

LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 02-2/24 on February 29, 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	D3-CAPS MAXIMA	colecalférol	capsules	50000IU; (10/1x10) in blister	Minskintercaps U.V., 26/3, Inzhenernaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Republic of Belarus	PoM	21963 (002478) 29.02.2024
2	D3-CAPS ULTRA	colecalférol	capsules chewing with orange flavour	500IU; (30/3x10) in blister	Minskintercaps U.V., 26/3, Inzhenernaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Republic of Belarus	OTC	21964 (002647) 29.02.2024
3	D3-CAPS ULTRA	colecalférol	capsules chewing with banana flavour	500IU; (30/3x10) in blister	Minskintercaps U.V., 26/3, Inzhenernaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Republic of Belarus	OTC	21965 (002647) 29.02.2024
4	Urdoxa 500	ursodeoxycholic acid	tablets film-coated	500mg; (50/5x10) in blister, (100/5x20) in blister	Alium AO, build. 1, No: 2, Quarter A, Obolensk settlement, Serpukhov urban district, 142279, Moscow reg.- quality control, batch releaser, Alium AO, No: 2, Quarter A, Obolensk settlement, Serpukhov urban district, 142279, Moscow region, Russia- bulk manufacturer, packager	Russia	Alium AO, No: 2, Quarter A, Obolensk settlement, Serpukhov urban district, 142279, Moscow region	Russia	PoM	21966 (005833) 29.02.2024
5	Alecensa	alectinib (alectinib hydrochloride)	capsules hard	150mg; (56/8x7) in blister, (224/4x56) in blister	F. Hoffmann La Roche Ltd., Grenzacherstrasse 124, 4058 Basel- batch releaser, Excella GmbH & Co.KG, Numberger st. 12, Feucht, Bayern 90537, Germany- bulk manufacturer, Delpharm Milano S.R.L, Via Carnevale,1, Segrate (MI), 20054, Italy- packager, quality control	Switzerland	F. Hoffmann La Roche Ltd., Grenzacherstrasse 124 Basel, 4070	Switzerland	PoM	21967 (648006) 29.02.2024

6	Telmista AM	amlodipine (amlodipine besilate), telmisartan	tablets	5mg+40mg: (30/3x10) 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	21968 (001104) 29.02.2024
7	Telmista AM	amlodipine (amlodipine besilate), telmisartan	tablets	5mg+80mg: (30/3x10) 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	21969 (001104) 29.02.2024
8	Telmista AM	amlodipine (amlodipine besilate), telmisartan	tablets	10mg+40mg: (30/3x10) 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	21970 (001104) 29.02.2024
9	Telmista AM	amlodipine (amlodipine besilate), telmisartan	tablets	10mg+80mg: (30/3x10) 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	21971 (001104) 29.02.2024
10	Lixiana	edoxaban (edoxaban tosylate monohydrate)	tablets film-coated	15mg: (14/1x14) in blister, (1000-300000) (in-bulk) in bag	Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen	Germany	Servier JSC, 125196, Lesnaya str., 7, floor 7/8/9, Moscow	Russia	PoM	21972 (005956) 29.02.2024
11	Lixiana	edoxaban (edoxaban tosylate monohydrate)	tablets film-coated	15mg: (14/1x14) in blister	LLC SERVIER RUS, 108828, Krasnopakhorskoe district, quarter 158, estate 2, bld. 1, Moscow- packager, quality control, batch releaser, Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen, Germany- bulk manufacturer	Russia	Servier JSC, 125196, Lesnaya str., 7, floor 7/8/9, Moscow	Russia	PoM	21973 (005956) 29.02.2024
12	Lixiana	edoxaban (edoxaban tosylate monohydrate)	tablets film-coated	30mg: (14/1x14) in blister, (28/2x14) in blister, (98/7x14) in blister, (1000-300000) (in-bulk) in bag	Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen	Germany	Servier JSC, 125196, Lesnaya str., 7, floor 7/8/9, Moscow	Russia	PoM	21974 (005956) 29.02.2024
13	Lixiana	edoxaban (edoxaban tosylate monohydrate)	tablets film-coated	30mg: (14/1x14) in blister, (28/2x14) in blister, (98/7x14) in blister	LLC SERVIER RUS, 108828, Krasnopakhorskoe district, quarter 158, estate 2, bld. 1, Moscow- packager, quality control, batch releaser, Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen, Germany- bulk manufacturer	Russia	Servier JSC, 125196, Lesnaya str., 7, floor 7/8/9, Moscow	Russia	PoM	21975 (005956) 29.02.2024
14	Lixiana	edoxaban (edoxaban tosylate monohydrate)	tablets film-coated	60mg: (14/1x14) in blister, (28/2x14) in blister, (98/7x14) in blister, (1000-300000) (in-bulk) in bag	Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen	Germany	Servier JSC, 125196, Lesnaya str., 7, floor 7/8/9, Moscow	Russia	PoM	21976 (005956) 29.02.2024

15	Lixiana	edoxaban (edoxaban tosylate monohydrate)	tablets film-coated	60mg; (14/1x14) in blister, (28/2x14) in blister, (98/7x14) in blister	LLC SERVIER RUS, 108828, Krasnopakhorskoe district, quarter 158, estate 2, bld. 1, Moscow- packager, quality control, batch releaser, Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen, Germany- bulk manufacturer	Russia	Servier JSC, 125196, Lesnaya str., 7, floor 7/8/9, Moscow	Russia	PoM	21977 (005956) 29.02.2024
16	Sedistress	dry extract of passiflora, ethyl ester of alpha-bromisovaleric acid	tablets	300mg+10,2mg; (30/3x10) in blister, (60/6x10) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	OTC	21978 (007742) 29.02.2024

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 02-2/24 on February 29, 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	Algavak M	inactivated antigen of hepatitis A	suspension for i/m injection	not less than 160 ELISA U/0,5ml (1dose for children); (10/2x5) ampoules 0,5ml (10 doses)	Vector-BiAlgam JSC, Research and production area, city district Koltsovo work settlement, Koltsovo work settlement, building 104, room 201, Novosibirsk region, 630559	Russia	Vector-BiAlgam JSC, Research and production area, city district Koltsovo work settlement, Koltsovo work settlement, building 104, room 201, Novosibirsk region, 630559	Russia	PoM	21979 29.02.2024
2	Algavak M	inactivated antigen of hepatitis A	suspension for i/m injection	not less than 320 ELISA U/1ml (1dose for adult); (10/2x5) ampoules 1ml (10 doses)	Vector-BiAlgam JSC, Research and production area, city district Koltsovo work settlement, Koltsovo work settlement, building 104, room 201, Novosibirsk region, 630559	Russia	Vector-BiAlgam JSC, Research and production area, city district Koltsovo work settlement, Koltsovo work settlement, building 104, room 201, Novosibirsk region, 630559	Russia	PoM	21980 29.02.2024
3	Difluzol	fluconazole	capsules	150mg; (1) in blister	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	PoM	21981 29.02.2024
4	Kardiotex	meldonium (meldonium dihydrate)	solution for i/v and parabolbar injection	100mg/ml; (5/1x5) ampoules 5ml in blister, (10/2x5) ampoules 5ml 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	21982 29.02.2024
5	Arpeflu	umifenovir (umifenovir hydrochloride)	tablets film-coated	50mg; (30/3x10) in blister	Lekpharm JLLC, 223141, Minsk region, Logoysk, Minskaya str. 2a/4	Republic of Belarus	«Lekpharm» JLLC, 223141, Minsk region, Logoysk, Minskaya str. 2a, room 301	Republic of Belarus	OTC	21983 29.02.2024

6	Arpeflu	umifenovir (umifenovir hydrochloride)	tablets film-coated	100mg; (30/3x10) in blister	Lekpharm JLLC, 223141, Minsk region, Logoysk, Minskaya str. 2a/4	Republic of Belarus	«Lekpharm» JLLC, 223141, Minsk region, Logoysk, Minskaya str. 2a, room 301	Republic of Belarus	OTC	21984 29.02.2024
7	Scandonest	mepivacaine (mepivacaine hydrochloride)	solution for injection	30mg/ml; (50) cartridges 1,7ml	Septodont, 58 rue du Pont de Creteil, 94100 Saint- Maur- des- Fosses	France	Septodont, 58 rue du Pont de Creteil, 94100 Saint- Maur- des- Fosses	France	PoM	21985 29.02.2024
8	Sermion	nicergoline	tablets film-coated	30mg; (30/2x15) in blister	Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno (AP)	Italy	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	21986 29.02.2024
9	Furacilin Tatpharm	nitrofurural	tablets for solution for local and external use	20mg; (10) in blister, (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	21987 29.02.2024
10	Zeel	cartilago suis D6, coenzym A D8, embryo totalis suis D6, funiculus umbilicalis suis D6, nadidum D8, placenta totalis suis D6, sanguinaria canadensis D4, solanum dulcamara D3, symphytum officinale D6, acidum thiocticum D8, arnica montana D4, natrium diethyloxalaceticum D8, rhus toxicodendron D2, sulfur D6	solution for injection	2.0mg+2.0mg+2.0mg+2.0mg+2.0mg+2.0mg+3.0mg+10.0mg+10.0mg+2.0mg+20.0mg+2.0mg+10.0mg+3.6mg; (10) ampoules 2ml, (100) ampoules 2ml	Biologische Heilmittel Heel GmbH, Dr.-Reckeweg-Strasse 2-4, 76532 Baden-Baden	Germany	Biologische Heilmittel Heel GmbH, Dr.-Reckeweg-Strasse 2-4, 76532 Baden-Baden	Germany	PoM	21988 29.02.2024
11	Floxaton	levofloxacin (levofloxacin hemihydrate)	tablets film-coated	500mg; (10/1x10) in blister	Medochemie Ltd., (Central Factory), 1-10 Constantinoupoleos street, 3011 Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupoleos street, 3011 Limassol	Cyprus	PoM	21989 29.02.2024
12	Nurofen Forte	ibuprofen	tablets coated	400mg; (12/1x12) 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	21990 29.02.2024
13	Ramizek Combi	ramipril, amlodipine (amlodipine besilate)	capsules hard	5mg+5mg, (30/5x6) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice- quality control, batch releaser, Adamed Pharma S.A., 33, Szkolna St., 95-054 Ksawerow, Poland- bulk manufacturer, packager	Poland	Adamed Pharma S.A., 6A, Pi-enkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	PoM	21991 29.02.2024

14	Ramizek Combi	ramipril, amlodipine (amlodipine besilate)	capsules hard	10mg+5mg, (30/5x6) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice- quality control, batch releaser, Adamed Pharma S.A., 33, Szkolna St., 95-054 Ksawerow, Poland- bulk manufacturer, packager	Poland	Adamed Pharma S.A., 6A, Pi-enkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	PoM	21992 29.02.2024
15	Ramizek Combi	ramipril, amlodipine (amlodipine besilate)	capsules hard	10mg+10mg, (30/5x6) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice- quality control, batch releaser, Adamed Pharma S.A., 33, Szkolna St., 95-054 Ksawerow, Poland- bulk manufacturer, packager	Poland	Adamed Pharma S.A., 6A, Pi-enkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	PoM	21993 29.02.2024
16	Dexamethasone	dexamethasone (dexamethasone sodium phosphate)	solution for injection	4mg/ml; (5) ampoules 1ml, (5/1x5) ampoules 1ml in blister	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	PoM	21994 29.02.2024
17	Rutacid	hydrotalcite	tablets chewable	500mg; (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	21995 29.02.2024

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 02-2/24 on February 29,
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	Nadroparin calcium	nadroparin calcium	solution for injection	2850anti-XaIU/0,3ml; (5) pre-filled syringes 0,3ml	Moscow Endocrine Plant FSUE, 25, bld. 1, Novokhokhlovskaya st., Moscow, 109052- quality control, batch releaser, «Moscow Endocrine Plant» FSUE, 25, bld. 2, Novokhokhlovskaya st., Moscow, 109052, Russia- bulk manufacturer, packager	Russia	«Moscow Endocrine Plant» FSUE, 25, Novokhokhlovskaya st., Moscow 109052	Russia	PoM	21229/1/1 29.02.2024
2	Nadroparin calcium	nadroparin calcium	solution for injection	5700anti-XaIU/0,6ml; (5) pre-filled syringes 0,6ml	Moscow Endocrine Plant FSUE, 25, bld. 1, Novokhokhlovskaya st., Moscow, 109052- quality control, batch releaser, «Moscow Endocrine Plant» FSUE, 25, bld. 2, Novokhokhlovskaya st., Moscow, 109052, Russia- bulk manufacturer, packager	Russia	«Moscow Endocrine Plant» FSUE, 25, Novokhokhlovskaya st., Moscow 109052	Russia	PoM	21230/1/1 29.02.2024

3	Norvasc	amlodipine (amlodipine besilate)	tablets	5mg; (30/3x10) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau - packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	19129/4/2 29.02.2024
4	Norvasc	amlodipine (amlodipine besilate)	tablets	10mg; (30/3x10) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau - packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	19130/4/2 29.02.2024
5	Maviret	glecaprevir, pibrentasvir	tablets film-coated	100mg+40mg; (84(4x21(7x3)) in blister	AbbVie Deutschland GmbH & Co. KG, Knolstrasse, 67061 Ludwigshafen- batch releaser, packager, quality control, Fournier Laboratories Ireland Limited, Anngrove, Carrigtwohill, Co. Cork, Ireland- bulk manufacturer	Germany	AbbVie Biopharmaceuticals GmbH, Alte Steinhauserstrasse 14, 6330 Cham	Switzerland	PoM	18744/7/3 29.02.2024
6	Elocom	mometasone (mometasone furoate)	ointment	1mg/g; aluminum tube 15g	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	18795/5/2 29.02.2024

7	Diprosalic	betamethasone (betamethasone dipropionate), salicylic acid	ointment	0,5mg/g+30mg/g; 30g aluminium tube	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	21575/1/1 29.02.2024
8	No-spa	drotaverine (drotaverine hydrochloride)	solution for i/m and i/v injection	20mg/ml; (25/5x5) ampoules 2ml	Chinoin Pharmaceutical and Chemical Works Private Co. Ltd., 3510 Miskolc, Csanyikvolgy	Hungary	Opella Healthcare Commercial Ltd., 1138 Budapest, st.Vachi 133, b.E, floor 3	Hungary	PoM	20553/3/2 29.02.2024
9	Celestoderm-V cream with Garamycin	betamethasone (betamethasone 17-valerate), gentamicin (gentamicin sulfate)	cream	1mg/g+1mg/g; aluminium tube 30g	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	18373/4/2 29.02.2024
10	Cytosar	cytarabine	powder lyophilized for solution for injection	100mg; glass vial	Corden Pharma Latina S.p.A, Via Murillo7, Sermoneta, 04013 for	Italy	Pfizer H.C.P. Corporation, 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	20394/2/2 29.02.2024
11	Cytosar	cytarabine	powder lyophilized for solution for injection	500mg; glass vial	Corden Pharma Latina S.p.A, Via Murillo7, Sermoneta, 04013 for	Italy	Pfizer H.C.P. Corporation, 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	20395/2/2 29.02.2024

12	Citramon-Pharmstandard	acetylsalicylic acid, paracetamol, caffeine (caffeine monohydrate)	tablets	240mg+180mg+30mg: (10) in blister, (10/1x10/) in blister, (20/2x10/) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	21203/1/1 29.02.2024
13	Sandostatin LAR	octreotide (octreotide acetate)	powder for suspension for injection.	20mg; glass vial, 2ml solvent in pre-filled syringe, adapter and needle	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein- secondary packager, batch releaser, Novartis Pharmaceutical Manufacturing GmbH, Biochemiestrasse 10, Unterlangkampfen, Langkampfen, Tirol, 6336, Austria-bulk manufacturer, primary packager, Sandoz GmbH, Biochemiestrasse 10, 6336 Langkampfen, Austria-quality control, ABBOTT Biologicals B.V., Veerweg 12, 8121, AA Olst, the Netherlands-solvent manufacturer	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	18641/5/3 29.02.2024
14	Sandostatin LAR	octreotide (octreotide acetate)	powder for suspension for injection	30mg; glass vial, 2ml solvent in pre-filled syringe, adapter and needle	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein- secondary packager, batch releaser, Novartis Pharmaceutical Manufacturing GmbH, Biochemiestrasse 10, Unterlangkampfen, Langkampfen, Tirol, 6336, Austria-bulk manufacturer, primary packager, Sandoz GmbH, Biochemiestrasse 10, 6336 Langkampfen, Austria-quality control, ABBOTT Biologicals B.V., Veerweg 12, 8121, AA Olst, the Netherlands-solvent manufacturer	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	18642/5/3 29.02.2024
15	Aerius	desloratadine	tablets film-coated	5mg; (10/1x10) in blister	Bayer Bitterfeld GmbH, Ortsteil Greppin Salegaster Chaussee 1, 06803 Bitterfeld-Wolfen	Germany	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	PoM	21402/1/1 29.02.2024

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 02-2/24 on February 29,
2024

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1	Furosemide	furosemide	tablets	40mg; (50/5x10) in blister	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64A, No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	18847/1/2 29.02.2024
2	Nolpaza	pantoprazole (pantoprazole sodium)	powder for solution for injection	40mg; (1) glass vial, (10) glass vials	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- quality control, batch releaser, Sofarimex Industria Quimica e Farmaceutica, S.A. Av. das Industrias- Alto do Colaride, Cacem, 2735-213, Portugal- bulk manufacturer, packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	21796/1 29.02.2024
3	Fentanyl	fentanyl	solution for i/v and i/m injection	50mcg/ml; (10/2x5) ampoules 2ml in blister	FSUE «Moscow Endocrine Plant», 25, bld 1, Novokhokhlovskaya st., Moscow, 109052-quality control, batch releaser, FSUE «Moscow Endocrine Plant», 25, bld 2, Novokhokhlovskaya st., Moscow, 109052, Russia-bulk manufacturer, packager	Russia	FSUE «Moscow Endocrine Plant», 25, Novokhokhlovskaya st., Moscow 109052	Russia	PoM	19891/1 29.02.2024
4	Difluzol	fluconazole	capsules	150mg; (1) in blister	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	PoM	18557/1 29.02.2024
5	Metoject	methotrexate (methotrexate disodium)	solution for s/c injection	7.5mg/0.15ml; pre-filled syringe 0,15ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel-secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharnapark, 06861 Dessau-Rosslau, Germany-bulk manufacturer, primary packager	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	18461/4 29.02.2024

6	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	10mg/0.2ml; pre-filled syringe 0,2ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel-secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany-bulk manufacturer, primary packager	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	18462/4 29.02.2024
7	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	12.5mg/0.25ml; pre-filled syringe 0,25ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel-secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany-bulk manufacturer, primary packager	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	18463/4 29.02.2024
8	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	15mg/0.3ml; pre-filled syringe 0,3ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel-secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany-bulk manufacturer, primary packager	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	18464/4 29.02.2024
9	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	17.5mg/0.35ml; pre-filled syringe 0,35ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel-secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany-bulk manufacturer, primary packager	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	18465/4 29.02.2024
10	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	20mg/0.4ml; pre-filled syringe 0,4ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel-secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany-bulk manufacturer, primary packager	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	18466/4 29.02.2024
11	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	22.5mg/0.45ml; pre-filled syringe 0,45ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel-secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany-bulk manufacturer, primary packager	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	18467/4 29.02.2024
12	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	25mg/0.5ml; pre-filled syringe 0,5ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel-secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany-bulk manufacturer, primary packager	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	18468/4 29.02.2024

13	Ramizek Combi	ramipril, amlodipine (amlodipine besilate)	capsules hard	5mg+5mg, (30/5x6/) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice-batch releaser, Adamed Pharma S.A., 33, Szkolna St., 95-054 Ksawerow, Poland-bulk manufacturer, packager	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	PoM	17762/5/1 29.02.2024
14	Ramizek Combi	ramipril, amlodipine (amlodipine besilate)	capsules hard	10mg+5mg, (30/5x6/) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice-batch releaser, Adamed Pharma S.A., 33, Szkolna St., 95-054 Ksawerow, Poland-bulk manufacturer, packager	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	PoM	17763/5/1 29.02.2024
15	Ramizek Combi	ramipril, amlodipine (amlodipine besilate)	capsules hard	10mg+10mg, (30/5x6/) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice-batch releaser, Adamed Pharma S.A., 33, Szkolna St., 95-054 Ksawerow, Poland-bulk manufacturer, packager	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	PoM	17761/5/1 29.02.2024
16	NovoRapid FlexPen	insulin aspart	solution for s/c or i/v injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd- bulk manufacturer, primary packager, batch releaser, Novo Nordisk A/S, Brennum Park, DK-3400 Hillerod, Denmark- secondary packager, quality control	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	20594/3 29.02.2024
17	Levemir FlexPen	insulin detemir (recombinant)	solution for injection	100U/ml; (5) pre-filled pen 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	21637/1 29.02.2024
18	Ketorolac	ketorolac (ketorolac trometamol)	tablets film-coated	10mg; (10), (20/2x10/) 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	19964/2/1 29.02.2024
19	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	18639/6 29.02.2024
20	Ketorolac	ketorolac (ketorolac tromethamine)	solution for i/m injection	30mg/ml; (10) ampoules 1ml, (10) ampoules 1ml label banderol, (10) ampoules 1ml dividella	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, No10/1, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	21348/2 29.02.2024

21	Dexamethasone	dexamethasone (dexamethasone sodium phosphate)	solution for injection	4mg/ml; (5) ampoules 1ml, (5/1x5/) ampoules 1ml in blister	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	PoM	17777/2 29.02.2024
22	Ferrum LEK	iron (III) hydroxide with polymaltose complex	tablets chewable	100mg; (30/3x10) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	20950/1 29.02.2024
23	Victoza	liraglutide	solution for s/c injection	6mg/ml; (2) pre-filled pen 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd- bulk manufacturer, packager, quality control, batch releaser, Novo Nordisk A/S, Hallas Alle, DK-4400 Kalundborg, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	20181/2 29.02.2024
24	NovoMix 30 FlexPen	insulin aspart (recombinant)	suspension for injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	21703/1 29.02.2024
25	Norditropin NordiFlex	somatropin	solution for injection	6,7mg/ml; pre-filled pen 1,5ml	Novo Nordisk A/S, Novo Alle 1, Bagsvaerd, 2880- batch releaser, Novo Nordisk A/S Hallas Alle, Kalundborg, 4400, Denmark- bulk manufacturer, primary packager, Novo Nordisk A/S Kirke Vaerloesevej 30, Vaerloese, 3500, Denmark- secondary packager, 1. Novo Nordisk A/S Hallas Alle, Kalundborg, 4400, Denmark, 2. Novo Nordisk A/S, Hagedornsvej 1, Gentofte, 2820, Denmark- quality control (microbiological), Novo Nordisk A/S, Brogardsvej 66, Gentofte DK-2820, Denmark- quality control (physicochemical)	Denmark	Novo Nordisk A/S, Novo Alle, Bagsvaerd, 2880	Denmark	PoM	21458/1 29.02.2024
26	Rutacid	hydrotalcite	tablets chewable	500mg; (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	18122/1 29.02.2024
27	Vessel Due F	sulodexide	capsules	250LSU; (50/2x25/) in blister	Alfasigma S.p.A., Via Enrico Fermi, 1-65020, Alanno (Pescara)- packager, quality control, batch releaser, Catalent Italy S.p.A., Via Nettunense Km. 20, 100 - 04011 Aprilia (LT), Italy- bulk manufacturer	Italy	Alfasigma S.p.A., Via Ragazzi del' 99, 5-40133 Bologna (BO)	Italy	PoM	19351/3 29.02.2024

28	Propofol Kabi	propofol	emulsion for injection/infusion	10mg/ml; (5) ampoules 20ml in blister	Fresenius Kabi Austria GmbH, Hafnerstrasse 36, Graz, 8055-bulk manufacturer, primary packager, quality control, batch releaser, Fresenius Kabi Austria GmbH, Am Gewerbepark 6, Werndorf, 8402, Austria-secondary packager	Austria	Fresenius Kabi Deutschland GmbH, Else-Kroener-Strasse,1,61352 Bad Homburg	Germany	PoM	18775/3 29.02.2024
29	Propofol Kabi	propofol	emulsion for injection/infusion	10mg/ml; (1) glass vial 50ml in blister, (10) glass vial 50ml in blister	Fresenius Kabi Austria GmbH, Hafnerstrasse 36, Graz, 8055-bulk manufacturer, primary packager, quality control, batch releaser, Fresenius Kabi Austria GmbH, Estermannstrasse 17, Linz, 4020, Austria-secondary packager	Austria	Fresenius Kabi Deutschland GmbH, Else-Kroener-Strasse,1,61352 Bad Homburg	Germany	PoM	18776/5 29.02.2024
30	Vamloset	amlodipine (amlodipine besilate), valsartan	tablets film-coated	5mg+80mg; (30/3x10/) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	PoM	19760/1 29.02.2024
31	Vamloset	amlodipine (amlodipine besilate), valsartan	tablets film-coated	5mg+160mg; (30/3x10/) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	PoM	19761/1 29.02.2024
32	Vamloset	amlodipine (amlodipine besilate), valsartan	tablets film-coated	10mg+160mg; (30/3x10/) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	PoM	19762/1 29.02.2024
33	Salbutamol Pharmstandard VCH	salbutamol (salbutamol sulfate)	aerosol for inhalation dosed	100mcg/dose; 200 doses in aluminium container with metering valve and inhaler	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	PoM	20895/1 29.02.2024
34	Ketonal DUO	ketoprofen	capsules modified-release	150mg; (20/2x10) in blister, (30/3x10) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19541/5 29.02.2024
35	Sophalor	desloratadine	solution oral	0,5mg/ml; 120ml glass or plastic bottle and measuring cup	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia- batch releaser, Sopharma JSC, Vrabevo vlg. 5660, district of Lovetch, Bulgaria. Bulgaria-bulk manufacturer, packager, quality control	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	21547/1 29.02.2024
36	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, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	18608/5 29.02.2024

37	Cyclodol	trihexyphenidyl (trihexyphenidyl hydrochloride)	tablets	2mg; (40/1x40/) in blister, (48/2x24) 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	18827/1 29.02.2024
38	Ketonal Extra Plus 50mg granules for oral solution	ketoprofen (ketoprofen lysine)	granules for oral solution	50mg; (12) bipartite sachets	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana-batch releaser, Fine Foods & Pharmaceuticals N.T.M. S.p.A., Via Grignano, 43, 24041, Brembate (BG), Italy-bulk manufac- turer, packager, quality control	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	18583/6/1 29.02.2024

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 02-2/24 on February 29, 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	Metadon Alkaloid	methadone (methadone hydrochloride)	solution oral	10mg/ml; 100ml glass bottle and graduated pipette, 1000ml glass bottle	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	000653 29.02.2024
2	Noliprel A Forte	perindopril arginine, indapamide	tablets film-coated	5mg+1,25mg; (14) in plastic container, (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000175 29.02.2024
3	Noliprel A Forte	perindopril arginine, indapamide	tablets film-coated	5mg+1,25mg; (14) in plastic container, (30) in plastic container, (90) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000175 29.02.2024
4	Noliprel A Forte	perindopril arginine, indapamide	tablets film-coated	5mg+1,25mg; (14) in plastic container, (29) in plastic container, (30) in plastic container, (90) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000175 29.02.2024
5	Noliprel A Forte	perindopril arginine, indapamide	tablets film-coated	5mg+1,25mg; (14) in plastic container, (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284- batch releaser, packager, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000175 29.02.2024

6	Noliprel A	perindopril arginine, indapamide	tablets film-coated	2,5mg+0,625mg: (14) in plastic container, (29) in plastic container, (30) in plastic container, (90) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000179 29.02.2024
7	Noliprel A	perindopril arginine, indapamide	tablets film-coated	2,5mg+0,625mg: (14) in plastic container, (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000179 29.02.2024
8	Noliprel A	perindopril arginine, indapamide	tablets film-coated	2,5mg+0,625mg: (14) in plastic container, (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284- batch releaser, packager, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000179 29.02.2024
9	Noliprel A	perindopril arginine, indapamide	tablets film-coated	2,5mg+0,625mg: (14) in plastic container, (30) in plastic container, (90) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000179 29.02.2024