

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 11-1/25 on November 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	Kortipan	betamethasone (betamethasone dipropionate), betamethasone (betamethasone sodium phosphate)	suspension for injection	5mg/ml+2mg/ml; (5/1x5/) ampoules 1ml in blister	SC Balkan Pharmaceuticals SRL, Industrial street 7/A, MD-2091 Singera	Moldova	VEGAPHARM LLP, Unit 18, Normon road 53, Greenwich Centre Business Park, SE10 9QF, London	United Kingdom	PoM	23630 25.11.2025
2	Sitaget-M	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+500mg; (35/5x7/) 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	23631 25.11.2025
3	Sitaget-M	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+1000mg; (35/5x7/) 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	23632 25.11.2025
4	Sitacretin Plus	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+850mg; (30/3x10/) in blister	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansura-Aleppo	Syria	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansura-Aleppo	Syria	PoM	23633 25.11.2025
5	Sitacretin Plus	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+1000mg;(30/3x10/) in blister	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansura-Aleppo	Syria	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansura-Aleppo	Syria	PoM	23634 25.11.2025
6	Mukaltishka-Pharmstandard	althaeae radix dry extract	syrup	2g/100g; 100ml glass bottle, 100ml glass bottle and measuring spoon	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	23635 25.11.2025

7	Theorytin MF	theorytine	tablets	4mg; (10/1x10) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Centemo LLC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2.	Russia	OTC	23636 25.11.2025
8	Moxonidin Avexima	moxonidine	tablets film-coated	0,2mg; (60/6x10) in blister, (60/3x20) in blister, (100/5x20) in blister	Irbitskiy himfarmzavod OJSC, 124-a, K. Marksa str., Irbit, St. Sverdlovsk, 623856	Russia	Avexima OJSC, 31A/1, Leningradsky pr., Moscow, 125284	Russia	PoM	23637 25.11.2025
9	Moxonidin Avexima	moxonidine	tablets film-coated	0,4mg; (60/6x10) in blister, (60/3x20) in blister, (100/5x20) in blister	Irbitskiy himfarmzavod OJSC, 124-a, K. Marksa str., Irbit, St. Sverdlovsk, 623856	Russia	Avexima OJSC, 31A/1, Leningradsky pr., Moscow, 125284	Russia	PoM	23638 25.11.2025
10	Empa Pure	empagliflozin	tablets film-coated	10mg; (10/1x10) in blister	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansura-Aleppo	Syria	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansura-Aleppo	Syria	PoM	23639 25.11.2025
11	Empa Pure	empagliflozin	tablets film-coated	25mg; (10/1x10) in blister	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansura-Aleppo	Syria	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansura-Aleppo	Syria	PoM	23640 25.11.2025
12	Nuroton Duo Fast	ibuprofen	capsules	400mg; (10/1x10) in blister, (20/2x10) in blister, (30/3x10) in blister, (50/5x10) in blister, (100/10x10) in blister	Zahravi Pharmaceutical Company, Alinasab Industrial Town, Serum Darou St., Opp. Agricultural Training Center, 19th Km, Tehran Road, Tabriz	Iran	Giga Farm LLC, Gogunc St. 3/5, 3101, Gyumri	Republic of Armenia	OTC	23641 25.11.2025
13	ZETOR	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (30/3x10) in blister	GM Pharmaceuticals Ltd, Rustavi Highway 52,Tbilisi	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52,Tbilisi	Georgia	PoM	23642 25.11.2025
14	ZETOR	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (30/3x10) in blister	GM Pharmaceuticals Ltd, Rustavi Highway 52,Tbilisi	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52,Tbilisi	Georgia	PoM	23643 25.11.2025

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of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 11-1/25 on November 25, 2025

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1	Neobutin Retard	trimebutin	tablets modified-release film-coated	300mg; (20/2x10') in blister, (60/6x10') in blister	ALIUM JSC, Moscow region, Serpukhov city district, Obolensk settlement, Quarter A, No: 2, build. 1, 142279- quality control, batch releaser, ALIUM JSC, Moscow region, Serpukhov city district, Obolensk settlement, Quarter A, No: 2, 142279, Russia- bulk manufacturer, packager	Russia	ALIUM JSC, Moscow region, Serpukhov city, Obolensk settlement, Quarter A No: 2, 142279	Russia	PoM	23651 (001249) 25.11.2025
2	Amaryl M	glimepiride, metformin (metformin hydrochloride)	tablets film-coated	2mg+500mg; (30/3x10') in blister	Handok Inc., 78 Daepungsandan-ro, Daeso-myeon, Eumseong-gun, Chungcheongbuk-do	Republic of Korea	Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly	France	PoM	23652 (000437) 25.11.2025
3	Karvidil	carvedilol	tablets	6,25mg; (28/2x14') in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	23653 (005404) 25.11.2025
4	Karvidil	carvedilol	tablets	12,5mg; (28/2x14') in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	23654 (005404) 25.11.2025
5	Karvidil	carvedilol	tablets	25mg; (28/2x14') in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	23655 (005404) 25.11.2025
6	Mexiprim	ethylmethylhydroxypyridine succinate	solution for i/m and i/v injection	50mg/ml; (5/1x5') ampoules 2ml in blister, (10/2x5') ampoules 2ml in blister, (15/3x5') ampoules 2ml in blister	Scientific Technological Pharmaceutical Firm "POLYSAN" LLC, Salova str., Bld 72, Unit 2, Litt. A, Saint Petersburg, 192102	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	23656 (017581) 25.11.2025

7	Mexiprim	ethylmethylhydroxypyridine succinate	solution for i/m and i/v injection	50mg/ml; (5/1x5/) ampoules 5ml in blister, (10/2x5/) ampoules 5ml in blister, (15/3x5/) ampoules 5ml in blister	Scientific Technological Pharmaceutical Firm "POLYSAN" LLC, Salova str., Bld 72, Unit 2, Litt. A, Saint Petersburg, 192102	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	23657 (017581) 25.11.2025
8	Rexetin	paroxetine (paroxetine hydrochloride hemihydrate)	tablets film-coated	20mg; (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	23658 (016699) 25.11.2025
9	Miopriston	mifepristone	tablets	200mg; (1/1x1/) in blister, (2/2x1/) in blister, (3/3x1/) in blister, (5/5x1/) in blister, (2/1x2/) in blister, (4/2x2/) in blister, (6/3x2/) in blister, (10/5x2/) in blister, (3/1x3/) in blister, (6/2x3/) in blister, (9/3x3/) in blister, (15/5x3/) in blister	Obninsk Chemical Pharmaceutical Company JSC, Kaluga region, Obninsk, str. Kiev highway, 3a/3- batch releaser, Obninsk Chemical Pharmaceutical Company JSC, Kaluga region, Obninsk, str. Kiev highway, 107, Russia- bulk manufacturer, packager, quality control (physicochemical), "FARMOBORONA" Research and Testing center LTD, 46A, Gagarin St., Korolyov, Moscow Region, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	23659 (007263) 25.11.2025
10	Heptral	ademetionine	tablets enteric-coated	500mg; (10/1x10/) in blister, (20/2x10/) in blister	AbbVie S.r.l., S.R. 148 Pontina KM 52, SNC- Campoverde di Aprilia (loc. Aprilia)-04011 Aprilia (LT)	Italy	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	PoM	23660 (011403) 25.11.2025
11	Heptral	ademetionine	tablets enteric-coated	500mg; (10/1x10/) in blister, (20/2x10/) in blister	VEROPHARM JSC, Belgorod region, Belgorod district, Rabochaya str., 14, 308013- bulk manufacturer, secondary packager, quality control, batch releaser, VEROPHARM JSC, Belgorod region, Belgorod district, Rabochaya str., 14, corpus 1, 308013, Russia- primary packager	Russia	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	PoM	23661 (011403) 25.11.2025

12	Heptral	ademetionine	tablets enteric-coated	500mg; (10/1x10/) in blister, (20/2x10/) in blister	VEROPHARM JSC, Belgorod region, Belgorod district, Rabochaya str., 14, 308013- secondary packager, quality control, batch releaser, VEROPHARM JSC, Belgorod region, Belgorod district, Rabochaya str., 14, corpus 1, 308013, Russia- bulk manufacturer, primary packager	Russia	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	PoM	23662 (011403) 25.11.2025
13	Heptral	ademetionine	tablets enteric-coated	500mg; (10/1x10/) in blister, (20/2x10/) in blister	VEROPHARM JSC, Belgorod region, Belgorod district, Rabochaya str., 14, 308013- secondary packager, quality control, batch releaser, VEROPHARM JSC, Belgorod region, Belgorod district, Rabochaya str., 14, corpus 2, 308013, Russia- bulk manufacturer, VEROPHARM JSC, Belgorod region, Belgorod district, Rabochaya str., 14, corpus 1, 308013, Russia- primary packager	Russia	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	PoM	23663 (011403) 25.11.2025
14	Ciprofloxacin	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	250mg; (10/1x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	PoM	23664 (005771) 25.11.2025
15	Ciprofloxacin	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	500mg; (10/1x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	PoM	23665 (005771) 25.11.2025
16	Nifuroxazide	nifuroxazide	tablets film-coated	100mg; (30/3x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 24, Stroiteley str., Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	PoM	23666 (002466) 25.11.2025
17	Sermion	nicergoline	tablets coated	10mg; (50/2x25/) in blister, (90/6x15/) in blister, (100/4x25/) in blister	Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno (AP)	Italy	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	23667 (009917) 25.11.2025

18	Proflosin	tamsulosin (tamsulosin hydrochloride)	capsules gastro-resistant prolonged-release	0,4mg; (10/1x10') in blister, (30/3x10') in blister, (100/10x10') in blister	Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden- packager, quality control, batch releaser, Synthon Hispania,S.L., C/Castello, No, Sant Boi de Llobregat, Barcelona 08830, Spain- bulk manufacturer	Germany	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, L-1611	Luxembourg	PoM	23668 (009917) 25.11.2025
19	GONAL-f	follitropin alfa	solution for s/c injection	300IU/0,5ml; pre-filled syringe 0,5ml and (8) needles	Merck Serono S.p.A., Via delle Magnolie 15, 70026 Moduno (BA)	Italy	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	23669 (008759) 25.11.2025
20	GONAL-f	follitropin alfa	solution for s/c injection	450IU/0,75ml; pre-filled pen-syringe 0,75ml and (12) needles	Merck Serono S.p.A., Via delle Magnolie 15, 70026 Moduno (BA)	Italy	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	23670 (008759) 25.11.2025
21	GONAL-f	follitropin alfa	solution for s/c injection	900IU/1,5ml; (1) pre-filled pen-syringe 1,5ml and (20) needles	Merck Serono S.p.A., Via delle Magnolie 15, 70026 Moduno (BA)	Italy	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	23671 (008759) 25.11.2025
22	GONAL-f	follitropin alfa	solution for s/c injection	300IU/0,5ml; pre-filled syringe 0,5ml and (8) needles	Merck Serono S.p.A., Via delle Magnolie 15, 70026 Moduno (BA)- bulk manufacturer, primary packager, quality control, batch releaser, Merck Serono S.A., Zone Industrielle de l'Ourietaz, Street De Lurietta 151, Aubonne, 1170, Switzerland- secondary packager	Italy	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	23672 (008759) 25.11.2025
23	GONAL-f	follitropin alfa	solution for s/c injection	450IU/0,75ml; pre-filled pen-syringe 0,75ml and (12) needles	Merck Serono S.p.A., Via delle Magnolie 15, 70026 Moduno (BA)- bulk manufacturer, primary packager, quality control, batch releaser, Merck Serono S.A., Zone Industrielle de l'Ourietaz, Street De Lurietta 151, Aubonne, 1170, Switzerland- secondary packager	Italy	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	23673 (008759) 25.11.2025
24	GONAL-f	follitropin alfa	solution for s/c injection	900IU/1,5ml; (1) pre-filled pen-syringe 1,5ml and (20) needles	Merck Serono S.p.A., Via delle Magnolie 15, 70026 Moduno (BA)- bulk manufacturer, primary packager, quality control, batch releaser, Merck Serono S.A., Zone Industrielle de l'Ourietaz, Street De Lurietta 151, Aubonne, 1170, Switzerland- secondary packager	Italy	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	23674 (008759) 25.11.2025

25	Ketotifen	ketotifen (ketotifen fumarate)	tablets	1mg; (30/3x10') 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	PoM	23675 (018362) 25.11.2025
26	Siofor 500	metformin (metformin hydrochloride)	tablets film- coated	500mg; (30/3x10') in blister, (60/6x10') in blister, (120/12x10') 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 (physicochemical)	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	23676 (008442) 25.11.2025
27	Siofor 500	metformin (metformin hydrochloride)	tablets film- coated	500mg; (30/3x10') in blister, (60/6x10') in blister, (120/12x10') in blister	ZAO Berlin-Pharma, 248926, Kaluga 2nd, Avtomobilniy proezd, bld. 5	Russia	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	23677 (018362) 25.11.2025
28	Siofor 500	metformin (metformin hydrochloride)	tablets film- coated	500mg; (30/3x10') in blister, (60/6x10') in blister, (120/12x10') in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- batch releaser, Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden, Germany- bulk manufacturer, packager, quality control	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	23678 (018362) 25.11.2025
29	Ultravist	iopromide	solution for injection	623mg/ml (300mg iodine/ml); (10) glass vials 10ml, (10) glass vials 20ml, (10) glass vials 50ml, (10) glass vials 100ml, (10) glass vials 200ml, (8) glass vials 500ml, (10(2x5/1x5')) plastic cartridges 100ml, in pack, (10(2x5/1x5')) plastic cartridges 150ml, in pack	Bayer AG, Mullerstrasse 178, 13353, Berlin	Germany	Bayer AG, Kaiser-Wilhelm- Allee 1, 51373 Leverkusen	Germany	PoM	23679 (015857) 25.11.2025
30	Ultravist	iopromide	solution for injection	623mg/ml (300mg iodine/ml); (10) glass vials 20ml, (1) glass vial 50ml, (1) glass vial 100ml, (1) glass vial 200ml, (1) glass vial 500ml	Scientific Technological Pharmaceutical Firm "POLYSAN" LLC, Salova str., Bld 72, Unit 2, Litt. A, Saint Petersburg, 192102	Russia	Bayer AG, Kaiser-Wilhelm- Allee 1, 51373 Leverkusen	Germany	PoM	23680 (015857) 25.11.2025

31	Ultravist	iopromide	solution for injection	769mg/ml (370mg iodine/ml); (10) glass vials 30ml, (10) glass vials 50ml, (10) glass vials 100ml, (10) glass vials 200ml, (8) glass vials 500ml, (10(2x5/1x5)) plastic cartridges 100ml, in pack, (10(2x5/1x5)) plastic cartridges 150ml, in pack	Bayer AG, Mullerstrasse 178, 13353, Berlin	Germany	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	PoM	23681 (015857) 25.11.2025
32	Ultravist	iopromide	solution for injection	769mg/ml (370mg iodine/ml); (10) glass vials 30ml, (1) glass vial 50ml, (1) glass vial 100ml, (1) glass vial 200ml, (1) glass vial 500ml	Scientific Technological Pharmaceutical Firm "POLYSAN" LLC, Salova str., Bld 72, Unit 2, Litt. A, Saint Petersburg, 192102	Russia	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	PoM	23682 (015857) 25.11.2025
33	Camphor spirt-Argo	camphor	alcohol solution for external use	2%; 40ml glass vial	"Yaroslavl Pharmaceutical Factory" JSC, Yaroslavl Region, 150030, Yaroslavl, 1st Putevaya Street b.5	Russia	ARGO-PHARM LLC, 13/9 Sundukyan str., 0012 Yerevan	Republic of Armenia	OTC	23650 (024135) 25.11.2025
34	Rovastat	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (28/4x7/) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice- quality control, batch releaser, Adamed Pharma S.A., 33, Szkolna St., 95-054 Ksawerow, Poland- bulk manufacturer, packager	Poland	Adamed Pharma S.A., Pienkow, 6A, M. Adamkiewicza St., 05-152 Czosnow	Poland	PoM	23646 (021234) 25.11.2025
35	Rovastat	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (28/4x7/) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice- quality control, batch releaser, Adamed Pharma S.A., 33, Szkolna St., 95-054 Ksawerow, Poland- bulk manufacturer, packager	Poland	Adamed Pharma S.A., Pienkow, 6A, M. Adamkiewicza St., 05-152 Czosnow	Poland	PoM	23647 (021234) 25.11.2025
36	Rovastat Duo	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets	10mg+10mg; (30/3x10) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego st., 95-200 Pabianice	Poland	Adamed Pharma S.A., Pienkow, 6A, M. Adamkiewicza St., 05-152 Czosnow	Poland	PoM	23648 (023914) 25.11.2025
37	Rovastat Duo	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets	20mg+10mg; (30/3x10) in blister, (30/2x15) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego st., 95-200 Pabianice	Poland	Adamed Pharma S.A., Pienkow, 6A, M. Adamkiewicza St., 05-152 Czosnow	Poland	PoM	23649 (023914) 25.11.2025

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1	Eutropin S Pen Inj.	somatropin	solution for s/c injection	36IU; pre-filled pen 3ml	LG Chem, Ltd., 151, Osongsaengmyeong 1-ro, Osong-eup. Heungdeok-gu, Cheongju-si, Chungcheongbuk-do	Republic of Korea	LG Chem Ltd., 128 Yeoui-daero, Yeongdeungpo-gu, Seoul	Republic of Korea	PoM	23629 25.11.2025

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1	Seretide Accuhaler / Diskus	salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)	powder for inhalation	50mcg+100mcg; (1) plastic inhaler disk (60 doses)	Glaxo Wellcome Production, Zone Industrielle N 2, 23 Rue Lavoisier, 27000 Evreux	France	Laboratoire GlaxoSmithKline, 23 rue Francois Jacob, 92500 Rueil-Malmaison	France	PoM	23626 25.11.2025
2	Seretide Accuhaler / Diskus	salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)	powder for inhalation	50mcg+250mcg; (1) plastic inhaler disk (60 doses)	Glaxo Wellcome Production, Zone Industrielle N 2, 23 Rue Lavoisier, 27000 Evreux	France	Laboratoire GlaxoSmithKline, 23 rue Francois Jacob, 92500 Rueil-Malmaison	France	PoM	23627 25.11.2025
3	Seretide Accuhaler / Diskus	salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)	powder for inhalation	50mcg+500mcg; plastic inhaler disk (60 doses)	Glaxo Wellcome Production, Zone Industrielle N 2, 23 Rue Lavoisier, 27000 Evreux	France	Laboratoire GlaxoSmithKline, 100 route de Versailles 78163 Marly-Le-Roi Cedex	France	PoM	23628 25.11.2025

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of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 11-1/25 on November 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	FLUCONAZOLE- ASTERIA Cap.150mg	fluconazole	capsules hard	150mg; (2/2x1/) in blister, (10/1x10/) in blister, (100/10x10/) in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-Si, Chungcheongbuk-do	Republic of Korea	Asteria LLC, 72/3 Nairi Zaryan str., 0051 Yerevan	Republic of Armenia	PoM	23624 25.11.2025
2	Gamalte B6	magnesium glutamate hydrobromide, gamma-aminobutyric acid, gamma-amino- beta-hydroxybutyric acid, vitamin B6	solution oral	20mg/ml+20mg/ml+10mg/ ml+10mg/ml; 80ml glass bottle	Ferrer Internacional, 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	23625 25.11.2025

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 11-1/25 on November 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	Bromhexin-Pharmstandard	bromhexine (bromhexine hydrochloride)	tablets	8mg; (20/1x20) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	21839/2/1 25.11.2025
2	FLUCONAZOLE-ASTERIA Cap.150mg	fluconazole	capsules hard	150mg; (2/2x1) in blister, (10/1x10) in blister, (100/10x10) in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeon-ro, Jecheon-Si, Chungcheongbuk-do	Republic of Korea	Asteria LLC, 72/3 Nairi Zaryan str., 0051 Yerevan	Republic of Armenia	PoM	19828/2/1 25.11.2025
3	Stresam	etifoxine (etifoxine hydrochloride)	capsules	50mg; (60/3x20) in blister	Biocodex, 1 avenue Blaise Pascal, 60000 Beauvais	France	Biocodex, 22 Rue des Aqueducs, 94250 Gentilly	France	PoM	21950/4/1 25.11.2025
4	Ascophen-P-Oticipharm	paracetamol, acetylsalicylic acid, caffeine	tablets	200mg+200mg+40mg; (10) in blister, 10(1x10) in blister, 20(2x10) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "Oticipharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	21614/1/1 25.11.2025
5	DuTamsul	dutasteride, tamsulosin (tamsulosin hydrochloride)	capsules hard	0,5mg+0+4mg; (30) plastic container	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	Genericon Pharma Gesellschaft m.b.H., Hafnerstrasse 211, 8054, Graz, Styria	Austria	PoM	21273/4/1 25.11.2025

6	Tonsilgon N	marshmallow root, matricaria flowers, horsetail herb, walnut leaves, yarrow herb, oak bark, dandelion herb	tablets coated	8mg+6mg+10mg+12mg+4mg+4mg+4mg; (50/2x25) in blister	Bionorica SE, Kerschensteinerstrasse 11-15, 92318 Neumarkt in der Oberpfalz- packager, quality control, batch releaser, Rottendorf Pharma GmbH, Ostfelder Strasse 51-61, 59320 Ennigerloh, Germany- bulk manufacturer	Germany	Bionorica SE, Kerschensteinerstrasse 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	20499/1/1 25.11.2025
7	Tonsilgon N	marshmallow root, matricaria flowers, horsetail herb, walnut leaves, yarrow herb, oak bark, dandelion herb	drops oral	4mg/g+3mg/g+5mg/g+4mg/g+4mg/g+2mg/ g+4mg/g; glass container-dropper 100ml	Bionorica SE, Kerschensteiner str. 11-15, 92318 Neumarkt in der Oberpfalz	Germany	Bionorica SE, Kerschensteiner str. 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	20582/1/1 25.11.2025
8	Ascorbic acid with glucose	ascorbic acid, dextrose (dextrose monohydrate)	tablets	100mg+877mg; (40) in plastic container	Pharmstandard-Ufa VITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	Pharmstandard-Ufa VITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	OTC	21239/2/1 25.11.2025
9	Demiflu Forte	paracetamol	tablets	1000mg; (20/2x10) in blister, (40/4x10) 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	22398/1/1 25.11.2025
10	Acyclovir Vision	aciclovir	ointment eye	30mg/g; aluminium tube 5g	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	Antibiotic-Razgrad AD, 68, Aprilsko vastanie Blvd, Razgrad, 7200	Bulgaria	PoM	22622/1/1 25.11.2025
11	Tyzine	xylometazoline (xylometazoline hydrochloride)	spray nasal	0,5mg/ml; glass bottle 10ml (140 dose) with dosator	Delpharm Orleans, 5 avenue de Concyr, 45071 Orleans, Cedex 2	France	JTNL LLC, 121614, Moscow, Krylatskaya intercity municipal district, Krylatskaya str., 17, bld. 3	Russia	OTC	22969/1/1 25.11.2025
12	Tyzine	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; glass bottle 10ml (70 dose) with dosator	Delpharm Orleans, 5 avenue de Concyr, 45071 Orleans, Cedex 2	France	JTNL LLC, 121614, Moscow, Krylatskaya intercity municipal district, Krylatskaya str., 17, bld. 3	Russia	OTC	22970/1/1 25.11.2025

13	Anaesthesol	benzocaine, bismuth subgallate, zinc oxyde, levomenthol	suppositories rectal	100mg+40mg+20mg+4mg; (10/2x5)	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	20537/2/2 25.11.2025
14	Ciprofloxacin Demipharm	ciprofloxacin	tablets film-coated	500mg; (1), (8/1x8) and (16/2x8) 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	19927/3/1 25.11.2025

LIST

of variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting decision N
11-1/25 on November 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	AZARGA	timolol (timolol maleate), brinzolamide	drops eye (suspension)	5mg/ml+10mg/ml; plastic vial-dropper 5ml	Novartis Manufacturing N.V., Rijksweg 14, Puurs-Sint- Amands, 2870	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	JITI-N°002179-ITI- AM 25.11.2025
2	Prestarium A	perindopril (perindopril arginine)	tablets film- coated	5mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000574-ITI- AM 25.11.2025
3	Prestarium A	perindopril (perindopril arginine)	tablets film- coated	5mg; (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284- packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000574-ITI- AM 25.11.2025
4	Prestarium A	perindopril (perindopril arginine)	tablets film- coated	5mg; (30) in plastic container, (90/3x30) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000574-ITI- AM 25.11.2025
5	Prestarium A	perindopril (perindopril arginine)	tablets film- coated	5mg; (30) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000574-ITI- AM 25.11.2025
6	Prestarium A	perindopril (perindopril arginine)	tablets film- coated	10mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000574-ITI- AM 25.11.2025

7	Prestarium A	perindopril (perindopril arginine)	tablets film-coated	10mg; (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284-packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000574-ITI-AM 25.11.2025
8	Prestarium A	perindopril (perindopril arginine)	tablets film-coated	10mg; (30) in plastic container, (90/3x30) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000574-ITI-AM 25.11.2025
9	Prestarium A	perindopril (perindopril arginine)	tablets film-coated	10mg; (30) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000574-ITI-AM 25.11.2025
10	SIMBRINZA	brinzolamide, brimonidine (brimonidine tartrate)	drops eye, suspension	10mg/ml+2mg/ml; 5ml plastic vial-dropper	Novartis Manufacturing N.V., Rijksweg 14, Puurs-Sint- Amands, 2870	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	JITI-N°000013-ITI-AM 25.11.2025

LIST

of variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 11-1/25 on November 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	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	23310/1 25.11.2025
2	Relantan 200	progesterone	capsules soft	200mg; (30/3x10') in blister	Aversi-Rational Ltd, Chimakhuli Str. 14, 0198 Tbilisi- secondary packager, quality control, batch releaser, M/s.Steril-Gene Life Sciences (P) Ltd , No.45 Mangalam Main Road, Mangalam Village, Villianur Commune, Puducherry, 605110, India- bulk manufacturer, primary packager	Georgia	Aversi-Rational Ltd, Chimakhuli Str. 14, 0198 Tbilisi	Georgia	PoM	21410/2 25.11.2025
3	Septotele total lemon and elderflower	benzylamine (benzylamine hydrochloride), cetylpyridinium chloride	lozenges	3mg+1mg; (8/1x8') in blister, (16/2x8') in blister, (24/3x8') in blister, (32/4x8') in blister, (40/5x8') in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- quality control (microbiological), batch releaser, KRKA d.d., Novo mesto, Ulica Rada Pusenjaka 10, Ljutomer, 9240, Slovenia- bulk manufacturer, packager, 1. KRKA d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia 2.KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	21528/1 25.11.2025

4	Septotele total lemon and honey	benzylamine (benzylamine hydrochloride), cetylpyridinium chloride	lozenges	3mg+1mg; 16(2x8) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- quality control (microbiological), batch releaser, KRKA d.d., Novo mesto, Ulica Rada Pusenjaka 10, Ljutomer, 9240, Slovenia- bulk manufacturer, packager, 1. KRKA d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia 2.KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	21527/1 25.11.2025
5	Septotele total eucalyptus	benzylamine (benzylamine hydrochloride), cetylpyridinium chloride	pastilles	3mg+1mg; (8/1x8/), (16/2x8/), (24/3x8/), (32/4x8/), (40/5x8/), (48/6x8/), (56/7x8/), (64/8x8/), (72/9x8/), (80/10x8/), (88/11x8/), (96/12x8/), (104/13x8/), (112/14x8/), (120/15x8/), (128/16x8/), (136/17x8/), (144/18x8/), (152/19x8/), (160/20x8/), (168/21x8/), (176/22x8/), (184/23x8/), (192/24x8/), (200/25x8/), (208/26x8/), (216/27x8/), (224/28x8/), (232/29x8/), (240/30x8/), (248/31x8/), (256/32x8/), (264/33x8/), (272/34x8/), (280/35x8/), (288/36x8/), (296/37x8/), (304/38x8/), (312/39x8/), (320/40x8/), (328/41x8/), (336/42x8/), (344/43x8/), (352/44x8/), (360/45x8/), (368/46x8/), (376/47x8/), (384/48x8/), (392/49x8/), (400/50x8/), (408/51x8/), (416/52x8/), (424/53x8/), (432/54x8/), (440/55x8/), (448/56x8/), (456/57x8/), (464/58x8/), (472/59x8/), (480/60x8/), (488/61x8/), (496/62x8/), (504/63x8/), (512/64x8/), (520/65x8/), (528/66x8/), (536/67x8/), (544/68x8/), (552/69x8/), (560/70x8/), (568/71x8/), (576/72x8/), (584/73x8/), (592/74x8/), (600/75x8/), (608/76x8/), (616/77x8/), (624/78x8/), (632/79x8/), (640/80x8/), (648/81x8/), (656/82x8/), (664/83x8/), (672/84x8/), (680/85x8/), (688/86x8/), (696/87x8/), (704/88x8/), (712/89x8/), (720/90x8/), (728/91x8/), (736/92x8/), (744/93x8/), (752/94x8/), (760/95x8/), (768/96x8/), (776/97x8/), (784/98x8/), (792/99x8/), (800/100x8/), (808/101x8/), (816/102x8/), (824/103x8/), (832/104x8/), (840/105x8/), (848/106x8/), (856/107x8/), (864/108x8/), (872/109x8/), (880/110x8/), (888/111x8/), (896/112x8/), (904/113x8/), (912/114x8/), (920/115x8/), (928/116x8/), (936/117x8/), (944/118x8/), (952/119x8/), (960/120x8/), (968/121x8/), (976/122x8/), (984/123x8/), (992/124x8/), (1000/125x8/), (1008/126x8/), (1016/127x8/), (1024/128x8/), (1032/129x8/), (1040/130x8/), (1048/131x8/), (1056/132x8/), (1064/133x8/), (1072/134x8/), (1080/135x8/), (1088/136x8/), (1096/137x8/), (1104/138x8/), (1112/139x8/), (1120/140x8/), (1128/141x8/), (1136/142x8/), (1144/143x8/), (1152/144x8/), (1160/145x8/), (1168/146x8/), (1176/147x8/), (1184/148x8/), (1192/149x8/), (1200/150x8/), (1208/151x8/), (1216/152x8/), (1224/153x8/), (1232/154x8/), (1240/155x8/), (1248/156x8/), (1256/157x8/), (1264/158x8/), (1272/159x8/), (1280/160x8/), (1288/161x8/), (1296/162x8/), (1304/163x8/), (1312/164x8/), (1320/165x8/), (1328/166x8/), (1336/167x8/), (1344/168x8/), (1352/169x8/), (1360/170x8/), (1368/171x8/), (1376/172x8/), (1384/173x8/), (1392/174x8/), (1400/175x8/), (1408/176x8/), (1416/177x8/), (1424/178x8/), (1432/179x8/), (1440/180x8/), (1448/181x8/), (1456/182x8/), (1464/183x8/), (1472/184x8/), (1480/185x8/), (1488/186x8/), (1496/187x8/), (1504/188x8/), (1512/189x8/), (1520/190x8/), (1528/191x8/), (1536/192x8/), (1544/193x8/), (1552/194x8/), (1560/195x8/), (1568/196x8/), (1576/197x8/), (1584/198x8/), (1592/199x8/), (1600/200x8/), (1608/201x8/), (1616/202x8/), (1624/203x8/), (1632/204x8/), (1640/205x8/), (1648/206x8/), (1656/207x8/), 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(2192/274x8/), (2200/275x8/), (2208/276x8/), (2216/277x8/), (2224/278x8/), (2232/279x8/), (2240/280x8/), (2248/281x8/), (2256/282x8/), (2264/283x8/), (2272/284x8/), (2280/285x8/), (2288/286x8/), (2296/287x8/), (2304/288x8/), (2312/289x8/), (2320/290x8/), (2328/291x8/), (2336/292x8/), (2344/293x8/), (2352/294x8/), (2360/295x8/), (2368/296x8/), (2376/297x8/), (2384/298x8/), (2392/299x8/), (2400/300x8/), (2408/301x8/), (2416/302x8/), (2424/303x8/), (2432/304x8/), (2440/305x8/), (2448/306x8/), (2456/307x8/), (2464/308x8/), (2472/309x8/), (2480/310x8/), (2488/311x8/), (2496/312x8/), (2504/313x8/), (2512/314x8/), (2520/315x8/), (2528/316x8/), (2536/317x8/), (2544/318x8/), (2552/319x8/), (2560/320x8/), (2568/321x8/), (2576/322x8/), (2584/323x8/), (2592/324x8/), (2600/325x8/), (2608/326x8/), (2616/327x8/), (2624/328x8/), (2632/329x8/), (2640/330x8/), (2648/331x8/), (2656/332x8/), (2664/333x8/), (2672/334x8/), (2680/335x8/), (2688/336x8/), (2696/337x8/), (2704/338x8/), (2712/339x8/), 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12	Cefazolin	cefazolin (cefazolin sodium)	powder for solution for i/m and i/v injection	1000mg; (1) glass vials, (10) glass vials, (50) glass vials, (270) glass vials	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64/3, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	20701/2/1 25.11.2025
13	Fluconazole	fluconazole	capsules	50mg; (7) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64A, No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	21028/1 25.11.2025
14	Fluconazole	fluconazole	capsules	150mg; (1) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64A, No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	21029/1 25.11.2025
15	Cosopt PF	timolol (timolol maleate), dorzolamide (dorzolamide hydrochloride)	drops eye (solution)	5mg/ml+20mg/ml; plastic vial 10ml	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, Tubilux Pharma S.p.A., Via Costarica, 20/22, 00071 Pomezia/ Rome, Italy- bulk manufacturer, packager, quality control	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	PoM	19865/3 25.11.2025
16	Enalapril	enalapril (enalapril maleate)	tablets	5mg; (20/2x10) in blister, (30/3x10) in blister, (60/6x10) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64A, No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	21377/1 25.11.2025
17	Enalapril	enalapril (enalapril maleate)	tablets	10mg; (20/2x10) in blister, (30/3x10) in blister, (60/6x10) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64A, No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	21378/1 25.11.2025
18	Ketoprofen	ketoprofen	gel for external use	25mg/g; aluminium tube 30g	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	20168/2/1 25.11.2025
19	Spironolactone	spironolactone	tablets	25mg; (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	20061/2/1 25.11.2025

LIST

of registered variations under the EAEU procedure requiring registration and reformulation of registration certificate approved by the Center according to the meeting decision N 11-1/25 on November 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	Flavamed cough tablets	ambroxol (ambroxol hydrochloride)	tablets	30mg; (10/1x10) in blister, (20/2x10) in blister, (50/5x10) in blister	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- packager, quality control, batch releaser, Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden, Germany- bulk manufacturer	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	OTC	ЛП-№007582-ПТ-АМ 25.11.2025
2	Flavamed cough tablets	ambroxol (ambroxol hydrochloride)	tablets	30mg; (10/1x10) in blister, (20/2x10) in blister, (50/5x10) in blister	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie A.G., Tempelhofer Weg 83, 12347, Berlin, Germany- bulk manufacturer, 1. Berlin-Chemie A.G., Tempelhofer Weg 83, 12347, Berlin, Germany, 2. Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin, Germany- quality control (physicochemical)	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	OTC	ЛП-№007582-ПТ-АМ 25.11.2025
3	Flavamed cough tablets	ambroxol (ambroxol hydrochloride)	tablets	30mg; (10/1x10) in blister, (20/2x10) in blister, (50/5x10) in blister	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- packager, batch releaser, Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden, Germany- bulk manufacturer, quality control	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	OTC	ЛП-№007582-ПТ-АМ 25.11.2025

4	Flavamed cough tablets	ambroxol (ambroxol hydrochloride)	tablets	30mg; (10/1x10/) in blister, (20/2x10/) in blister, (50/5x10/) in blister	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- packager, batch releaser, Berlin-Chemie A.G., Tempelhofer Weg 83, 12347, Berlin, Germany- bulk manufacturer, Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden, Germany- quality control	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	OTC	ЛП-№007582-ПГ-AM 25.11.2025
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LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 11-1/25 on November 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	Lusefi	luseogliflozin	tablets film-coated	2,5mg; (30/2x15/) in blister, (60/4x15/) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Servier JSC, 125196, 7/8/9, Lesnaya str., 7, Moscow	Russia	PoM	ЖИТ-N*003622-ITI-AM 25.11.2025
2	Lusefi	luseogliflozin	tablets film-coated	5mg; (30/2x15/) in blister, (60/4x15/) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Servier JSC, 125196, 7/8/9, Lesnaya str., 7, Moscow	Russia	PoM	ЖИТ-N*003622-ITI-AM 25.11.2025
3	Tantum Verde	benzylamine (benzylamine hydrochloride)	spray for local use	0,255mg/dose; 30ml (176 doses) plastic container with pump dispenser	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. Via Vecchia Del Pinocchio, 22, 60131 Ancona	Italy	Angelini Pharma S.p.A., Viale, Amelia 70, 00181, Rome	Italy	OTC	ЖИТ-N*000747-ITI-AM 25.11.2025
4	Tantum Verde	benzylamine (benzylamine hydrochloride)	solution for local use	150mg/100ml; 120ml glass bottle and measuring cup, 240ml glass bottle and measuring cup, 500ml plastic bottle and measuring cup	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. Via Vecchia Del Pinocchio, 22, 60131 Ancona	Italy	Angelini Pharma S.p.A., Viale, Amelia 70, 00181, Rome	Italy	OTC	ЖИТ-N*000704-ITI-AM 25.11.2025
5	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	ЖИТ-N*004871-PF-AM 25.11.2025
6	Noliprel A Bi-forte	indapamide, perindopril arginine	tablets film-coated	2,5mg+10mg; (30) in plastic container	Servier (Ireland) Industries Ltd., Gorey Road, Arklow-Co. Wicklow, Y14 E284	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЖИТ-N*001806-ITI-AM 25.11.2025
7	Noliprel A Bi-forte	indapamide, perindopril arginine	tablets film-coated	2,5mg+10mg; (30) in plastic container, (90) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЖИТ-N*001806-ITI-AM 25.11.2025

8	Ropuido	rosuvastatin (rosuvastatin calcium)	tablets film-coated	5mg; (30/3x10') in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	JITI-N°003542-PT-AM 25.11.2025
9	Ropuido	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (30/3x10') in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	JITI-N°003542-PT-AM 25.11.2025
10	Ropuido	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (30/3x10') in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	JITI-N°003542-PT-AM 25.11.2025
11	Ropuido	rosuvastatin (rosuvastatin calcium)	tablets film-coated	40mg; (30/3x10') in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	JITI-N°003542-PT-AM 25.11.2025
12	Vermox	mebendazole	tablets	100mg; (6/1x6') in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Romania S.A., 99-105 Guza Voda str., Targu-Mures, Jud. Mures, 540306, Romania- bulk manufacturer, packager, quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°002347-ITI-AM 25.11.2025
13	Vermox	mebendazole	tablets	100mg; (6/1x6') in blister	Gedeon Richter Romania S.A., 99-105 Guza Voda str., Targu-Mures, Jud. Mures, 540306	Romania	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°002347-ITI-AM 25.11.2025