

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 08-1/25 on August 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	AqVitecan	irinotecan	concentrate for solution for infusion	100mg/5ml; (1) glass vial 5ml	AqVida GmbH, Kaiser-Wilhelm-Str. 89, Hamburg, 20355- batch releaser, AqVida GmbH, Werkstrasse 21, 23942 Dassow, Germany- bulk manufacturer, packager, quality control	Germany	Aversi-Rational Ltd, 33 David Kobakhidze Str., 0198 Tbilisi	Georgia	PoM	23366 25.08.2025
2	BIOMETHASONE	dexamethasone (dexamethasone disodium phosphate)	solution for injection	1,52mg/ml; glass vial 50ml	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	23367 25.08.2025
3	Mexaj	ethylmethylhydroxypyridine succinate	solution for i/v and i/m injection	50mg/ml; (5) ampoules 2ml, (10) ampoules 2ml	Velfarm LLC, Kurgan Region, Kurgan city, Prospekt Konstitutsii, Building 11	Russia	SPEY MEDICAL LTD, Lynton house 7-12 Tavistock square, London, WC1H9LT	UK	PoM	23368 25.08.2025
4	Amva Denk 5/80mg	amlodipine (amlodipine besilate), valsartan	tablets film-coated	5mg+80mg; (28/4x7/) in blister	Balkanpharma Dupnitsa AD, 3 Samokovsko Shosse Street, Dupnitsa 2600	Bulgaria	DENK PHARMA GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	23369 25.08.2025
5	Amva Denk 5/160mg	amlodipine (amlodipine besilate), valsartan	tablets film-coated	5mg+160mg; (28/4x7/) in blister	Balkanpharma Dupnitsa AD, 3 Samokovsko Shosse Street, Dupnitsa 2600	Bulgaria	DENK PHARMA GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	23370 25.08.2025
6	Amva Denk 10/160mg	amlodipine (amlodipine besilate), valsartan	tablets film-coated	10mg+160mg; (28/4x7/) in blister	Balkanpharma Dupnitsa AD, 3 Samokovsko Shosse Street, Dupnitsa 2600	Bulgaria	DENK PHARMA GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	23371 25.08.2025

7	Diampa LT	empagliflozin, linagliptin	tablets film-coated	10mg+5mg; (28/4x7) 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	23372 25.08.2025
8	Diampa LT	empagliflozin, linagliptin	tablets film-coated	25mg+5mg; (28/4x7) 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	23373 25.08.2025
9	Vegacef	ceftriaxone (ceftriaxone sodium)	powder for solution for injection/infusion	1000mg; (1) glass vial 10ml	ACS Dobfar S.p.A., Via Alessandro Fleming 2, 37135, Verona	Italy	Vegapharm LLP, Unit 18, Normon road 53, Greenwich Centre Business park, SE10 9QF, London	United Kingdom	PoM	23374 25.08.2025
10	Montiget	montelukast (montelukast sodium)	tablets chewable	5mg; (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	23375 25.08.2025
11	Montiget	montelukast (montelukast sodium)	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	23376 25.08.2025
12	Ketaneim	ketoprofen	solution for i/m injection	100mg/2ml; (5/1x5) ampoules 2ml in blister, (10/1x10) ampoules 2ml in blister	Vetprom AD, Otez Paissij str. 26, Radomir 2400	Bulgaria	NEO UNIVERSE LLP, Block 18, Norman Road 53, Greenwich Centre Business Park, London, SE10 9QF	United Kingdom	PoM	23377 25.08.2025
13	Aciclovir Avexima	aciclovir	tablets	400mg; (20/2x10) in blister	Irbitskiy himfarmzavod OJSC, 124-a/1, K. Marksa str., Irbit, St. Sverdlovsk, 623856-quality control, batch releaser, Irbitskiy himfarmzavod OJSC, 124-a, K. Marksa str., Irbit, St. Sverdlovsk, 623856, Russia- bulk manufacturer, packager	Russia	Avexima OJSC, 31A/1, Leningradsky pr., Moscow, 125284	Russia	PoM	23378 25.08.2025
14	Diazolin-Pharmstandard	mebhydrolin (mebhydrolin napadisylate)	dragee	50mg; (10/1x10) in blister	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	OTC	23379 25.08.2025
15	Diazolin-Pharmstandard	mebhydrolin (mebhydrolin napadisylate)	dragee	100mg; (10/1x10) in blister	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	OTC	23380 25.08.2025

16	Caripazim-MedFlorina	papain	powder lyophilized for solution for injection	350PE; (1) glass vial, (10) glass vials	LLC MedFlorina, Moscow Region, Serpukhov Urban District, Obolensk Settlement, Quarter B, Building 33- bulk manufacturer, packager, quality control (physicochemical), batch releaser, ICLS Biotechnology LLC, Moscow Region, Leninsky Urban District, Vidnoye City, 8 Liniya Street, Building 10A, Russia- quality control (microbiological)	Russia	LLC MedFlorina, Moscow Region, Serpukhov Urban District, Obolensk Settlement, Quarter B, Building 33	Russia	PoM	23381 25.08.2025
17	Omeprazole Pharmproject	omeprazole	capsules gastro-resistant	20mg; (100/10x10) in blister	Health Care Formulations Pvt. Ltd, C/8, Sardar Estate, Ajwa Road, Vadodara (Gujarat), 390019	India	Pharmproject LLC, G. Maharu St., 133, 0020, Yerevan	Republic of Armenia	PoM	23382 25.08.2025
18	Starcox	etoricoxib	tablets film-coated	60mg; (30/3x10) 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	23383 25.08.2025
19	Starcox	etoricoxib	tablets film-coated	90mg; (30/3x10) 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	23384 25.08.2025
20	Starcox	etoricoxib	tablets film-coated	120mg; (30/3x10) 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	23385 25.08.2025
21	Diampa-M	empagliflozin, metformin (metformin hydrochloride)	tablets film-coated	12,5mg+1000mg; (28/4x7) 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	23386 25.08.2025
22	Diampa-M	empagliflozin, metformin (metformin hydrochloride)	tablets film-coated	12,5mg+500mg; (28/4x7) 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	23387 25.08.2025
23	Diampa-M	empagliflozin, metformin (metformin hydrochloride)	tablets film-coated	5mg+1000mg; (28/4x7) 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	23388 25.08.2025
24	Diampa-M	empagliflozin, metformin (metformin hydrochloride)	tablets film-coated	5mg+500mg; (28/4x7) 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	23389 25.08.2025

25	Roviget	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (30/3x10) 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	23390 25.08.2025
26	Roviget	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (30/3x10) 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	23391 25.08.2025

LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 08-1/25 on August 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	Panthomecol Plus	dexpantenol, chlorhexidine (chlorhexidine digluconate)	cream for external use	52,5mg/g+8,02mg/g: aluminium tube 25g, aluminium tube 30g, aluminium tube 50g, plastic tube 25g, plastic tube 30g, plastic tube 50g	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, c.1- quality control, batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia- bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	23325 (010214) 25.08.2025
2	Kameton	chlorobutanol (chlorobutanol hydrate), camphora, L-menthol, eucalyptus oil	aerosol for local use	6,67mg/g+6,67mg/g+6,67mg/g+6,67mg/g: 30g aluminium container with vertical pump dispenser, 45g aluminium container with vertical pump dispenser, 30g aluminium container with vertical pump dispenser and horizontal pump dispenser, 45g aluminium container with vertical pump dispenser and horizontal pump dispenser	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	23326 (023700) 25.08.2025
3	GENFERON LIGHT	interferon alfa-2b, taurine	suppositories vaginal and rectal	125000IU+5mg; (10/2x5/)	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalneye, Krasnogorsk Urban District, Moscow Region, 143422	Russia	BIOCAD JSC, d. 38, str.1, pomeshch. 89, Intracity Municipality the Settlement of Strelna, ul. Svyazi, Saint Petersburg, 198515	Russia	PoM	23327 (018340) 25.08.2025

4	GENFERON LIGHT	interferon alfa-2b, taurine	suppositories vaginal and rectal	125000IU+5mg; (10/2x5/)	PK-137 LLC, bld. 2, 5557th proyezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460	Russia	BIOCAD JSC, d. 38, str.1, pomeshch. 89, Intracity Municipality the Settlement of Strelna, ul. Svyazi, Saint Petersburg, 198515	Russia	PoM	23328 (023700) 25.08.2025
5	GENFERON LIGHT	interferon alfa-2b, taurine	suppositories vaginal and rectal	250000IU+5mg; (10/2x5/)	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalneye, Krasnogorsk Urban District, Moscow Region, 143422	Russia	BIOCAD JSC, d. 38, str.1, pomeshch. 89, Intracity Municipality the Settlement of Strelna, ul. Svyazi, Saint Petersburg, 198515	Russia	PoM	23329 (023700) 25.08.2025
6	GENFERON LIGHT	interferon alfa-2b, taurine	suppositories vaginal and rectal	250000IU+5mg; (10/2x5/)	PK-137 LLC, bld. 2, 5557th proyezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460	Russia	BIOCAD JSC, d. 38, str.1, pomeshch. 89, Intracity Municipality the Settlement of Strelna, ul. Svyazi, Saint Petersburg, 198515	Russia	PoM	23330 (023700) 25.08.2025
7	Avegra BIOCAD	bevacizumab	concentrate for solution for infusion	25mg/ml; (1) glass vial 0,5ml, (1) glass vial 4ml, (1) glass vial 16ml, (1) glass vial 0,5ml in blister, (1) glass vial 4ml in blister, (1) glass vial 16ml in blister	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	23331 (013046) 25.08.2025
8	Avegra BIOCAD	bevacizumab	concentrate for solution for infusion	25mg/ml; (1) glass vial 0,5ml, (1) glass vial 4ml, (1) glass vial 16ml, (1) glass vial 0,5ml in blister, (1) glass vial 4ml in blister, (1) glass vial 16ml in blister	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422- quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422, Russia- bulk manufacturer, packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	23332 (023700) 25.08.2025
9	Avegra BIOCAD	bevacizumab	concentrate for solution for infusion	25mg/ml; (1) glass vial 4ml, (1) glass vial 16ml, (1) glass vial 4ml in blister, (1) glass vial 16ml in blister	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	23333 (023700) 25.08.2025

10	Avegra BIOCAD	bevacizumab	concentrate for solution for infusion	25mg/ml; (1) glass vial 0,5ml, (1) glass vial 4ml, (1) glass vial 16ml, (1) glass vial 0,5ml in blister, (1) glass vial 4ml in blister, (1) glass vial 16ml in blister	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460-secondary packager, quality control, batch releaser, BIOCAD JSC, Intracity Municipality the Settlement of Strelina, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515, Russia- bulk manufacturer, primary packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelina, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	23334 (023700) 25.08.2025
11	Avegra BIOCAD	bevacizumab	concentrate for solution for infusion	25mg/ml; (1) glass vial 0,5ml, (1) glass vial 4ml, (1) glass vial 16ml, (1) glass vial 0,5ml in blister, (1) glass vial 4ml in blister, (1) glass vial 16ml in blister	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460-secondary packager, quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalneye, Krasnogorsk Urban District, Moscow Region, 143422, Russia- bulk manufacturer, primary packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelina, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	23335 (023700) 25.08.2025
12	Sumatriptan	sumatriptan (sumatriptan succinate)	tablets film-coated	50mg; (2/2x1/) in blister, (4/2x2/) in blister, (6/2x3/) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapayev str., Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapayev str., Borisov 222518, Minsk region	Belarus	PoM	23336 (002749) 25.08.2025
13	Sumatriptan	sumatriptan (sumatriptan succinate)	tablets film-coated	100mg; (2/2x1/) in blister, (4/2x2/) in blister, (6/2x3/) in bli	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapayev str., Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapayev str., Borisov 222518, Minsk region	Belarus	PoM	23337 (002749) 25.08.2025
14	Concor	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (30/3x10/) in blister, (30/1x30/) in blister, (50/5x10/) in blister, (50/2x25/) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, Valovaya Street 35, Moscow 115054	Russia	PoM	23338 (007854) 25.08.2025
15	Concor	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg; (30/3x10/) in blister, (30/1x30/) in blister, (50/5x10/) in blister, (50/2x25/) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, Valovaya Street 35, Moscow 115054	Russia	PoM	23339 (007854) 25.08.2025
16	Concor Cor	bisoprolol (bisoprolol fumarate)	tablets film-coated	2,5mg; (30/1x30/) in blister, (50/2x25/) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, Valovaya Street 35, Moscow 115054	Russia	PoM	23340 (004360) 25.08.2025

17	Phosphogliv URSO-Pharmstandard	ursodeoxycholic acid, sodium glycyrrhizinate (glycyrrhizinic acid trisodium)	capsules	250mg+35mg; (50/5x10) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	PoM	23341 (002679) 25.08.2025
18	GENFERON	interferon alfa-2b, benzocaine, taurine	suppositories vaginal and rectal	500000IU+55mg+10mg; (10/2x5/)	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalneye, Krasnogorsk Urban District, Moscow Region, 143422	Russia	BIOCAD JSC, d. 38, str.1, pomeshch. 89, Intracity Municipality the Settlement of Strelina, ul. Svyazi, Saint Petersburg, 198515	Russia	PoM	23342 (000307) 25.08.2025
19	GENFERON	interferon alfa-2b, benzocaine, taurine	suppositories vaginal and rectal	500000IU+55mg+10mg; (10/2x5/)	PK-137 LLC, bld. 2, 5557th proyezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460	Russia	BIOCAD JSC, d. 38, str.1, pomeshch. 89, Intracity Municipality the Settlement of Strelina, ul. Svyazi, Saint Petersburg, 198515	Russia	PoM	23343 (000307) 25.08.2025
20	GENFERON	interferon alfa-2b, benzocaine, taurine	suppositories vaginal and rectal	1000000IU+55mg+10mg; (10/2x5/)	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalneye, Krasnogorsk Urban District, Moscow Region, 143422	Russia	BIOCAD JSC, d. 38, str.1, pomeshch. 89, Intracity Municipality the Settlement of Strelina, ul. Svyazi, Saint Petersburg, 198515	Russia	PoM	23344 (000307) 25.08.2025
21	GENFERON	interferon alfa-2b, benzocaine, taurine	suppositories vaginal and rectal	1000000IU+55mg+10mg; (10/2x5/)	PK-137 LLC, bld. 2, 5557th proyezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460	Russia	BIOCAD JSC, d. 38, str.1, pomeshch. 89, Intracity Municipality the Settlement of Strelina, ul. Svyazi, Saint Petersburg, 198515	Russia	PoM	23345 (000307) 25.08.2025
22	No-spa	drotaverine (drotaverine hydrochloride)	solution for i/m and i/v injection	20mg/ml; (25/5x5/) ampoules 2ml	Chinoim Pharmaceutical and Chemical Works Ltd., 3510 Miskolc, Csanyikveld	Hungary	Opella Healthcare Commercial Ltd., 1138 Budapest, st.Vachi 133, b.E, floor 3	Hungary	PoM	23346 (016120) 25.08.2025
23	Polyoxidonium	azoximer bromide	powder lyophilized for solution for injection and local use	6mg; (5) glass vials 3ml, (50) glass vials 3ml	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	PoM	23347 (018137) 25.08.2025

24	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	150mg; glass vial	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	23348 (011157) 25.08.2025
25	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	150mg; glass vial	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk Urban District, Moscow Region, 143422- quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk Urban District, Moscow Region, 143422, Russia- bulk manufacturer, packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	23349 (011157) 25.08.2025
26	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	150mg; glass vial	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	23350 (011157) 25.08.2025
27	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	150mg; glass vial	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460- secondary packager, quality control, batch releaser, BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515, Russia- bulk manufacturer, primary packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	23351 (011157) 25.08.2025
28	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	150mg; glass vial	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460- secondary packager, quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk Urban District, Moscow Region, 143422, Russia- bulk manufacturer, primary packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	23352 (011157) 25.08.2025

29	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	440mg; glass vial and glass vial with 20ml solvent	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	23353 (011157) 25.08.2025
30	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	440mg; glass vial and glass vial with 20ml solvent	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk Urban District, Moscow Region, 143422- quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk Urban District, Moscow Region, 143422, Russia- bulk manufacturer, packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	23354 (011157) 25.08.2025
31	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	440mg; glass vial and glass vial with 20ml solvent	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	23355 (011157) 25.08.2025
32	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	440mg; glass vial and glass vial with 20ml solvent	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460- secondary packager, quality control, batch releaser, BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515, Russia- bulk manufacturer, primary packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	23356 (011157) 25.08.2025
33	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	440mg; glass vial and glass vial with 20ml solvent	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460- secondary packager, quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk Urban District, Moscow Region, 143422, Russia- bulk manufacturer, primary packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	23357 (011157) 25.08.2025

34	Egilok	metoprolol (metoprolol tartrate)	tablets	25mg; (60) in glass container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65- packager, batch releaser, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23358 (000742) 25.08.2025
35	Egilok	metoprolol (metoprolol tartrate)	tablets	50mg; (60) in glass container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65- packager, batch releaser, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23359 (000742) 25.08.2025
36	Egilok	metoprolol (metoprolol tartrate)	tablets	100mg; (30) in glass container, (60) in glass container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65- packager, batch releaser, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23360 (000742) 25.08.2025
37	Fromilid	clarithromycin	tablets film-coated	250mg; (14/2x7) 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	23361 (005291) 25.08.2025
38	Fromilid	clarithromycin	tablets film-coated	500mg; (14/2x7) 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	23362 (005291) 25.08.2025
39	Sulfasalazin	sulfasalazine	tablets film-coated	500mg; (50/5x10) 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	23363 (003775) 25.08.2025
40	Sulfasalazin	sulfasalazine	tablets film-coated	500mg; (50/5x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, quality control, batch releaser, KRKA d.d., Novo mesto, Ulica Rada Pusenjaka 10, Ljutomer, 9240, Slovenia- packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	23364 (003775) 25.08.2025
41	Thiosol	thioctic acid	solution for i/v infusion	25mg/ml; (5) glass vial 24ml	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	PoM	23365 (014432) 25.08.2025

42	IntraSol	sodium chloride, potassium chloride, magnesium chloride hexahydrate, calcium chloride dihydrate, sodium acetate trihydrate, L-malic acid	solution for infusion	6,8g/l+0,3g/l +0,20g/l +0,37g/l +3,27g/l +0,67g/l; 500ml plastic pack	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	23322 (015310) 25.08.2025
43	Farmorubicin Rapid Dissolution	epirubicin (epirubicin hydrochloride)	powder lyophilized for solution for infusion	10mg; (1) glass vial 10ml	Corden Pharma Latina S.p.A, Via Murillo 7, Sermoneta, 04013	Italy	Pfizer Inc., 66 Hudson Boulevard East New York, NY 10001-2192	USA	PoM	23323 (013176) 25.08.2025
44	Farmorubicin Rapid Dissolution	epirubicin (epirubicin hydrochloride)	powder lyophilized for solution for infusion	50mg; (1) glass vial 25ml	Corden Pharma Latina S.p.A, Via Murillo 7, Sermoneta, 04013	Italy	Pfizer Inc., 66 Hudson Boulevard East New York, NY 10001-2192	USA	PoM	23324 (013176) 25.08.2025

LIST

of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 08-1/25 on August 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	Levoplant	levonorgestrel	implant sub-dermal	75mg; (20/10x2) rods in sachet	Shanghai Dahua Pharmaceutical Co., Ltd. 3503 Changzheng Road, Chongming District Shanghai	China	Shanghai Dahua Pharmaceutical Co., Ltd. 3503 Changzheng Road, Chongming District Shanghai	China	PoM	23321 25.08.2025

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 08-1/25 on August 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	Iburodem 600	ibuprofen	tablets film-coated	600mg; (20/2x10) in blister; (30/3x10) in blister; (60/6x10) in blister	Medinfar Manufacturing S.A, Parque Industrial Armando Martins Tavares, Rua Outeiro Da Armada No 5, Condeixa-A-Nova, 3150-194 Sebal	Portugal	Demi Pharm Griboyedovi 12, ap. 25, Sevan 1501	Republic of Armenia	PoM	23298 25.08.2025
2	Trio Vision	neomycin (neomycin sulfate), polymyxin B (polymyxin B sulfate), dexamethasone	drops eye (suspension)	3500IU/ml+6000IU/ml+1mg/ml; plastic vial 5ml	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	PoM	23299 25.08.2025
3	Herbion ivy lozenges	ivy leaf dry extract	lozenges	35mg; (16/2x8) in blister; (32/4x8) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- quality control (physicochemical- HPLC test Assay and identification of ivy leaf dry extract and microbiological), batch releaser, KRKA d.d., Novo mesto, Ulica Rada Pusenjaka 10, Ljutomer, 9240, Slovenia- bulk manufacturer, packager, KRKA d.d., Novo mesto, Povhovaulica 5, 8501 Novo Mesto, Slovenia- quality control (physicochemical- GC test Residual solvents: ethanol)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	23300 25.08.2025

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 08-1/25 on August 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	Anginovag	dequalinium (dequalinium chloride), tyrothricin, enoxolone (beta-glycyrrhetic acid), hydrocortisone (hydrocortisone acetate), lidocaine (lidocaine hydrochloride)	spray oromucosal	1mg/ml+ 4mg/ml+0,6mg/ml+0,6mg/ml+1mg/ml; 20ml (200 doses) plastic container and pump dispenser	Ferrer Internacional, S.A., Joan Buscalla, 1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer Internacional, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	OTC	23303 25.08.2025
2	Metoprolol	metoprolol (metoprolol tartrate)	tablets	50mg; (30/3x10) 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	23304 25.08.2025
3	Amlodipine	amlodipine (amlodipine besilate)	tablets	5mg; (30/3x10) 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	23305 25.08.2025
4	FUROSEMIDE	furosemide	tablets	40mg; (40/1x40) in blister, (40/4x10) 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	23306 25.08.2025

5	Tenikam	tenoxicam	powder lyophilized for solution for injection	20mg; (1) glass vial and solvent in ampoule 2ml	GM Pharmaceuticals Ltd, 65, Qvemo Phonichala str., Tbilisi-secondary packager, quality control (physicochemical), batch releaser, Anfarm Hellas S.A., Schimatari Viotias, 32009, Greece- bulk manufacturer, primary packager, quality control (microbiological)	Georgia	GM Pharmaceuticals Ltd, 65, Qvemo Phonichala str., Tbilisi 0165	Georgia	PoM	23307 25.08.2025
6	Sympathyl	eschscholtzia extract, hawthorn extract, magnesium oxide	tablets film-coated	20mg+75mg+124,35mg; (40/2x20/) in blister	Innothera Chouzy, Rue Rene Chantereau, Chouzy-sur-Cisse, Valloire-sur-Cisse, 41150	France	Laboratoire Innotech International, 22, Avenue Aristide Briand, 94110 Arcueil	France	OTC	23308 25.08.2025
7	TETRACYCLINE EYE OINTMENT 1%	tetracycline	ointment eye	10mg/g; aluminium tube 3g	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	23309 25.08.2025
8	Deep Relief	ibuprofen, levomenthol (menthol)	gel for external use	50mg/g+30mg/g; 15g aluminum tube, 50g aluminum tube, 100g aluminum tube	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	OTC	23310 25.08.2025
9	Strepsils Express	dichlorobenzyl alcohol, amylmetacresol, lidocaine (lidocain hydrochloride monohydrate)	lozenges	1,2mg+0,6mg+10mg; (24/2x12/) in blister, (24/3x8) in blister	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	OTC	23311 25.08.2025
10	Lisinopril	lisinopril (lisinopril dihydrate)	tablets	5mg; (24/1x24/) 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	23312 25.08.2025
11	Digoxin	digoxin	tablets	0,25mg; (40/1x40/) 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	23313 25.08.2025
12	5% Glucose solution for injection	glucose anhydrous	solution for infusion	50mg/ml; 100ml plastic pack, 200ml plastic pack, 250ml plastic pack, 400ml plastic pack, 500ml plastic pack, 1000ml plastic pack, 2000ml plastic pack and 3000ml plastic pack	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	23314 25.08.2025

13	10% Glucose solution for injection	glucose anhydrous	solution for infusion	100mg/ml; 100ml plastic pack, 200ml plastic pack, 250ml 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	23315 25.08.2025
14	Gamlate B6	magnesium glutamate hydrobromide, gamma-aminobutyric acid, gamma-amino-beta-hydroxybutyric acid, vitamin B6	tablets coated	75mg+75mg+37mg+37mg; (20/2x10/) in blister	Ferrer International, S.A., Joan Buscalla,1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer International, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	PoM	23316 25.08.2025
15	Eurofer	iron (III)-hydroxide polymaltose complex	syrup	10mg/ml; glass bottle 60ml, glass bottle 120ml	Osoth Inter Laboratories Co., Ltd., 600/9 Moo 11, Sukhaphiban 8 Road, Nong Kham, Si Racha, Chonburi 20230	Thailand	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	23317 25.08.2025
16	Metypred	methylprednisolone	tablets	4mg; (30) in plastic container	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	PoM	23318 25.08.2025
17	Metypred	methylprednisolone	tablets	16mg; (30) in plastic container	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	PoM	23319 25.08.2025
18	Meropenem-Asteria	meropenem	powder for solution for i/v injection/ infusion	500mg; (1) glass vial, (10) glass vials	Hankook Korus Pharm Co., Ltd, 78 Daepungsandan-ro, Daeso-myeon, Eumseong-gun, Chungcheongbuk-do	Republic of Korea	Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan	Republic of Armenia	PoM	23320 25.08.2025

LIST

of the variations requiring registration approved by the Center according to the meeting decision N 08-1/25 on August 25, 202

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	Arbidol-Oticipharm Pro	umifenovir (umifenovir hydrochloride)	capsules	100mg; (10/1x10) in blister, (20/2x10) in blister, (40/4x10) in blister	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov str., 6, building 1	Russia	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov str., 6, building 1, 238315	Russia	OTC	23393 25.08.2025
2	Azitrox-Oticipharm Pro	azithromycin (azithromycin dihydrate)	capsules	250mg; (6/1x6) in blister	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov str., 6, building 1	Russia	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov str., 6, building 1, 238315	Russia	PoM	23394 25.08.2025
3	Azitrox-Oticipharm Pro	azithromycin (azithromycin dihydrate)	capsules	500mg; (2/1x2) in blister, (3/1x3) in blister	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov str., 6, building 1	Russia	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov str., 6, building 1, 238315	Russia	PoM	23395 25.08.2025

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 08-1/25 on August 25, 202

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	Doxycycline EXPRESS-Pharmstandard	doxycycline (doxycycline monohydrate)	tablets dispersible	100mg; (10/1x10) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	PoM	22466/1/1 25.08.2025
2	Metoprolol	metoprolol (metoprolol tartrate)	tablets	50mg; (30/3x10) 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	19486/1/1 25.08.2025
3	FUROSEMIDE	furosemide	tablets	40mg; (40/1x40) in blister, (40/4x10) 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	19358/1/1 25.08.2025
4	Arbidol-Oticipharm Pro	umifenovir (umifenovir hydrochloride)	capsules	100mg; (10/1x10) in blister, (20/2x10) in blister, (40/4x10) in blister	Pharmstandard-Leksredstva OJSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	"Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov str., 6, building 1, 238315	Russia	OTC	22668/1/1 25.08.2025
5	Maxicold Rhino-Oticipharm	phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid, paracetamol	powder for oral solution with lemon flavour	10mg+20mg+50mg+325mg; (5) sachets 15g, (10) sachets 15g	Pharmstandard-Leksredstva JSC, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC JSC "Oticipharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	22909/1/1 25.08.2025
6	Maxicold Rhino-Oticipharm	phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid, paracetamol	powder for oral solution with orange flavour	10mg+20mg+50mg+325mg; (5) sachets 15g, (10) sachets 15g	Pharmstandard-Leksredstva JSC, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC JSC "Oticipharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	22910/1/1 25.08.2025

7	Maxicold Rhino-Oticipharm	phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid, paracetamol	powder for oral solution with raspberry flavour	10mg+20mg+50mg+325mg; (5) sachets 15g, (10) sachets 15g	Pharmstandard-Leksredstva JSC, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC JSC "Oticipharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	22911/1/1 25.08.2025
8	Azitrox-Oticipharm Pro	azithromycin (azithromycin dihydrate)	capsules	250mg; (6/1x6) in blister	Pharmstandard-Leksredstva OJSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov str., 6, building 1, 238315	Russia	PoM	22978/1/1 25.08.2025
9	Azitrox-Oticipharm Pro	azithromycin (azithromycin dihydrate)	capsules	500mg; (2/1x2) in blister, (3/1x3) in blister	Pharmstandard-Leksredstva OJSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov str., 6, building 1, 238315	Russia	PoM	22979/1/1 25.08.2025
10	Lisinopril	lisinopril (lisinopril dihydrate)	tablets	5mg; (24/1x24) 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	19618/2/1 25.08.2025
11	Lisinopril	lisinopril (lisinopril dihydrate)	tablets	10mg; (24/1x24) 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	22018/2/1 25.08.2025
12	Digoxin	digoxin	tablets	0,25mg; (40/1x40) 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	19617/1/1 25.08.2025
13	MELON-RATIONAL	ambroxol (ambroxol hydrochloride), salbutamol (salbutamol sulfate), guaifenesin	tablets	15mg+2mg+100mg; (30/3x10) in blister	Aversi-Rational Ltd, Chirakhuli Str. 14, 0198 Tbilisi- secondary packager, quality control, batch releaser, Geno Pharmaceuticals Pvt. Ltd, Tivim Industrial Estate, Karaswada Mapusa, Goa 403526, India- bulk manufacturer, primary packager	Georgia	Aversi-Rational Ltd, Chirakhuli Str. 14, 0198 Tbilisi	Georgia	PoM	21746/2/2 25.08.2025
14	Orlobin-NEO	amikacin (amikacin sulfate)	solution for injection/ infusion	500mg/2ml; (1) glass vial 2ml, (5) ampoules 2ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Medicus S.A., 10 Valaoritou str., GR 144 52, Metamorfofi, Attiki	Greece	PoM	21414/3/3 25.08.2025

15	Gonadotropin chorionic	gonadotrophin chorionic	powder lyophilized for solution for i/m injection	5000IU; (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	22444/1/1 25.08.2025
16	Meropenem-Asteria	meropenem	powder for solution for i/v injection/ infusion	500mg; (1) glass vial, (10) glass vials	Hankook Korus Pharm Co., Ltd, 78 Daepungsandan-ro, Daeso-myeon, Eumseong-gun, Chungcheongbuk-do	Republic of Korea	Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan	Republic of Armenia	PoM	19512/2/1 25.08.2025
17	Tobradex	tobramycin, dexamethasone	ointment eye	3mg/g+1mg/g; 3,5g aluminium tube	Novartis Manufacturing N.V., Rijksweg 14, Puurs-Sint- Amands, 2870	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	21669/1/1 25.08.2025
18	Amoxicillin + Clavulanic acid EXPRESS- Pharmstandard	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets dispersible	125mg+31,25mg; (14/2x7/) in blister	Pharmaceutical Firm "LEKKO" CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 280- quality control, batch releaser, Pharmaceutical Firm "LEKKO" CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager	Russia	Pharmaceutical Firm "LEKKO" CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s. 278	Russia	PoM	22657/1/1 25.08.2025
19	Amoxicillin + Clavulanic acid EXPRESS- Pharmstandard	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets dispersible	250mg+62,5mg; (14/2x7/) in blister	Pharmaceutical Firm "LEKKO" CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 280- quality control, batch releaser, Pharmaceutical Firm "LEKKO" CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager	Russia	Pharmaceutical Firm "LEKKO" CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s. 278	Russia	PoM	22658/1/1 25.08.2025
20	Amoxicillin + Clavulanic acid EXPRESS- Pharmstandard	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets dispersible	500mg+125mg; (14/2x7/) in blister	Pharmaceutical Firm "LEKKO" CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 280- quality control, batch releaser, Pharmaceutical Firm "LEKKO" CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager	Russia	Pharmaceutical Firm "LEKKO" CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s. 278	Russia	PoM	22659/1/1 25.08.2025

21	Amoxicillin + Clavulanic acid EXPRESS- Pharmstandard	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets dispersible	875mg+125mg; (14/2x7/) in blister	Pharmaceutical Firm "LEKKO" CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 280- quality control, batch releaser, Pharmaceutical Firm "LEKKO" CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager	Russia	Pharmaceutical Firm "LEKKO" CJSC, 601125, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s. 278	Russia	PoM	22660/1/1 25.08.2025
22	Amoxicillin EXPRESS- Pharmstandard	amoxicillin (amoxicillin trihydrate)	tablets dispersible	125mg; (20/2x10/) in blister	Pharmaceutical Firm "LEKKO" CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 280- quality control, batch releaser, Pharmaceutical Firm "LEKKO" CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager	Russia	Pharmaceutical Firm "LEKKO" CJSC, 601125, Vladimir region, Volginsky settlement, Zavodskaya s. 278	Russia	PoM	22462/1/1 25.08.2025
23	Amoxicillin EXPRESS- Pharmstandard	amoxicillin (amoxicillin trihydrate)	tablets dispersible	250mg; (20/2x10/) in blister	Pharmaceutical Firm "LEKKO" CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 280- quality control, batch releaser, Pharmaceutical Firm "LEKKO" CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager	Russia	Pharmaceutical Firm "LEKKO" CJSC, 601125, Vladimir region, Volginsky settlement, Zavodskaya s. 278	Russia	PoM	22463/1/1 25.08.2025
24	Amoxicillin EXPRESS- Pharmstandard	amoxicillin (amoxicillin trihydrate)	tablets dispersible	500mg; (20/2x10/) in blister	Pharmaceutical Firm "LEKKO" CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 280- quality control, batch releaser, Pharmaceutical Firm "LEKKO" CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager	Russia	Pharmaceutical Firm "LEKKO" CJSC, 601125, Vladimir region, Volginsky settlement, Zavodskaya s. 278	Russia	PoM	22464/1/1 25.08.2025

25	Amoxicillin EXPRESS- Pharmstandard	amoxicillin (amoxicillin trihydrate)	tablets dispersible	1000mg; (20/2x10/) in blister	Pharmaceutical Firm "LEKKO" CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 280- quality control, batch releaser, Pharmaceutical Firm "LEKKO" CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager	Russia	Pharmaceutical Firm "LEKKO" CJSC, 601125, Vladimir region, Volginsky settlement, Zavodskaya s. 278	Russia	PoM	22465/1/1 25.08.2025
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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 08-1/25 on August 25, 202

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	Dioxydine	dioxidine	drops ear	2,5mg/ml; 10ml plastic vial-dropper	Grotex LLC, Industrialniy av. 71, bld. 2, lit. A, Saint Petersburg, 195279	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	PoM	ЛПТ-№010290-ИТИ-АМ 25.08.2025

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of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 08-1/25 on August 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	Pelethrocin Plus	diosmin, hesperidin	tablets film-coated	450mg+50mg; (30/2x15/) in blister, (60/4x15/) in blister	Help S.A. Pedini, Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 144 52, Metamorphosis, Attika	Greece	OTC	21185/1 25.08.2025
2	Tobradex	tobramycin, dexamethasone	drops eye (suspension)	3mg/ml+1mg/ml; 5ml plastic vial	S.A. Alcon-Couvreur N.V., Rijksweg 14, Puurs-Sint- Amands, 2870	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18048/5/1 25.08.2025
3	Acnamino MR 100mg Capsules	minocycline (minocycline hydrochloride)	capsules hard	100mg; (56/8x7/) in blister	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB- batch releaser, Dexcel Ltd., 1 Dexcel Street, Or-Akiva 3060000, Israel- bulk manufacturer, packager, quality control (physicochemical), The Institute for Food Microbiology and Consumer Goods Ltd., 9 HaShalom Road, Nesher, Israel- quality control (microbiological)	UK	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB	UK	PoM	21674/4 25.08.2025

4	Traumeel	achillea millefolium D3, napellus D2, arnica montana D2, atropa bella-donna D2, bellis perennis D2, calendula officinalis D2, echinacea D2, echinacea purpurea D2, hamamelis virginiana D1, hepar sulfuris D6, hypericum perforatum D2, matricaria recutita D3, mercurius solubilis Hahnemanni D6, symphytum officinale D6	solution for injection	2,2mg/2,2ml+1,32mg/2,2ml +2,2mg/2,2ml+2,2mg/2,2ml +1,1mg/2,2ml+2,2mg/2,2ml +0,55mg/2,2ml+0,55mg/2,2ml +0,22mg/2,2ml+2,2mg/2,2ml +0,66mg/2,2ml+2,2mg/2,2ml +1,1mg/2,2ml+2,2mg/2,2ml (10) ampoules 2,2ml, (100) ampoules 2,2ml	Biologische Heilmittel Heel GmbH, Dr.-Reckeweg-Strasse 2-4, 76532 Baden-Baden	Germany	Biologische Heilmittel Heel GmbH, Dr.- Reckeweg-Strasse 2-4, 76532 Baden-Baden	Germany	PoM	19591/2 25.08.2025
5	TETRACYCLINE EYE OINTMENT 1%	tetracycline	ointment eye	10mg/g; aluminium tube 3g	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	19237/1 25.08.2025
6	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	19061/1 25.08.2025
7	Katarel	tenoxicam	powder lyophilized and solvent for solution for i/m/i/v injection	20mg; glass vial and solvent in ampoule 2ml	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	20295/2 25.08.2025
8	Levicitam	levetiracetam	tablets film-coated	250mg; (30/3x10) in blister, (60/6x10) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	22104/2 25.08.2025
9	Levicitam	levetiracetam	tablets film-coated	500mg; (30/3x10) in blister, (60/6x10) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	22105/2 25.08.2025
10	Eurofer	iron (III)-hydroxide polymaltose complex	syrup	10mg/ml; glass bottle 60ml, glass bottle 120ml	Osoth Inter Laboratories Co., Ltd., 600/9 Moo 11, Sukhaphiban 8 Road, Nong Kham, Si Racha, Chonburi 20230	Thailand	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	19271/1 25.08.2025

11	Wobenzym	pancreatin, trypsin, chymotrypsin, bromelain, papain, amylase, lipase, rutoside trihydrate	tablets gastro-resistant	300 prot.UA+360FIP-U+300FIP-U+225FIP-U+90FIP-U+50FIP-U+34FIP-U+50mg (40/2x20) and (200/10x20) in blister, (800) in plastic container	Mucos Emulsionsgesellschaft mbH, Miraustrasse 17, D-13509 Berlin	Germany	Mucos Pharma GmbH & Co. KG, Miraustrasse 17, D-13509 Berlin	Germany	OTC	21258/5 25.08.2025
12	Metypred	methylprednisolone	tablets	4mg; (30) in plastic container	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	PoM	19033/1 25.08.2025
13	Metypred	methylprednisolone	tablets	16mg; (30) in plastic container	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	PoM	19034/1 25.08.2025
14	Voltaren Retard	diclofenac (diclofenac sodium)	tablets prolonged-release	75mg; (20/2x10) in blister	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20294/2 25.08.2025
15	KISQALI	ribociclib (ribociclib succinate)	tablets film-coated	200mg; (21/1x21) in PA/AL/PVC blister, (21/1x21) in PVC/PCTFE blister, (63/3x21) in PA/AL/PVC blister, (63/3x21) in PVC/PCTFE blister	Novartis Pharmaceutical Manufacturing LLC, Verovskova Ulica 57, Ljubljana 1000	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22412/1 25.08.2025
16	KISQALI	ribociclib (ribociclib succinate)	tablets film-coated	200mg; (21/1x21) in blister, (63/3x21) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein AG, 4332- packager, batch releaser, Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd., 10 Tuas Bay Lane, 637461 Singapore, Singapore- bulk manufacturer, quality control	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20278/4 25.08.2025
17	Nicorette	nicotine	spray	1mg/dose; (1) plastic container 13,2ml(150 dose) with pump dispenser, (2) plastic container 13,2ml(150 dose) with pump dispenser	McNeil AB Norrebroplatsen 2, Helsingborg, 25109	Sweden	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	OTC	18839/2/1 25.08.2025
18	Cratal	crataegus, leonurus, taurine	tablets	43mg+87mg+867mg; (20/2x10) in blister	SIC "Borshchahivskiy Chemical-Pharmaceutical Plant" PJSC, 17, Mira St, Kyiv, 03134	Ukraine	SIC "Borshchahivskiy Chemical-Pharmaceutical Plant" PJSC, 17, Mira St, Kyiv, 03134	Ukraine	OTC	18664/1 25.08.2025

19	Ceftriaxone 1g powder for solution for injection or infusion	ceftriaxone (ceftriaxone sodium)	powder for solution for injection or infusion	1000mg; (10) glass vials	CP Pharmaceuticals Ltd., Ash Road North, Wrexham, LL13 9UF- batch releaser, Labesfal-Laboratorios Almiro, S.A, Zona Industrial do Lagedo, Santiago de Besteiros, 3465-157, Portugal- bulk manufacturer, packager, quality control	UK	Wockhardt UK Ltd., Ash Road North, Wrexham, LL13 9UF	UK	PoM	19283/1 25.08.2025
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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 08-1/25 on August 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	Xarelto	rivaroxaban	tablets film-coated	10mg; (30/3x10/) in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	ЛПТ-№003802-ПТ-АМ 25.08.2025
2	Xarelto	rivaroxaban	tablets film-coated	10mg; (30/3x10/) 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	ЛПТ-№003802-ПТ-АМ 25.08.2025
3	Mesinil	nimesulide	tablets	100mg; (30/3x10) in blister	Pharmtechnology LLC, 22, Korzhenevskogo str., 220024, Minsk	Republic of Belarus	Giga Farm LLC, Gogunts str. 3/5, Gyumri	Republic of Armenia	PoM	ЛПТ-№005647-ПТ-АМ 25.08.2025
4	Azirex	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3/) in blister	Pharmtechnology LLC, Korzhenevskogo str., 22, 220024, Minsk	Republic of Belarus	Giga Farm LLC, Gogunca str.3/5, Gyumri	Republic of Armenia	PoM	ЛПТ-№002360-ПТ-АМ 25.08.2025
5	Tetracaine	tetracaine (tetracaine hydrochloride)	drops eye	10mg/ml; 10ml plastic vial-dropper	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	ЛПТ-№006443-ПТ-АМ 25.08.2025
6	Kaporiza	rizatriptane (rizatriptane benzoate)	orodispersible tablets	10mg; (2/1x2/) in blister, (6/1x6/) in blister	Emcure Pharmaceuticals Ltd., Plot No. P-1 & P-2, I.T.B.T., Park Phase-II, M.I.D.C., Hinjwadi, Pune-411057	India	"Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	PoM	ЛПТ-№001129-ПТ-АМ 25.08.2025

7	Kaporiza	rizatriptane (rizatriptane benzoate)	orodispersible tablets	10mg; (2/1x2/) in blister, (6/1x6/) in blister, (6/3x2/) in blister	SotexPharmFirm" CJSC, bld. 11, village Belikovo, Sergiev-Posad municipal district, Moscow Region- quality control, batch releaser, " Emcure Pharmaceuticals Ltd., Plot No. P-1 & P-2, I.T.B.T., Park Phase-II, M.I.D.C., Hinjwadi, Pune-411057, India- bulk manufacturer, primary packager, "Sotex"PharmFirm" CJSC, bld. 12, village Belikovo, Sergiev-Posad municipal district, Moscow Region, Russia- secondary packager	Russia	"Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, city Sergiev-Posad, Moscow Region, 141345	Russia	PoM	ЛПТ-№001129-PT-AM 25.08.2025
8	Thiogamma	thioctic acid	tablets film-coated	600mg; (30/3x10/) in blister, (60/6x10/) in blister, (100/10x10/) in blister	Dragenopharm Apotheker Puschl GmbH, Gollstrasse 1, 84529 Tittmoning- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological)	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen	Germany	PoM	ЛПТ-№000229-ITI-AM 25.08.2025
9	Thiogamma	thioctic acid	tablets film-coated	600mg; (30/3x10/) in blister, (60/6x10/) in blister, (100/10x10/) in blister	Worwag Pharma Operations Sp. z o.o., Ul. Gen. Mariana Langiewiczza 58, Konstantynow Lodzki, 95-050- bulk manufacturer, packager, quality control (physicochemical), batch releaser, MIKROLAB Spotka z ograniczona odpowiedzialnoscia, ul. Lubelska 5/7, 03-802 Warszawa, Poland- quality control (microbiological)	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen	Germany	PoM	ЛПТ-№000229-ITI-AM 25.08.2025
10	Cavinton	vinpocetine	tablets	5mg; (50/2x25/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛПТ-№002164-ITI-AM 25.08.2025
11	Cavinton	vinpocetine	tablets	5mg; (50/2x25/) in blister	Gedeon Richter-RUS JSC, Lesnaya st. 40, Shuvoye, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, quality control, batch releaser, Gedeon Richter-RUS JSC, Lesnaya st. 43/5, Shuvoye, Moscow region, Yegoriyevsky district, 140342, RussiaGedeon Richter-RUS JSC, Lesnaya st. 43/5, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager	Russia	Gedeon Richter Plc., Gyomroi ut 19-21, Budapest, 1103	Hungary	PoM	ЛПТ-№002164-ITI-AM 25.08.2025

12	Rozamet	metronidazole	cream for external use	10mg/g; aluminum tube 25g	JADRAN-GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	JADRAN-GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	OTC	JIT-N°006064- ITI-AM 25.08.2025
13	Efleira	netakimab	solution for subcutaneous injection	60mg/ml; (2/2x1/) glass syringes 1 ml in blister, (2/2x1/) glass syringes 1 ml in blister and N2 alcohol swabs, (2/1x2/) plastic autoinjector 1ml in blister, (2/1x2/) plastic autoinjector 1ml in blister and (2) alcohol swabs	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	JIT-N°005293- ITI-AM 25.08.2025
14	Efleira	netakimab	solution for subcutaneous injection	60mg/ml; (2/2x1/) glass syringes 1 ml in blister, (2/2x1/) glass syringes 1 ml in blister and N2 alcohol swabs, (2/1x2/) plastic autoinjector 1ml in blister, (2/1x2/) plastic autoinjector 1ml in blister and (2) alcohol swabs	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422- quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422, Russia- bulk manufacturer, packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	JIT-N°005293- ITI-AM 25.08.2025
15	Cavinton Forte	vinpocetine	tablets	10mg; (30/2x15/) in blister, (90/6x15/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JIT-N°002183- ITI-AM 25.08.2025
16	Cavinton Forte	vinpocetine	tablets	10mg; (30/2x15/) in blister, (90/6x15/) in blister	Gedeon Richter-RUS JSC, Lesnaya st. 40, Shuvoye, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, quality control, batch releaser, Gedeon Richter-RUS JSC, Lesnaya st. 43/5, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JIT-N°002183- ITI-AM 25.08.2025
17	Preductal MR	trimetazidine (trimetazidine dihydrochloride)	tablets film-coated modified-release	35mg; (60/2x30/) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JIT-N°000386- ITI-AM 25.08.2025
18	Preductal MR	trimetazidine (trimetazidine dihydrochloride)	tablets film-coated modified-release	35mg; (60/2x30/) 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	JIT-N°000386- ITI-AM 25.08.2025
19	Caffetin Duo	ibuprofen, paracetamol	tablets film-coated	200mg+500mg; (10/1x10/) in blister, (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	OTC	JIT-N°005636- PI-AM 25.08.2025

20	Chondroxid Artra	chondroitin sulfate (chondroitin sulfate sodium)	ointment for external use	50mg/g; 30g aluminium tube or plastic tube	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, s.1- quality control, batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia- bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	ЛПТ-№003306- ITI-AM 25.08.2025
21	Coraxan 5mg	ivabradine	tablets film-coated	5mg; (14/1x14/) in blister, (28/2x14/) in blister, (52/2x26/) in blister, (56/4x14/) in blister, (1000-300000) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№000306- ITI-AM 25.08.2025
22	Coraxan 5mg	ivabradine	tablets film-coated	5mg; (14/1x14/) in blister, (28/2x14/) in blister, (52/2x26/) in blister, (56/4x14/) in blister, (1000-300000) in plastic container	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	PoM	ЛПТ-№000306- ITI-AM 25.08.2025
23	Coraxan 5mg	ivabradine	tablets film-coated	5mg; (14/1x14/) in blister, (28/2x14/) in blister, (52/2x26/) in blister, (56/4x14/) in blister, (1000-300000) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№000306- ITI-AM 25.08.2025
24	Coraxan 7,5mg	ivabradine	tablets film-coated	7,5mg; (14/1x14/) in blister, (28/2x14/) in blister, (52/2x26/) in blister, (56/4x14/) in blister, (1000-300000) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№000306- ITI-AM 25.08.2025
25	Coraxan 7,5mg	ivabradine	tablets film-coated	7,5mg; (14/1x14/) in blister, (28/2x14/) in blister, (52/2x26/) in blister, (56/4x14/) in blister, (1000-300000) in plastic container	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	PoM	ЛПТ-№000306- ITI-AM 25.08.2025

26	Coraxan 7,5mg	ivabradine	tablets film-coated	7,5mg; (14/1x14/) in blister, (28/2x14/) in blister, (52/2x26/) in blister, (56/4x14/) in blister, (1000-300000) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№000306-ITI-AM 25.08.2025
27	Nalgesin	naproxen (naproxen sodium)	tablets film-coated	275mg; (10/1x10/) in blister, (20/2x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- packager, quality control, batch releaser, Unichem Laboratories Limited, Plots 15, 16, 17, 17A,18, Pilerne Industrial Estate, Pilerne, Bardez GoA, 403511, India- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	ЛПТ-№000256-ITI-AM 25.08.2025
28	Nalgesin	naproxen (naproxen sodium)	tablets film-coated	275mg; (10/1x10/) in blister, (20/2x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Labena, d.o.o, Teslova 30, 1000 Lyublyana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	ЛПТ-№000256-ITI-AM 25.08.2025
29	Nalgesin	naproxen (naproxen sodium)	tablets film-coated	275mg; (10/1x10/) in blister, (20/2x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	ЛПТ-№000256-ITI-AM 25.08.2025
30	Nalgesin forte	naproxen (naproxen sodium)	tablets film-coated	550mg; (10/1x10/) in blister, (20/2x10/) in blister, (60/6x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- packager, quality control, batch releaser, Unichem Laboratories Limited, Plots 15, 16, 17, 17A,18, Pilerne Industrial Estate, Pilerne, Bardez GoA, 403511, India- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	ЛПТ-№000259-ITI-AM 25.08.2025
31	Nalgesin forte	naproxen (naproxen sodium)	tablets film-coated	550mg; (10/1x10/) in blister, (20/2x10/) in blister, (60/6x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Labena, d.o.o, Teslova 30, 1000 Lyublyana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	ЛПТ-№000259-ITI-AM 25.08.2025
32	Nalgesin forte	naproxen (naproxen sodium)	tablets film-coated	550mg; (10/1x10/) in blister, (20/2x10/) in blister, (60/6x10/) 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	ЛПТ-№000259-ITI-AM 25.08.2025

33	Klion-D 100	metronidazole, miconazole (miconazole nitrate)	tablets vaginal	100mg+100mg; (10/1x10) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- bulk manufacturer, packager, quality control (physicochemical), Gedeon Richter Plc., 2510 Dorog, Esztergomi st. 27, Hungary- quality control (microbiological)	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛПТ-№004189- ITI-AM 25.08.2025
34	Klion-D 100	metronidazole, miconazole (miconazole nitrate)	tablets vaginal	100mg+100mg; (10/1x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, batch releaser, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛПТ-№004189- ITI-AM 25.08.2025
35	Klion-D 100	metronidazole, miconazole (miconazole nitrate)	tablets vaginal	100mg+100mg; (10/1x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest, Hungary- bulk manufacturer, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛПТ-№004189- ITI-AM 25.08.2025