality control (microbiological)	Hungary	Gedeon Richter Plc., Gyomroi ut 19-21, 1103 Budapest	Hungary	OTC	ЛПТ-№001219- ITI-AM 24.07.2025
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