

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 12-1/25 on December 12, 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	CinnoVex	interferon beta-1a	powder lyophilized for solution for i/m injection	30mcg (6MIU); (4/4x1) glass pre-filled syringe 0,5 ml and needle in plastic tray	CinnaGen Co., Plot No. 72, 74, 87, 88, 3rd Sq., Simin Dasht Non-Governmental Industrial Area, Fardis Country, Alborz Province	Iran	CinnaGen Co., Plot No. 72, 74, 87, 88, 3rd Sq., Simin Dasht Non-Governmental Industrial Area, Fardis Country, Alborz Province	Iran	PoM	23716 12.12.2025
2	Cosentyx	secukinumab	lyophilisate for solution for subcutaneous injection	150mg; glass vial	Lek Pharmaceuticals d.d. Verovskova Str. 57, 1526 Ljubljana- secondary packager, batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland - bulk manufacturer, primary packager, quality control	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	23717 12.12.2025
3	Formisonid-Pharmstandard	budesonide + formoterol fumarate dihydrate	powder for inhalation, pre-dispensed	80mcg+4,5mcg; (30/3x10) in blister, (60/6x10) in blister, (120/12x10) in blister, (30/3x10) in blister and plastic inhaler device, (60/6x10) in blister and plastic inhaler device, (120/12x10) in blister and plastic inhaler device, plastic inhaler device (60 doses), plastic inhaler device (60 doses) in plastic container	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	PoM	23718 12.12.2025

4	Formisonid-Pharmstandard	budesonide, formoterol (formoterol fumarate dihydrate)	powder for inhalation, pre-dispensed	160mcg+4,5mcg; (30/3x10') in blister, (60/6x10') in blister, (120/12x10') in blister, (30/3x10') in blister and plastic inhaler device, (60/6x10') in blister and plastic inhaler device, (120/12x10') in blister and plastic inhaler device, plastic inhaler device (60 doses), plastic inhaler device (60 doses) in plastic container	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	PoM	23719 12.12.2025
5	Formisonid-Pharmstandard	budesonide, formoterol (formoterol fumarate dihydrate)	powder for inhalation, pre-dispensed	320mcg+ 9mcg; (30/3x10') in blister, (60/6x10') in blister, (120/12x10') in blister, (30/3x10') in blister and plastic inhaler device, (60/6x10') in blister and plastic inhaler device, (120/12x10') in blister and plastic inhaler device, plastic inhaler device (60 doses), plastic inhaler device (60 doses) in plastic container	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	PoM	23720 12.12.2025
6	FLUCO	fluconazole	capsules	150mg; (8/1x8) in blister, (80/10x8) in blister	A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan- packager, quality control, batch releaser, RELAX BIOTECH PVT. LTD, 862/1, G.I.D.C., MAKARPURA, BARODA- 390010, India- bulk manufacturer	Republic of Armenia	A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan	Republic of Armenia	PoM	23721 12.12.2025
7	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 50ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvecchio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23722 12.12.2025
8	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 100ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvecchio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23723 12.12.2025

9	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 200ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23724 12.12.2025
10	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 50ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- bulk manufacturer, primary packager, quality control, batch releaser, Pharma Partners S.r.L., Via Ettore Strobino 55/57, Prato, 59100, Italy- secondary packager	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23725 12.12.2025
11	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 100ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- bulk manufacturer, primary packager, quality control, batch releaser, Pharma Partners S.r.L., Via Ettore Strobino 55/57, Prato, 59100, Italy- secondary packager	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23726 12.12.2025
12	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 200ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- bulk manufacturer, primary packager, quality control, batch releaser, Pharma Partners S.r.L., Via Ettore Strobino 55/57, Prato, 59100, Italy- secondary packager	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23727 12.12.2025
13	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 50ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- bulk manufacturer, primary packager, quality control (physicochemical), batch releaser, Pharma Partners S.r.L., Via Ettore Strobino 55/57, Prato, 59100, Italy- secondary packager, Eurofins Biolab S.r.L., Via Bruno Buzzi 2, Vimodrone 20055, Italy- quality control (microbiological, biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23728 12.12.2025

14	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 100ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- bulk manufacturer, primary packager, quality control (physicochemical), batch releaser, Pharma Partners S.r.l., Via Ettore Strobino 55/57, Prato, 59100, Italy- secondary packager, Eurofins Biolab S.r.l., Via Bruno Buzzi 2, Vimodrone 20055, Italy- quality control (microbiological, biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23729 12.12.2025
15	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 200ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- bulk manufacturer, primary packager, quality control (physicochemical), batch releaser, Pharma Partners S.r.l., Via Ettore Strobino 55/57, Prato, 59100, Italy- secondary packager, Eurofins Biolab S.r.l., Via Bruno Buzzi 2, Vimodrone 20055, Italy- quality control (microbiological, biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23730 12.12.2025
16	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 50ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- bulk manufacturer, primary packager, quality control (physicochemical, microbiological), batch releaser, Pharma Partners S.r.l., Via Ettore Strobino 55/57, Prato, 59100, Italy- secondary packager, Charles River Laboratories France C.R.L.F., 2109, Route de Chatillon, Romans, 01400, France- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23731 12.12.2025
17	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 100ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- bulk manufacturer, primary packager, quality control (physicochemical, microbiological), batch releaser, Pharma Partners S.r.l., Via Ettore Strobino 55/57, Prato, 59100, Italy- secondary packager, Charles River Laboratories France C.R.L.F., 2109, Route de Chatillon, Romans, 01400, France- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23732 12.12.2025

18	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 200ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- bulk manufacturer, primary packager, quality control (physicochemical, microbiological), batch releaser, Pharma Partners S.r.l., Via Ettore Strobino 55/57, Prato, 59100, Italy- secondary packager, Charles River Laboratories France C.R.L.F., 2109, Route de Chatillon, Romans, 01400, France- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23733 12.12.2025
19	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 50ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- packager, quality control, batch releaser, Kedrion S.p.A., Strada Statale 7 Bis Km 19 5 Sant Antimo, Naples, 80029, Italy- bulk manufacturer	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23734 12.12.2025
20	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 100ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- packager, quality control, batch releaser, Kedrion S.p.A., Strada Statale 7 Bis Km 19 5 Sant Antimo, Naples, 80029, Italy- bulk manufacturer	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23735 12.12.2025
21	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 200ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- packager, quality control, batch releaser, Kedrion S.p.A., Strada Statale 7 Bis Km 19 5 Sant Antimo, Naples, 80029, Italy- bulk manufacturer	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23736 12.12.2025
22	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 50ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- primary packager, quality control, batch releaser, Kedrion S.p.A., Strada Statale 7 Bis Km 19 5 Sant Antimo, Naples, 80029, Italy- bulk manufacturer, Pharma Partners S.r.l., Via Ettore Strobino 55/57, Prato, 59100, Italy- secondary packager	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23737 12.12.2025

23	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 100ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- primary packager, quality control, batch releaser, Kedrion S.p.A., Strada Statale 7 Bis Km 19 5 Sant Antimo, Naples, 80029, Italy- bulk manufacturer, Pharma Partners S.r.l., Via Ettore Strobino 55/57, Prato, 59100, Italy- secondary packager	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvecchio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23738 12.12.2025
24	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 200ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- primary packager, quality control, batch releaser, Kedrion S.p.A., Strada Statale 7 Bis Km 19 5 Sant Antimo, Naples, 80029, Italy- bulk manufacturer, Pharma Partners S.r.l., Via Ettore Strobino 55/57, Prato, 59100, Italy- secondary packager	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvecchio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23739 12.12.2025
25	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 50ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- packager, quality control (physicochemical, microbiological), batch releaser, Strada Statale 7 Bis Km 19 5 Sant Antimo, Naples, 80029, Italy- bulk manufacturer, Charles River Laboratories France C.R.L.F., 2109, Route de Chatillon, Romans, 01400, France- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvecchio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23740 12.12.2025
26	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 100ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- packager, quality control (physicochemical, microbiological), batch releaser, Strada Statale 7 Bis Km 19 5 Sant Antimo, Naples, 80029, Italy- bulk manufacturer, Charles River Laboratories France C.R.L.F., 2109, Route de Chatillon, Romans, 01400, France- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvecchio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23741 12.12.2025

27	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 200ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- packager, quality control (physicochemical, microbiological), batch releaser, Strada Statale 7 Bis Km 19 5 Sant Antimo, Naples, 80029, Italy- bulk manufacturer, Charles River Laboratories France C.R.L.F., 2109, Route de Chatillon, Romans, 01400, France- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvecchio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23742 12.12.2025
28	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 50ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- packager, quality control(physicochemical, microbiological), batch releaser, Kedrion S.p.A., Strada Statale 7 Bis Km 19 5 Sant Antimo, Naples, 80029, Italy- bulk manufacturer, Eurofins Biolab S.r.l., Via Bruno Buzzi 2, Vimodrone 20055, Italy- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvecchio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23743 12.12.2025
29	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 100ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- packager, quality control(physicochemical, microbiological), batch releaser, Kedrion S.p.A., Strada Statale 7 Bis Km 19 5 Sant Antimo, Naples, 80029, Italy- bulk manufacturer, Eurofins Biolab S.r.l., Via Bruno Buzzi 2, Vimodrone 20055, Italy- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvecchio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23744 12.12.2025
30	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 200ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- packager, quality control (physicochemical, microbiological), batch releaser, Kedrion S.p.A., Strada Statale 7 Bis Km 19 5 Sant Antimo, Naples, 80029, Italy- bulk manufacturer, Eurofins Biolab S.r.l., Via Bruno Buzzi 2, Vimodrone 20055, Italy- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvecchio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23745 12.12.2025

31	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 50ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- primary packager, quality control (physicochemical, microbiological), batch releaser, Kedrion S.p.A., Strada Statale 7 Bis Km 19.5 Sant'Antimo, Naples, 80029, Italy- bulk manufacturer, Pharma Partners S.r.l., Via Ettore Strobino 55/57, Prato, 59100, Italy- secondary packager, Eurofins Biolab S.r.l., Via Bruno Buzzi 2, Vimodrone 20055, Italy- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelveccchio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23746 12.12.2025
32	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 100ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- primary packager, quality control (physicochemical, microbiological), batch releaser, Kedrion S.p.A., Strada Statale 7 Bis Km 19.5 Sant'Antimo, Naples, 80029, Italy- bulk manufacturer, Pharma Partners S.r.l., Via Ettore Strobino 55/57, Prato, 59100, Italy- secondary packager, Eurofins Biolab S.r.l., Via Bruno Buzzi 2, Vimodrone 20055, Italy- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelveccchio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23747 12.12.2025
33	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 200ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- packager, quality control (physicochemical, microbiological), batch releaser, Kedrion S.p.A., Strada Statale 7 Bis Km 19.5 Sant'Antimo, Naples, 80029, Italy- bulk manufacturer, Eurofins Biolab S.r.l., Via Bruno Buzzi 2, Vimodrone 20055, Italy- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelveccchio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23748 12.12.2025

34	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 50ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- primary packager, quality control (physicochemical, microbiological), batch releaser, Kedrion S.p.A., Strada Statale 7 Bis Km 19.5 Sant Antimo, Naples, 80029, Italy- bulk manufacturer, Pharma Partners S.r.l., Via Ettore Strobino 55/57, Prato, 59100, Italy- secondary packager, Charles River Laboratories France C.R.L.F., 2109, Route de Chatillon, Romans, 01400, France- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23749 12.12.2025
35	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 100ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- primary packager, quality control (physicochemical, microbiological), batch releaser, Kedrion S.p.A., Strada Statale 7 Bis Km 19.5 Sant Antimo, Naples, 80029, Italy- bulk manufacturer, Pharma Partners S.r.l., Via Ettore Strobino 55/57, Prato, 59100, Italy- secondary packager, Charles River Laboratories France C.R.L.F., 2109, Route de Chatillon, Romans, 01400, France- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23750 12.12.2025
36	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 200ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- primary packager, quality control (physicochemical, microbiological), batch releaser, Kedrion S.p.A., Strada Statale 7 Bis Km 19.5 Sant Antimo, Naples, 80029, Italy- bulk manufacturer, Pharma Partners S.r.l., Via Ettore Strobino 55/57, Prato, 59100, Italy- secondary packager, Charles River Laboratories France C.R.L.F., 2109, Route de Chatillon, Romans, 01400, France- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23751 12.12.2025

37	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 200ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- bulk manufacturer, packager, quality control (physicochemical, microbiological), batch releaser, Eurofins Biolab S.r.l., Via Bruno Buzzi 2, Vimodrone 20055, Italy- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23752 12.12.2025
38	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 100ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- bulk manufacturer, packager, quality control (physicochemical, microbiological), batch releaser, Eurofins Biolab S.r.l., Via Bruno Buzzi 2, Vimodrone 20055, Italy- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23753 12.12.2025
39	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 200ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- bulk manufacturer, packager, quality control (physicochemical, microbiological), batch releaser, Eurofins Biolab S.r.l., Via Bruno Buzzi 2, Vimodrone 20055, Italy- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23754 12.12.2025
40	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 50ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- bulk manufacturer, packager, quality control (physicochemical, microbiological), batch releaser, Charles River Laboratories France C.R.L.F., 2109, Route de Chatillon, Romans, 01400, France- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23755 12.12.2025
41	Ig Vena	human normal immunoglobulin	solution for infusion	50mg/ml; glass vial 100ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- bulk manufacturer, packager, quality control (physicochemical, microbiological), batch releaser, Charles River Laboratories France C.R.L.F., 2109, Route de Chatillon, Romans, 01400, France- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvechio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23756 12.12.2025

42	Ig Vena	human normal imunoglobulin	solution for infusion	50mg/ml; glass vial 200ml	Kedrion S.p.A., Via Provinciale, Loe Bolognana, Gallicano 55027- bulk manufacturer, packager, quality control (physicochemical, microbiological), batch releaser, Charles River Laboratories France C.R.L.F., 2109, Route de Chatillon, Romans, 01400, France- quality control (biological)	Italy	Kedrion S.p.A., Loc. Ai ContiFrazione Castelvecchio Pascoli, Barga, Lucca (LU), 55051	Italy	PoM	23757 12.12.2025
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of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 12-1/25 on December 12, 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	SNUPPIK	oxymetazoline (oxymetazoline hydrochloride)	drops nasal	0,1mg/ml; 5ml plastic vial with pump dispenser	Hemomont d.o.o., 81000, Podgorica, Ilije Plamenca bb	Montenegro	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	OTC	23698 (005865) 12.12.2025
2	SNUPPIK	oxymetazoline (oxymetazoline hydrochloride)	drops nasal	0,1mg/ml; 5ml plastic vial with pump dispenser	Hemofarm A.D. 26300, Vrsac, Beogradskii put bb- batch releaser, Hemomont d.o.o., 81000, Podgorica, Ilije Plamenca bb, Montenegro- bulk manufacturer, packager, quality control	Serbia	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	OTC	23699 (005865) 12.12.2025
3	Xiltess	rivaroxaban	tablets film-coated	2,5mg; (56/4x14) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23700 (006653) 12.12.2025
4	Xiltess	rivaroxaban	tablets film-coated	10mg; (10/1x10) in blister, (28/2x14) in blister, (98/7x14) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23701 (006653) 12.12.2025
5	Xiltess	rivaroxaban	tablets film-coated	15mg; (28/2x14) in blister, (42/3x14) in blister, (98/7x14) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23702 (006653) 12.12.2025
6	Xiltess	rivaroxaban	tablets film-coated	20mg; (28/2x14) in blister, (98/7x14) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23703 (006653) 12.12.2025

7	Valsacor INDA	valsartan, indapamide	tablets modified release	80mg+1,5mg: (30/3x10') in blister, (60/6x10') in blister, (90/9x10') in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	23704 (006109) 12.12.2025
8	Valsacor INDA	valsartan, indapamide	modified release tablets	160mg+1,5mg: (30/3x10') in blister, (60/6x10') in blister, (90/9x10') in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	23705 (006109) 12.12.2025
9	Otrivin	xylometazoline (xylometazoline hydrochloride)	spray metered dose nasal with menthol and eucalypt flavour	140mcg/dose; 10ml (60 dose) plastic vial with pump dispenser	Haleon CH SARI, Route de l' Etraz, Nyon, 1260	Switzerland	JSC "Haleon Rus", Presnenskaya Naberezhnaya, 10, unit III, room 9, 6 floor, Moscow, 123112	Russia	OTC	23706 (006109) 12.12.2025
10	Milurit	allopurinol	tablets	100mg; (50) in glass bottle, (100) in glass bottle	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23707 (000201) 12.12.2025
11	Milurit	allopurinol	tablets	300mg; (30) in glass bottle, (100) in glass bottle	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly u. 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	23708 (000201) 12.12.2025
12	Amelotex	meloxicam	tablets	15mg; (10/1x10') in blister, (20/2x10') in blister	SotexPharmFirm" CJSC, bld. 11, village Belikovo, Sergiev-Posad urban district, Moscow Region- quality control, batch releaser Replek Farm Ltd, Skopje, 188 str. Kozle, 1000 Skopje, Republic of North Macedonia- bulk manufacturer, primary packager, "Sotex"PharmFirm" CJSC, bld. 12, village Belikovo, Sergiev-Posad urban district, Moscow Region, 141345, Russia- secondary packager	Russia	"Sotex"PharmFirm" CJSC, bld. 11, village Belikovo, Sergiev-Posad, Moscow Region, 141345	Russia	PoM	23709 (005741) 12.12.2025

13	Rosulip	rosuvastatin (rosuvastatin zinc)	tablets film-coated	5mg; (14/2x7/) in blister, (28/4x7/) in blister, (56/8x7/) in blister, (84/12x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23710 (004334) 12.12.2025
14	Rosulip	rosuvastatin (rosuvastatin zinc)	tablets film-coated	5mg; (14/2x7/) in blister, (28/4x7/) in blister, (56/8x7/) in blister, (84/12x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23711 (004334) 12.12.2025
15	Rosulip	rosuvastatin (rosuvastatin zinc)	tablets film-coated	10mg; (14/2x7/) in blister, (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23712 (004334) 12.12.2025
16	Rosulip	rosuvastatin (rosuvastatin zinc)	tablets film-coated	20mg; (14/2x7/) in blister, (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23713 (004334) 12.12.2025
17	GastroGuard	calcium carbonate, magnesium carbonate	tablets chewable	680mg+80mg; (16/2x8) in blister, (24/3x8) in blister, (48/6x8) 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	23714 (003359) 12.12.2025
18	Zovirax	aciclovir	cream for external use	50mg/g; aluminium tube 2g, aluminium tube 5g, aluminium tube 10g or 2g plastic bottle with dispenser device	Glaxo Wellcome Operations, Harmire Road, Barnard Castle, DL12 8DT	UK	JSC "Haleon Rus", Presnenskaya Naberezhnaya, 10, unit III, room 9, 6 floor, Moscow, 123112	Russia	OTC	23715 (009775) 12.12.2025
19	Iod-Argo	iodide	solution alcohol for external use	50mg/ml; 10ml glass vial, 25ml glass vial, 100ml 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	23695 (026257) 12.12.2025

20	Proculin	naphazoline (naphazoline hydrochloride)	drops eye (solution)	0,3mg/ml; plastic container 10ml	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- quality control, batch releaser, Mefar Ilac Sanayii A.S., Ramazanoglu, Mah. Ensar-Cad. No:20, 34906 Kurtkoy-Pendik, Istanbul, Turkey- bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of Armenia	OTC	23696 (019430) 12.12.2025
21	Furagin	furazidin	tablets	50mg; (30/3x10/) in blister	Kyivmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	Kyivmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	PoM	23697 (029893) 12.12.2025

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 12-1/25 on December 12, 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	Cipro-Tech	ciprofloxacin	drops eye/ear	3mg/ml; 5ml bottle-dropper, 10ml bottle-dropper	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	23691 12.12.2025
2	Mucaltin Tatpharm	althaea officinalis extract	tablets	50mg (10) in strip	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	OTC	23692 12.12.2025

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 12-1/25 on December 12, 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	Folic Acid	folic acid	tablets	5mg; (20/2x10') in blister	Replek Farm Ltd, Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	Esculap Ltd., 17/2, 1 block, Davidashen, 0054, Yerevan	Republic of Armenia	PoM	23693 12.12.2025
2	Iono-Tech	sodium acetate (sodium acetate trihydrate), sodium chloride, potassium chloride, calcium chloride (calcium chloride dihydrate), magnesium chloride (magnesium chloride hexahydrate)	solution for infusion	5mg/ml+5,85mg/ml+0,302mg/ml+0,36mg/ml+0,25mg/ml; 50ml plastic pack, 100ml plastic pack, 200ml plastic pack, 250ml plastic pack, 400ml plastic pack, 500ml plastic pack, 1000ml plastic pack	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	23694 12.12.2025

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-1/25 on December 12, 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	MicroLax	sodium citrate, sodium laurylsulfoacetate, sorbitol solution	solution rectal	90mg/ml+9mg/ml+893mg/ml; (4) microenema 5ml, (12) microenema 5ml	Delpharm Orleans, 5 avenue de Concy, 45071 Orleans, Cedex 2	France	JTNL LLC, 121614, Moscow, Krylatskaya intercity municipal district, Krylatskaya str., 17, bld. 3	Russia	OTC	20483/1/1 12.12.2025
2	Euphylline	aminophylline	tablets	150mg; (10/1x10) in blister, (30/3x10) in blister, (10) 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	20261/1/1 12.12.2025
3	Enterofuryl	nifuroxazide	suspension oral	200mg/5ml; 90ml suspension in 125ml glass bottle and plastic measuring spoon (2,5ml/5ml)	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek Limited Liability Company, Savvinskaya naberezhnaya 11, Moscow	Russia	PoM	20382/5/1 12.12.2025
4	Enterofuryl	nifuroxazide	capsules	100mg; (30/3x10) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek Limited Liability Company, Savvinskaya naberezhnaya 11, Moscow	Russia	PoM	20982/4/1 12.12.2025
5	Enterofuryl	nifuroxazide	capsules	200mg; (16/2x8) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek Limited Liability Company, Savvinskaya naberezhnaya 11, Moscow	Russia	PoM	20983/4/1 12.12.2025
6	Lysobact	lysozyme (lysozyme hydrochloride), pyridoxine (pyridoxine hydrochloride)	lozenges compressed	20mg+10mg; (10/1x10) in blister, (30/3x10) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek Limited Liability Company, Savvinskaya naberezhnaya 11, Moscow	Russia	OTC	21236/2/1 12.12.2025

7	Salbutamol-PHST	salbutamol (salbutamol sulfate)	aerosol for inhalation dosed	100mcg/dose; 200 doses in aluminium container with metering valve and inhaler, 300 doses in aluminium container with metering valve and inhaler	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18 for Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan, Russia	Russia	Bionorica SE, Kerschensteiner str. 11-15, 92318 Neumarkt in der Oberpfalz	Germany	PoM	20895/3/2 12.12.2025
8	Panthenol-PHST	dexpantenol	foam for external use	50mg/g; aluminium container 58g	Pharmstandard-Leksredstva OJSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva OJSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	22647/1/1 12.12.2025
9	Analgin-Pharmstandard	metamizole (metamizole sodium)	tablets	500mg; (10/1x10/) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	ARGO-PHARM LLC, 13/9 Sundukyan str., 0012 Yerevan	Republic of Armenia	OTC	22436/2/1 12.12.2025
10	Paracetamol-PHST	paracetamol	tablets	500mg; (10/1x10/) in blister, (20/2x10/) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	ARGO-PHARM LLC, 13/9 Sundukyan str., 0012 Yerevan	Republic of Armenia	OTC	22328/1/1 12.12.2025
11	Trimecor MR	trimetazidine (trimetazidine dihydrochloride)	tablets film-coated modified-release	35mg; (30/3x10/) in blister, (60/6x10/) in blister	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	19435/3/1 12.12.2025
12	Next-Oticipharm Pro	ibuprofen, paracetamol	tablets film-coated	400mg+200mg; (2/1x2/) in blister, (4/2x2/) in blister, (6/1x6/) in blister, (10/1x10/) in blister, (12/1x12/) in blister, (12/2x6/) in blister, (20/2x10/) in blister, (24/2x12/) in blister	Pharmstandard-Leksredstva JSC, 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	OTC	20881/1/1 12.12.2025
13	Enalapril	enalapril (enalapril maleate)	tablets	5mg; (20/2x10/) in blister	Hemofarm LLC, 249035, Obninsk, Kaluga Region, 62 Kievskoye highway- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Farmoborona Test Center, Ltd., 141074, Korolyov, Moscow Region, Gagarin St., 46A, Russia-quality control (microbiological) for Nizhpharm JSC, 603105, Nizhny Novgorod, GSP-459, Salganskaya st., 7, Russia	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	20842/3/2 12.12.2025

14	Enalapril	enalapril (enalapril maleate)	tablets	10mg; (20/2x10) in blister	Hemofarm LLC, 249035, Obninsk, Kaluga Region, 62 Kievskoye highway- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Farmoborona Test Center, Ltd., 141074, Korolyov, Moscow Region, Gagarin St., 46A, Russia- quality control (microbiological) for Nizhpharm JSC, 603105, Nizhny Novgorod, GSP-459, Salganskaya st., 7, Russia	Russia	Demi Pharm Griboyedovi 12, ap. 25, Sevan 1501	Republic of Armenia	PoM	20843/3/2 12.12.2025
15	Enalapril	enalapril (enalapril maleate)	tablets	20mg; (20/2x10) in blister	Hemofarm LLC, 249035, Obninsk, Kaluga Region, 62 Kievskoye highway- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Farmoborona Test Center, Ltd., 141074, Korolyov, Moscow Region, Gagarin St., 46A, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	PoM	20844/3/2 12.12.2025
16	Enterol 250	lyophilized cells of saccharomyces boulardii	powder for oral suspension	250mg; (10) sachets	Biocodex, 1 avenue Blaise Pascal, 60000 Beauvais	France	Biocodex, 22 Rue des Aqueducs, 94250 Gentilly	France	OTC	21508/2/1 12.12.2025
17	Enterol 250	lyophilized cells of saccharomyces boulardii	capsules	250mg; (10) in glass bottle	Biocodex, 1 avenue Blaise Pascal, 60000 Beauvais	France	Biocodex, 22 Rue des Aqueducs, 94250 Gentilly	France	OTC	21507/2/1 12.12.2025
18	Vegtasone Uno	mometasone (mometasone furoate)	cream	1mg/g; aluminium tube 15g	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	Belinda Laboratories LLP, Unit 18, 53 Norman road, Greenwich Centre Business park, SE10 9QF, London	UK	PoM	20066/3/1 12.12.2025

LIST

of variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting decision N
12-1/25 on December 12, 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	Octretex	octreotide (octreotide acetate)	solution for infusion and intracutaneous injection	0,1mg/ml; (5/1x5/) ampoules 1ml in blister, (10/2x5/) ampoules 1ml in blister	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region- quality control, batch releaser, "Sotex"PharmFirm" CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, Russia- bulk manufacturer, packager	Russia	"Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	PoM	ЖПТ-№003439-ПТ-АМ 12.12.2025
2	Cytotec	misoprostol	tablets	200mcg; (60/6x10/) in blister	Piramal Healthcare UK Limited, Whalton Road Morpeth, Northumberland, NE61 3YA	UK	Pfizer Inc., 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	ЖПТ-№002326-ПТ-АМ 12.12.2025

LIST

of variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-1/25 on December 12, 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	Contractubex	extract cepae, heparin (heparin sodium), allantoin	gel for external use	100mg/g+50IU/g+10mg/g; 20g aluminium tube	Merz Pharma GmbH & Co. KGaA, Ludwigstrasse 22, Reinheim, Hessen, 64354	Germany	Merz Pharmaceuticals GmbH, Eckenheimer Landstrasse 100, 60318 Frankfurt/Main	Germany	OTC	21081/3/1 12.12.2025
2	Cosentyx	secukinumab	solution for subcutaneous injection	150mg/ml; (1) pre-filled pen, (2) pre-filled pens	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20893/4/2 12.12.2025
3	Cosentyx	secukinumab	solution for subcutaneous injection	150mg/ml; (1) pre-filled syringe, (2) pre-filled syringes	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20894/4/2 12.12.2025
4	Cosentyx	secukinumab	lyophilisate for solution for subcutaneous injection	150mg; glass vial	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20892/4/1 12.12.2025
5	Sinaflan	fluocinolone acetonide	ointment for external use	0,25mg/g; aluminum tube 15g	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, No2, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	PoM	21633/1 12.12.2025
6	Cefotaxime	cefotaxime (cefotaxime sodium)	powder for solution for injection	500mg; (10) glass vials, (50) glass vials, (270) glass vials	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64/3, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	PoM	21408/2 12.12.2025

7	Cefotaxime	cefotaxime (cefotaxime sodium)	powder for solution for i/m and i/v injection	1000mg; (10) glass vials, (50) glass vials, (270) glass vials	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64/3, Chapayev str., Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapayev str., Borisov 222518, Minsk region	Republic of Belarus	PoM	20659/2/1 12.12.2025
8	Euphyllin	aminophylline	solution for i/v injection	24mg/ml; (10) ampoules 5ml label banderol, (10/2x5/) ampoules 5ml	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapayeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapayeva, Borisov, Minsk region	Republic of Belarus	PoM	21777/2 12.12.2025
9	Mucaltin Tatpharm	althaea officinalis extract	tablets	50mg; (10) in strip	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	OTC	19362/1 12.12.2025
10	Lonsurf	tipiracil (tipiracil hydrochloride), trifluridine	tablets film-coated	6,14mg+15mg; (60/6x10/) in blister	Taiho Pharmaceutical Co. Ltd., Kitajima Plant, 1-1, Iuchi, Takabo, Kitajima-cho, Itano-gun, 771-0206 Tokushima, Japan-bulk manufacturer, Les Laboratoires Servier Industrie, 905, route de Saran, 45520 Gidy-packager, quality control, batch releaser	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes Cedex	France	PoM	23140/1 12.12.2025
11	Lonsurf	tipiracil (tipiracil hydrochloride), trifluridine	tablets film-coated	8,19mg+20mg; (60/6x10/) in blister	Taiho Pharmaceutical Co. Ltd., Kitajima Plant, 1-1, Iuchi, Takabo, Kitajima-cho, Itano-gun, 771-0206 Tokushima, Japan-bulk manufacturer, Les Laboratoires Servier Industrie, 905, route de Saran, 45520 Gidy-packager, quality control, batch releaser	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes Cedex	France	PoM	23141/1 12.12.2025
12	Lonsurf	tipiracil (tipiracil hydrochloride), trifluridine	tablets film-coated	6,14mg+15mg; (60/6x10/) in blister	Taiho Pharmaceutical Co. Ltd., Kitajima Plant, 1-1, Iuchi, Takabo, Kitajima-cho, Itano-gun, 771-0206 Tokushima, Japan-bulk manufacturer, Servier (Ireland) Industries Limited, Gorey Road, Arklow, Y14 E284- packager, quality control, batch releaser	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes Cedex	France	PoM	23142/1 12.12.2025
13	Lonsurf	tipiracil (tipiracil hydrochloride), trifluridine	tablets film-coated	8,19mg+20mg; (60/6x10/) in blister	Taiho Pharmaceutical Co. Ltd., Kitajima Plant, 1-1, Iuchi, Takabo, Kitajima-cho, Itano-gun, 771-0206 Tokushima, Japan-bulk manufacturer, Servier (Ireland) Industries Limited, Gorey Road, Arklow, Y14 E284- packager, quality control, batch releaser	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes Cedex	France	PoM	23143/1 12.12.2025

14	Iodinol	iodine	solution for external use	1mg/ml; 100ml glass bottle, 100ml plastic bottle	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	OTC	19773/3 12.12.2025
15	Nasonex	mometasone (mometasone furoate)	spray nasal (suspension)	50mcg/dose; 18g (140 dose) plastic bottle with spray pump 18g (140 dose)	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	22715/2 12.12.2025
16	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	23389/1 12.12.2025
17	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	23388/1 12.12.2025
18	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	23387/1 12.12.2025
19	Diampa	empagliflozin	tablets film-coated	25mg; (14/2x7/) in blister	Getz Pharma (Pvt) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	Getz Pharma (Pvt.) Limited, 29-30/27, Korangi Industrial Area, Karachi 74900	Pakistan	PoM	23214/1 12.12.2025
20	Tafinlar	dabrafenib	capsules hard	75mg; (120) in plastic container	Novartis Pharmaceutical Manufacturing LLC, Verovskova Ulica 57, Ljubljana, 1000	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20247/3 12.12.2025
21	Tinctura Crataegi	fructus crataegi	tincture	100mg/ml; glass bottle 30ml	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	OTC	22139/1 12.12.2025
22	Orgalutran	ganirelix (ganirelix acetate)	solution for s/c injection	0,25mg/0,5ml; (5) pre-filled syringes 0,5ml	N.V. Organon, Kloosterstraat 6, 5349 AB Oss- secondary packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Schutzenstrasse 87 and 99/101, D-88212 Ravensburg, Germany- bulk manufacturer, primary packager, quality control	the Netherlands	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	22980/1 12.12.2025
23	Janumet	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+850mg (56/4x14) in blister	Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem- packager, quality control, batch releaser, Aesica Queenborough Limited, Queenborough Kent ME 11 5EL, UK- bulk manufacturer	the Netherlands	Merck Sharp & Dohme LLC, 126 East Lincoln Avenue Rahway, New Jersey, 07065	USA	PoM	19550/4/1 12.12.2025

24	Janumet	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+1000mg (56/4x14) in blister	Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem- packager, quality control, batch releaser, Aesica Queenborough Limited, Queenborough Kent ME 11 5EL, UK- bulk manufacturer	the Netherlands	Merck Sharp & Dohme LLC, 126 East Lincoln Avenue Rahway, New Jersey, 07065	USA	PoM	19551/4/1 12.12.2025
25	Janumet	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+500mg; (56/4x14) in blister	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem- packager, quality control, batch releaser, Patheon Puerto Rico, Inc., State Road 670, Km. 2,7 Manati, Puerto Rico, 00674, USA- bulk manufacturer	the Netherlands	Merck Sharp & Dohme LLC, 126 East Lincoln Avenue Rahway, New Jersey, 07065	USA	PoM	21085/2/1 12.12.2025
26	Janumet	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+850mg; (56/4x14) in blister	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem- packager, quality control, batch releaser, Patheon Puerto Rico, Inc., State Road 670, Km. 2,7 Manati, Puerto Rico, 00674, USA- bulk manufacturer	the Netherlands	Merck Sharp & Dohme LLC, 126 East Lincoln Avenue Rahway, New Jersey, 07065	USA	PoM	21086/2/1 12.12.2025
27	Janumet	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+1000mg; (56/4x14) in blister	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem- packager, quality control, batch releaser, Patheon Puerto Rico, Inc., State Road 670, Km. 2,7 Manati, Puerto Rico, 00674, USA- bulk manufacturer	the Netherlands	Merck Sharp & Dohme LLC, 126 East Lincoln Avenue Rahway, New Jersey, 07065	USA	PoM	21087/2/1 12.12.2025
28	Dutasteride/ Tamsulosin	dutasteride, tamsulosin (tamsulosin hydrochloride)	capsules modified-release	0,5mg+0+4mg; (30) plastic container	Sag Manufacturing S.L., Carretera Nacional 1, Km 36, 28750, San-Agustin-Del-Guadalix	Spain	Laboratorio STADA, S.L, Frederic Mompou, 5, 08960 Sant-Just-Desvern (Barcelona)	Spain	PoM	22999/1 12.12.2025
29	IMMUNOMAX BIO	peptidoglycan	powder lyophilized for solution for i/m injection	200IU; (3) glass vial	IMMAPHARMA LLC, 18/11, st. Gamaleya, Moscow, 123098- batch releaser, bulk manufacturer, packager, quality control (physicochemical), Avexima Sibir LLC, 7, st. Hercen, Kemerovskaya region, Kuzbass, Anjero-Sudjensk, 652473, Russia- quality control (microbiological)	Russia	Avexima OJSC, 31A/1, Leningradsky pr., Moscow, 125284	Russia	PoM	20679/2 12.12.2025

30	Metabet SR	metformin (metformin hydrochloride)	tablets prolonged-release	500mg; (28/2x14) in blister	Morningside Pharmaceuticals Ltd, 5 Pavilion Way, Loughborough, LE115GW- batch releaser, USV Ltd, H-17/ H-18, O IDC, Mahatma Gandhi Udyog Nagar, Dabhel, Daman, 396210, India- bulk manufacturer, packager, Zeta Analytical LTD, Colonial Way, Unit 3, Watford Hertfordshire, WD24 4YR, United Kingdom- quality control (physicochemical), Kennet Bioservices Limited, 6 Kingsdown Orchard, Hyde Road, Swindon, SN2 7RR, UK- quality control (microbiological)	UK	Morningside Healthcare Ltd. Unit C, Harcourt Way Leicester LE19 1WP	UK	PoM	22920/1 12.12.22025
31	Metabet SR	metformin (metformin hydrochloride)	tablets prolonged-release	1000mg; (28/2x14) in blister	Morningside Pharmaceuticals Ltd, 5 Pavilion Way, Loughborough, LE115GW- batch releaser, USV Ltd, H-17/ H-18, O IDC, Mahatma Gandhi Udyog Nagar, Dabhel, Daman, 396210, India- bulk manufacturer, packager, Zeta Analytical LTD, Colonial Way, Unit 3, Watford Hertfordshire, WD24 4YR, United Kingdom- quality control (physicochemical), Kennet Bioservices Limited, 6 Kingsdown Orchard, Hyde Road, Swindon, SN2 7RR, UK- quality control (microbiological)	UK	Morningside Healthcare Ltd. Unit C, Harcourt Way Leicester LE19 1WP	UK	PoM	22921/1 12.12.22025

LIST

of variations requiring registration approved by the Center according to the meeting decision approved by the Center according to the meeting
decision N 12-1/25 on December 12, 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	Metabet SR	metformin (metformin hydrochloride)	tablets prolonged-release	500mg; (28/2x14) in blister	Morningside Pharmaceuticals Ltd, second floor, Boss Court, 7 Barton Close, Grove Park, Leicester, LE19 1SJ- batch releaser, USV Ltd, H-17/ H-18, OI DC, Mahatma Gandhi Udyog Nagar, Dabhel, Daman, 396210, India- bulk manufacturer, packager, Zeta Analytical LTD, Colonial Way, Unit 3, Watford Hertfordshire, WD24 4YR, United Kingdom- quality control (physicochemical), Kennet Bioservices Limited, 6 Kingsdown Orchard, Hyde Road, Swindon, SN2 7RR, UK- quality control (microbiological)	UK	Morningside Healthcare Ltd. Unit C, Harcourt Way Leicester LE19 1WP	UK	PoM	23684 12.12.2025
2	Metabet SR	metformin (metformin hydrochloride)	tablets prolonged-release	1000mg; (28/2x14) in blister	Morningside Pharmaceuticals Ltd, second floor, Boss Court, 7 Barton Close, Grove Park, Leicester, LE19 1SJ- batch releaser, USV Ltd, H-17/ H-18, OI DC, Mahatma Gandhi Udyog Nagar, Dabhel, Daman, 396210, India- bulk manufacturer, packager, Zeta Analytical LTD, Colonial Way, Unit 3, Watford Hertfordshire, WD24 4YR, United Kingdom- quality control (physicochemical), Kennet Bioservices Limited, 6 Kingsdown Orchard, Hyde Road, Swindon, SN2 7RR, UK- quality control (microbiological)	UK	Morningside Healthcare Ltd. Unit C, Harcourt Way Leicester LE19 1WP	UK	PoM	23685 12.12.2025

3	Metabet SR	metformin (metformin hydrochloride)	tablets prolonged-release	500mg; (28/2x14) in blister	Aspire Pharma Ltd, second floor, Boss Court, 7 Barton Close, Grove Park, Leicester, LE19 1SJ- batch releaser, USV Ltd, H-17/ H-18, O IDC, Mahatma Gandhi Udyog Nagar, Dabhel, Daman, 396210, India- bulk manufacturer, packager, Zeta Analitical LTD, Colonial Way, Unit 3, Watford Hertfordshire, WD24 4YR, United Kingdom- quality control (physicochemical), Kennet Bioservices Limited, 6 Kingsdown Orchard, Hyde Road, Swindon, SN2 7RR, UK- quality control (microbiological)	UK	Morningside Healthcare Ltd. Unit C, Harcourt Way Leicester LE19 1WP	UK	PoM	23686 12.12.2025
4	Metabet SR	metformin (metformin hydrochloride)	tablets prolonged-release	1000mg; (28/2x14) in blister	Aspire Pharma Ltd, second floor, Boss Court, 7 Barton Close, Grove Park, Leicester, LE19 1SJ- batch releaser, USV Ltd, H-17/ H-18, O IDC, Mahatma Gandhi Udyog Nagar, Dabhel, Daman, 396210, India- bulk manufacturer, packager, Zeta Analitical LTD, Colonial Way, Unit 3, Watford Hertfordshire, WD24 4YR, United Kingdom- quality control (physicochemical), Kennet Bioservices Limited, 6 Kingsdown Orchard, Hyde Road, Swindon, SN2 7RR, UK- quality control (microbiological)	UK	Morningside Healthcare Ltd. Unit C, Harcourt Way Leicester LE19 1WP	UK	PoM	23687 12.12.2025

5	Metabet SR	metformin (metformin hydrochloride)	tablets prolonged-release	500mg; (28/2x14) in blister	Aspire Pharma Ltd, Unit 4, Rotherbrook Court, Bedford Road, Petersfield, GU32 3QG- batch releaser, USV Ltd, H-17/ H-18, OI DC, Mahatma Gandhi Udyog Nagar, Dabhel, Daman, 396210, India- bulk manufacturer, packager, Zeta Analitical LTD, Colonial Way, Unit 3, Watford Hertfordshire, WD24 4YR, United Kingdom- quality control (physicochemical), Kennet Bioservices Limited, 6 Kingsdown Orchard, Hyde Road, Swindon, SN2 7RR, UK- quality control (microbiological)	UK	Morningside Healthcare Ltd. Unit C, Harcourt Way Leicester LE19 1WP	UK	PoM	23688 12.12.2025
6	Metabet SR	metformin (metformin hydrochloride)	tablets prolonged-release	1000mg; (28/2x14) in blister	Aspire Pharma Ltd, Unit 4, Rotherbrook Court, Bedford Road, Petersfield, GU32 3QG- batch releaser, USV Ltd, H-17/ H-18, OI DC, Mahatma Gandhi Udyog Nagar, Dabhel, Daman, 396210, India- bulk manufacturer, packager, Zeta Analitical LTD, Colonial Way, Unit 3, Watford Hertfordshire, WD24 4YR, United Kingdom- quality control (physicochemical), Kennet Bioservices Limited, 6 Kingsdown Orchard, Hyde Road, Swindon, SN2 7RR, UK- quality control (microbiological)	UK	Morningside Healthcare Ltd. Unit C, Harcourt Way Leicester LE19 1WP	UK	PoM	23689 12.12.2025

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-1/25 on December 12, 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	Caffetin	paracetamol, propyphenazone, caffeine, codeine (codeine phosphate)	tablets	250mg+210mg+50mg+10mg; (12/2x6) in strip, (10/1x10) in strip	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°001832-ITI-AM 12.12.2025
2	Bretaris Genuair	acridinium (acridinium bromide)	powder for inhalation	322mcg/dose; (1) inhaler (30 unit doses), (1) inhaler (60 unit doses), (3) inhaler (180/3x60/ unit doses)	Industrias Farmaceuticas Almirall S.A., Ctra. De Martorel 41-61, 08740 Sant Andreu de la Barca, Barcelona	Spain	Berlin-Chemie AG, Glienicke Weg 125, 12489 Berlin	Germany	PoM	JITI-N°000310-PT-AM 12.12.2025
3	Respisalf	salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)	capsules for inhalation	50mcg+100mcg; (30/3x10) in blister, (30/3x10) in blister with inhaler, (30) in plastic container, (30) plastic container with inhaler, (60/6x10) in blister, (60/6x10) in blister with inhaler, (60/2x30) plastic container, (60/2x30) plastic container with inhaler, (90/9x10) in blister, (90/9x10) in blister with inhaler	PSK Pharma Ltd, 5 Programmistov st., building 1, Dubna, Dubna urban district, Moscow Region, 141983	Russia	PSK Pharma Ltd, 5 Programmistov st., building 1, Dubna, Dubna urban district, Moscow Region, 141983	Russia	PoM	JITI-N°000624-ITI-AM 12.12.2025
4	Respisalf	salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)	capsules for inhalation	50mcg+250mcg; (30/3x10) in blister, (30/3x10) in blister with inhaler, (30) in plastic container, (30) plastic container with inhaler, (60/6x10) in blister, (60/6x10) in blister with inhaler, (60/2x30) plastic container, (60/2x30) plastic container with inhaler, (90/9x10) in blister, (90/9x10) in blister with inhaler	PSK Pharma Ltd, 5 Programmistov st., building 1, Dubna, Dubna urban district, Moscow Region, 141983	Russia	PSK Pharma Ltd, 5 Programmistov st., building 1, Dubna, Dubna urban district, Moscow Region, 141983	Russia	PoM	JITI-N°000624-ITI-AM 12.12.2025

5	Respialf	salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)	capsules for inhalation	50mcg+500mcg; (30/3x10) in blister, (30/3x10) in blister with inhaler, (30) in plastic container, (30) plastic container with inhaler, (60/6x10) in blister, (60/6x10) in blister with inhaler, (60/2x30) plastic container, (60/2x30) plastic container with inhaler, (90/9x10) in blister, (90/9x10) in blister with inhaler	PSK Pharma Ltd, 5 Programmistov st., building 1, Dubna, Dubna urban district, Moscow Region, 141983	Russia	PSK Pharma Ltd, 5 Programmistov st., building 1, Dubna, Dubna urban district, Moscow Region, 141983	Russia	PoM	JITI-N°000624-ITI-AM 12.12.2025
6	Lorista	losartan (losartan potassium)	tablets film-coated	25mg; (28/2x14) 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	JITI-N°001718-ITI-AM 12.12.2025
7	Lorista	losartan (losartan potassium)	tablets film-coated	50mg; (28/2x14) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°001718-ITI-AM 12.12.2025
8	Lorista	losartan (losartan potassium)	tablets film-coated	100mg; (28/2x14) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°001718-ITI-AM 12.12.2025
9	Septanest with adrenaline	articaine (articaine hydrochloride), adrenaline (adrenaline tartrate)	solution for injection	40mg/ml+5mcg/ml; (50/5x10) cartridges 1,7ml in blister	Septodont, 58 rue du Pont de Creteil, Saint-Maur-des-Fosses, 94100	France	Septodont, 58 rue du Pont de Creteil, Saint-Maur-des-Fosses, 94100	France	PoM	JITI-N°008279-ITI-AM 12.12.2025
10	Septanest with adrenaline	articaine (articaine hydrochloride), adrenaline (adrenaline tartrate)	solution for injection	40mg/ml+10mcg/ml; (50/5x10) cartridges 1,7ml in blister	Septodont, 58 rue du Pont de Creteil, Saint-Maur-des-Fosses, 94100	France	Septodont, 58 rue du Pont de Creteil, Saint-Maur-des-Fosses, 94100	France	PoM	JITI-N°008279-ITI-AM 12.12.2025
11	Pronoran	piribedil	tablets prolonged-release coated	50mg; (30/2x15) in blister, (30/1x30) in blister	Les Laboratoires Servier Industrie, 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, Rue Carnot, 92284 Suresnes Cedex	France	PoM	JITI-N°003873-ITI-AM 12.12.2025
12	Pronoran	piribedil	tablets prolonged-release coated	50mg; (29/1x29) in blister, (30/1x30) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow-packager, quality control, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France-bulk manufacturer	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes Cedex	France	PoM	JITI-N°003873-ITI-AM 12.12.2025
13	Pronoran	piribedil	tablets prolonged-release coated	50mg; (29/1x29) in blister, (30/1x30) 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	JITI-N°003873-ITI-AM 12.12.2025

14	Lorista H	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	50mg+12,5mg; (28/2x14) 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	JITI-N*001972-ITI-AM 12.12.2025
15	Lorista H	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	50mg+12,5mg; (28/2x14) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N*001972-ITI-AM 12.12.2025
16	Lorista H	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	50mg+12,5mg; (28/2x14) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, batch releaser, Labena, d.o.o, Teslova 30, 1000 Lyublyana, Slovenia- quality control	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N*001972-ITI-AM 12.12.2025
17	Lorista HD	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+25mg; (28/2x14) 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	JITI-N*001992-ITI-AM 12.12.2025
18	Lorista HD	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+25mg; (28/2x14) in blister	Krka-RUS LLC 50 Moskovskaya str., Istra, Moscow region 143500	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N*001992-ITI-AM 12.12.2025
19	Lorista HD	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+25mg; (28/2x14) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, batch releaser; Labena d.o.o, Teslova 30, 1000 Lublyana, Slovenia - quality control	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N*001992-ITI-AM 12.12.2025
20	Oncaspar	Pegaspargase	lyophilizate for solution for i/m injection and infusion	750IU/ml; glass vial 5ml	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy- quality control, batch releaser, Lyophilization Services of New England, Inc (LSNE), 25 Commerce Drive, Bedford, New Hampshire (NH) 03110, USA- bulk manufacturer, primary packager, Exelead Inc., 6925 Guion Road, Indianapolis, Indiana (IN) 46268, USA- secondary packager	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N*000545-ITI-AM 12.12.2025

21	Massido	nebivolol (nebivolol hydrochloride)	tablets	5mg; (28/2x14) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- batch releaser, CADILA PHARMACEUTICALS LTD. PLOT NO. 1389 TRASAD ROAD, DHOLKA- 382225, Dist: AHMEDABAD,GUJARAT STATE, India- bulk manufacturer, packager, quality control	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	ЈИП-№007584-PT- AM 12.12.2025
22	Tribestan	tribulus terrestris herb dry extract	tablets film- coated	250mg; (60/6x10) in blister, (180/18x10) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	ЈИП-№004989-ITI- AM 12.12.2025