

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 03-1/24 on March 15, 2024

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	Otisfen	phenazone, lidocaine (lidocaine hydrochloride)	drops ear	40mg/g+10mg/g; plastic vial-dropper 10g	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	OTC	21997 15.03.2024
2	PARACETAMOL 500mg tablets	paracetamol	tablets	500mg; (1000/100x10) in blister	M/s Medopharm, No. 34-B, Industrial Area, Kolar district, Malur, 563 160, Karnataka	India	Troge Scientific Research I. PVT.LTD., Tower C, Unit No-A-12-A, 2nd floor, Alphathum, sector-90, Noida 201305, Gautam Buddha nagar, Uttar Pradesh	India	OTC	21998 15.03.2024

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of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 03-1/24 on March 15,
2024

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	Aripegis	aripirazole	tablets	10mg; (28/2x14) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22000 (001778) 15.03.2024
2	Aripegis	aripirazole	tablets	15mg; (28/2x14) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22001 (001778) 15.03.2024
3	Caffetin Rapid	ibuprofen (ibuprofen lysine)	tablets film-coated	400mg; (10/1x10) in blister, (20/2x20) 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	21999 (004158) 15.03.2024

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 03-1/24 on March 15, 2024

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	Ketonal Forte	ketoprofen	tablets film-coated	100mg; (20) in glass container	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	22002 15.03.2024
2	Levocom	levodopa, carbidopa	tablets	250mg+25mg; (30/3x10) in blister, (100/10x10) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	22003 15.03.2024
3	Peptomet	domperidone	tablets film-coated	10mg; (30/3x10) in blister	Remedica Ltd., Limassol Industrial Estate, Aharnon street, 3056 Limassol	Cyprus	Remedica Ltd., Limassol Industrial Estate, Aharnon street, 3056 Limassol	Cyprus	PoM	22004 15.03.2024
4	CoLosar-Denk 100/12,5	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+12,5mg; (28/2x14) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	22005 15.03.2024
5	Orabloc	articaine (articaine hydrochloride), adrenaline (adrenaline tartrate)	solution for injection	40mg/ml+10mcg/ml; (100/10x10) cartridges 1,8ml in blister	Pierrel S.p.A., S.S. Appia, 7 Bis, 46/48 Capua (CE) 81043	Italy	Pierrel S.p.A., S.S. Appia, 7 Bis, 46/48 Capua (CE) 81043	Italy	PoM	22006 15.03.2024

6	Sandimmun Neoral	ciclosporin	capsules soft	25mg; (50/10x5) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany- bulk manufacturer, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany- quality control (physicochemical), 1. Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland, 2. Gelita AG, Gammelsbacher Str. 2, 69412 Eberbach, Germany- quality control (microbiological)	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	22007 15.03.2024
7	Sandimmun Neoral	ciclosporin	capsules soft	50mg; (50/10x5) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany- bulk manufacturer, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany- quality control (physicochemical), 1. Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland, 2. Gelita AG, Gammelsbacher Str. 2, 69412 Eberbach, Germany- quality control (microbiological)	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	22008 15.03.2024
8	Sandimmun Neoral	ciclosporin	capsules soft	100mg; (50/10x5) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany- bulk manufacturer, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany- quality control (physicochemical), 1. Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland, 2. Gelita AG, Gammelsbacher Str. 2, 69412 Eberbach, Germany- quality control (microbiological)	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	22009 15.03.2024

9	Anastrozole Denk 1mg	anastrozole	tablets film-coated	1mg; (30/3x10) in blister	Haupt Pharma Muenster GmbH, Schleebrueggenkamp 15, Upeenberg, Muenster, North Rhine-Westphalia, 48159	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	22010 15.03.2024
10	Lodigrel	clopidogrel (clopidogrel hydro-sulfate)	tablets film-coated	75mg; (14/2x7) in blister, (28/4x7) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22011 15.03.2024
11	Actrapid Penfill	insulin human	solution for injection	100IU/ml; (5) glass cartridges 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	22012 15.03.2024
12	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	5mg; (56/4x14) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22013 15.03.2024
13	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	15mg; (56/4x14) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22014 15.03.2024
14	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	20mg; (56/4x14) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22015 15.03.2024
15	Melarena	melatonin	tablets film-coated	3mg; (10/1x10) in blister, (30/3x10) in blister	Hemofarm LLC, 249035, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	22016 15.03.2024
16	Losar-Denk 25	losartan (losartan potassium)	tablets film-coated	25mg; (28/2x14) blisters	Denk Pharma GmbH & Co. KG, Goellstr. 1, Tittmoning, 84529, Bayern- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LSSE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	22017 15.03.2024
17	Lisinopril	lisinopril (lisinopril dihydrate)	tablets	10mg; (24/1x24) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	22018 15.03.2024
18	Biseptol	sulfamethoxazole, trimethoprim	tablets	100mg+20mg; (20/1x20) in blister	Adamed Pharma S.A., 5 Marszalka Jozefa Pilsudskiego Str., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pi-enkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	PoM	22019 15.03.2024
19	Biseptol	sulfamethoxazole, trimethoprim	tablets	400mg+80mg; (20/1x20) in blister	Adamed Pharma S.A., 5 Marszalka Jozefa Pilsudskiego Str., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pi-enkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	PoM	22020 15.03.2024

20	Theraflex Chondrocream Forte	chondroitin sulfate, meloxicam	cream for external use	50mg/g+10mg/g; 30g aluminium tube, 100g aluminium tube	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	JSC BAYER, 3rd Rybinskaya st., 18, build. 2, 107113 Moscow	Russia	OTC	22021 15.03.2024
21	Vitasilk	benzoyl peroxide	gel for external use	50mg/g; aluminium tube 25g	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	22022 15.03.2024

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 03-1/24 on March 15, 2024

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	Ultrix Quadri Tetravalent inactivated split influenza vaccine	influenza virus antigen tipe	solution for i/m injection	15mcg/dose+15mcg/dose+15mcg/dose+15mcg/dose; (1) pre-filled syringes 0,5ml, (10) pre-filled syringes 0,5ml	FORT LLC, Ryazan district, Ryazan Oblast, Okskoye rural settlement, Jaltunovo, pharm complex, bld. 1j, 390540	Russia	FORT LLC, Ryazan district, Ryazan oblast, Okskoye rural settlement, Jaltunovo, pharm complex, bld. 1a, 390540	Russia	PoM	20915/1/1 15.03.2024
2	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	21085/1/1 15.03.2024

3	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	21086/1/1 15.03.2024
4	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	21087/1/1 15.03.2024
5	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	19550/3/1 15.03.2024
6	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	19551/3/1 15.03.2024

7	Amlodipine	amlodipine (amlodipine besilate)	tablets	5mg; (10/1x10/) in blister, (30/3x10/) in blister	Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo St., 1- quality control, batch releaser, Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st. 1/5, No6, Republic of Belarus- bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	18443/1/1 15.03.2024
8	Xalatan	latanoprost	drops eye	50mcg/ml; 2,5ml plastic container	Pfizer Manufacturing Belgium, Rijksweg 12, Puurs-Sint-Amands, 2870	Belgium	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	17980/5/2 15.03.2024
9	Piracetam	piracetam	capsules	400mg; (10) in blister, (60/6x10/) in blister	Open joint stock company «Borisovskiy zavod medicinskikh preparatov», 64A, No4, 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	18824/1/1 15.03.2024
10	Sevo-Anesteran	sevoflurane	liquid for inhalation	100%; 250ml glass bottle	Rompharm Company SRL, Str. Drumul Garii Otopeni No52, Otopeni city, Ilfov county, 075100, building Rompharm 3- batch releaser, Rompharm Company SRL, Eroilor Str., No 1A, Otopeni city, Ilfov county, 075100, building Rompharm 2, Romania- secondary packager, quality control (physicochemical), Rompharm Company SRL, Eroilor Str., No1A, Otopeni city, Ilfov county, 075100, building Rompharm 1, Romania-bulk manufacturer, primary packager, quality control (microbiological)	Romania	Rompharm Company SRL, Eroilor Str., No 1A, Otopeni city, Ilfov county, 075100	Romania	PoM	18604/2/1 15.03.2024
11	Hydrochlorothiazide	hydrochlorothiazide	tablets	25mg; (20/2x10) 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, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	PoM	21058/2/1 15.03.2024

12	Metformin	metformin (metformin hydrochloride)	tablets	500mg; (30/3x10) in blister	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	20886/1/1 15.03.2024
13	Metformin	metformin (metformin hydrochloride)	tablets	1000mg; (30/2x15) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	21926/1/1 15.03.2024
14	Spazmaton	metamizole (metamizole sodium), pitofenone (pitofenone hydrochloride), fempiverinium bromide	solution for i/m injection	500mg/1ml+2mg/1ml+0,02mg/1ml; (10) ampoules 5ml label banderol, (10) ampoules 5ml dividella, (10) ampoules 5ml CAMA	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	20221/2/1 15.03.2024
15	Trittico	trazodone	tablets prolonged-release	150mg; (20/2x10) in blister	Aziende Chimiche Riunite Angelini Francesco ACRAFS.p.A., Via Vecchia del Pinocchio, 22-60100 Ancona	Italy	Angelini Pharma S.p.A. Viale Amelia, 70-00181 Rome	Italy	PoM	19129/5/2 15.03.2024
16	Nevanac	nepafenac	drops eye (suspension)	1mg/ml; plastic bottle 5ml	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs-Sint-Amands	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19456/1/1 15.03.2024

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 03-1/24 on March 15, 2024

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1	Cetrotide	cetorelix (cetorelix acetate)	powder lyophilized for solution for s/c injection	0,25mg; N7 glass vials with powder, N7 prefilled syringes with solvent 1ml, N14 needles, N14 alcohol swabs; N1 glass vials with powder, N1 prefilled syringes with solvent 1ml, N 2 needles, N 2 alcohol swabs	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt- batch releaser, FAREVA PAU 2, 50 chemin de Mazerolles, 64320 Idron, France- powder bulk manufacturer, primary packager, ABBOTT Biologicals B.V. Veerweg 12, 8121 AA Olst, the Netherlands- solvent bulk manufacturer, primary packager, quality control, FAREVA PAU 1, Avenue du Beam, 64320 Idron, France- powder quality control, ABBOTT Biologicals B.V. Veerweg 12, 8121 AA Olst, the Netherlands- secondary packager	Germany	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	20360/2 15.03.2024
2	Advagraf	tacrolimus	capsules prolonged-release	0,5mg; (50/5x10) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry, V93 FC86	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	PoM	19027/5/1 15.03.2024
3	Advagraf	tacrolimus	capsules prolonged-release	1mg; (50/5x10) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry, V93 FC86	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	PoM	19028/5/1 15.03.2024
4	Advagraf	tacrolimus	capsules prolonged-release	5mg; (50/5x10) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry, V93 FC86	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	PoM	19029/5/1 15.03.2024
5	Amoxil	amoxicillin (amoxicillin trihydrate)	tablets	250mg; (20/2x10) in blister	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	PoM	21317/1 15.03.2024
6	Amoxil	amoxicillin (amoxicillin trihydrate)	tablets	500mg; (20/2x10) in blister	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	PoM	21318/1 15.03.2024

7	Allochol	cattle bile dried, dried garlic, charcoal activated, nettle leaves	tablets coated	80mg+40mg+25mg+5mg; (10/1x10/) in blister, (50) plastic container	Irbitskiy himfarmzavod OJSC, 124-a, K. Marksa str., Irbit, St. Sverdlovsk, 623856	Russia	Irbitskiy himfarmzavod OJSC, 172, Kirova str., Irbit, St. Sverdlovsk, 623856	Russia	OTC	19109/1 15.03.2024
8	Bilobil forte	ginkgo biloba leaf dry extract	capsules	80mg; (20/2x10/) in blister, (60/6x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	19708/1 15.03.2024
9	Survanta	beractant (phospholipids)	suspension intratracheal	25mg/ml; glass vial 4ml	AbbVie Inc., 1401 Sheridan Road, North Chicago, Illinois 60064- bulk manufacturer, primary packager, quality control, batch releaser, AbbVie Inc., 1 North Waukegan Road, North Chicago, Illinois 60064, USA- secondary packager	USA	AbbVie Biopharmaceuticals GmbH, Alte Steinhäuserstrasse 14, 6330 Cham	Switzerland	PoM	20956/1 15.03.2024
10	Peptomat	domperidone	tablets film-coated	10mg (30/3x10/) in blister	Remedica Ltd., Limassol Industrial Estate, Aharnon street, 3056 Limassol	Cyprus	Remedica Ltd., Limassol Industrial Estate, Aharnon street, 3056 Limassol	Cyprus	PoM	17659/2 15.03.2024
11	Orabloc	articaine (articaine hydrochloride), adrenaline (adrenaline tartrate)	solution for injection	40mg/ml+10mcg/ml; (100/10x10) cartridges 1,8ml in blister	Pierrel S.p.A., S.S. Appia, Capua (CE) 81043	Italy	Pierrel S.p.A., Strada statale Appia, 7 Bis, 46/48 Capua (CE) 81043	Italy	PoM	18536/3/1 15.03.2024
12	Kenalog 40	triamcinolone (triamcinolone acetone)	suspension for injection	40mg/ml; (5) ampoules 1ml	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	20162/1 15.03.2024
13	Bicillin-3	benzathine benzylpenicillin, benzylpenicillin sodium, benzylpenicillin procaine	powder for i/m suspension for injection	200000IU+200000IU+200000IU; (40) glass vials	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	20222/2 15.03.2024
14	Bicillin-5	benzathine benzylpenicillin, benzylpenicillin procaine	powder for i/m suspension for injection	1200000IU+300000IU; (40) glass vials	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	20223/2 15.03.2024
15	Ceftriaxon	ceftriaxone (ceftriaxone sodium)	powder for solution for injection	500mg; (10) glass vials	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	21420/1 15.03.2024

16	Ceftriaxon	ceftriaxone (ceftriaxone sodium)	powder for solution for injection	1000mg; (10) glass vials	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	21421/1 15.03.2024
17	Lodigrel	clopidogrel (clopidogrel hydrosulfate)	tablets film-coated	75mg; (14/2x7) in blister, (28/4x7) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	18408/5 15.03.2024
18	Losar-Denk 25	losartan (losartan potassium)	tablets film-coated	25mg; (28/2x14) blisters	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	18143/4 15.03.2024
19	Actilyse	alteplase	powder lyophilized for solution for infusion with solvent	50mg; glass vial and glass vial with solvent 50ml	Boehringer Ingelheim Pharma GmbH & Co. KG, Birkendorfer str. 65, 88397 Biberach a.d.R.	Germany	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein	Germany	PoM	20988/2 15.03.2024
20	Flucinar	fluocinolone acetonide	ointment for external use	0,25mg/g; aluminium tube 15g	Pharmaceutical Company Jelfa S.A., ul. Wincen-tego Pola 21, 58-500 Jelenia Gora	Poland	BAUSCH Health LLC, Shab-olovka st. 31, building 5, 115162, Moscow	Russia	PoM	19987/1 15.03.2024
21	Biseptol	sulfamethoxazole, trimethoprim	tablets	100mg+20mg; (20/1x20) in blister	Adamed Pharma S.A., 5 Marszalka Jozefa Pilsudskiego Str., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pi-enkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	PoM	18263/5/1 15.03.2024
22	Biseptol	sulfamethoxazole, trimethoprim	tablets	400mg+80mg; (20/1x20) in blister	Adamed Pharma S.A., 5 Marszalka Jozefa Pilsudskiego Str., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pi-enkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	PoM	18264/5/2 15.03.2024
23	Miropriston	mifepristone	tablets	200mg; (3/1x3) in blister	Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 107- bulk manufacturer, packager, Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 3a/3, Russia- quality control (physical/chemical), batch releaser, Test center «FARMOBORONA» LTD., 46A, Gagarin st., Korolyov, Moscow Region, 141074, Russia - quality control (microbiological)	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	20787/2/1 15.03.2024
24	Strepsils Express	dichlorobenzyl alcohol, amylmetacresol, lidocaine (lidocain hydrochloride monohydrate)	lozenges	1,2mg+0.6mg+10mg; (24/2x12) in blister, (24/3x8) in blister	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	OTC	19542/2 15.03.2024

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 03-1/24 on March 15, 2024

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	Lonsurf	trifluridine, tipiracil (tipiracil hydrochloride)	tablets film-coated	15mg+6,14mg; (20/2x10) in blister, (40/4x10) in blister, (60/6x10) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy- packager, batch releaser, Taiho Pharmaceutical Co. Ltd., Kitajima Plant, 1-1, Iuchi, Takabo, Kitajima-cho, Itano-gun, 771-0206 Tokushima, Japan- bulk manufacturer	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000011/1/1 15.03.2024
2	Lonsurf	trifluridine, tipiracil (tipiracil hydrochloride)	tablets film-coated	20mg+8,19mg; (20/2x10) in blister, (40/4x10) in blister, (60/6x10) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy- packager, batch releaser, Taiho Pharmaceutical Co. Ltd., Kitajima Plant, 1-1, Iuchi, Takabo, Kitajima-cho, Itano-gun, 771-0206 Tokushima, Japan- bulk manufacturer	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000011/1/1 15.03.2024
3	Sulid	nimesulide	granules for oral suspension	100mg; (30) sachets 2g	AVVA RUSJSC, Kirov region, Kirov city, Luganskaya Str. 53A	Russia	TOO «AVVA Kazakhstan», 050008, city Almaty, Almaly region, Abaya avenue, 109B, room 501	Republic of Kazakhstan	PoM	004593 15.03.2024