

## LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 01-2/24 on January 31, 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	Ibuprofen Denk 400	ibuprofen	tablets film-coated	400mg; (20/2x10) in blister, (100/10x10) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning, Bayern- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	OTC	21894 31.01.2024
2	Tadafort 5	tadalafil	tablets film-coated	5mg; (4/2x2) in blister	IBN AL-Haytham Pharma Industries Co., Al Mansoura, Aleppo	Syria	IBN AL-Haytham Pharma Industries Co., Al Mansoura, Aleppo	Syria	PoM	21895 31.01.2024

LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision 01-2/24 on January 31,  
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	Noliprel A Bi-forte	indapamide, perindopril arginine	tablets film-coated	2,5mg+10mg; (30) in plastic container	Servier (Ireland) Industries Ltd., Gorey Road, Arklow-Co. Wicklow, Y14 E284	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21900 (004440) 31.01.2024
2	Noliprel A Bi-forte	indapamide, perindopril arginine	tablets film-coated	2,5mg+10mg; (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	21901 (004440) 31.01.2024
3	Tetraxim	Diphtheria toxoid, Tetanus toxoid, Bordetella pertussis antigens: pertussis toxoid, filamentous haemagglutinin, hepatitis B surface antigen, Poliovirus (inactivated): type 1 (Mahoney), type 2 (MEF-1), type 3 (Saukett)	suspension for i/m injection	not less than 20IU/0,5ml+not less than 40IU/0,5ml+25mcg/0,5ml+25mcg/0,5ml+10mcg/0,5ml+40D antigen units/0,5ml+8D antigen units/0,5ml+32D antigen units/0,5ml; (1) pre-filled syringe 0,5ml and (1) needle, (1) pre-filled syringe 0,5ml and (2) needles, (1) pre-filled syringe 0,5ml with needle	Sanofi Pasteur SA, Parc Industriel d'Incarville, 27100 Val de Reuil	France	Sanofi Pasteur SA, 14 Espace Henry Vallee, 69007 Lyon	France	PoM	21902 (076923) 31.01.2024

4	Tetraxim	Diphtheria toxoid, Tetanus toxoid, Bordetella pertussis antigens: pertussis toxoid, filamentous haemagglutinin, hepatitis B surface antigen, Poliovirus (inactivated): type 1 (Mahoney), type 2 (MEF-1), type 3 (Saukett)	suspension for i/m injection	not less than 20IU/0,5ml+not less than 40IU/0,5ml+25mcg/0,5ml+25mcg/0,5ml+10mcg/0,5ml+40D antigen units/0,5ml+8D antigen units/0,5ml+32D antigen units/0,5ml; (1) pre-filled syringe 0,5ml and (1) needle, (1) pre-filled syringe 0,5ml and (2) needles, (1) pre-filled syringe 0,5ml with needle	Sanofi Pasteur SA, 1541 Avenue Marcel Merieux, Marcy L'Etoile, 69280- bulk manufacturer, secondary packager, quality control, batch releaser, Sanofi Pasteur SA, Parc Industriel d'Incarville, 27100 Val de Reuil, France- primary packager	France	Sanofi Pasteur SA, 14 Espace Henry Vallee, 69007 Lyon	France	PoM	21903 (076923) 31.01.2024
5	Nalgesin	naproxen (naproxen sodium)	tablets film-coated	275mg; (10/1x10/) in blister, (20/2x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	21904 (000567) 31.01.2024
6	Nalgesin	naproxen (naproxen sodium)	tablets film-coated	275mg; (10/1x10/) in blister, (20/2x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- packager, quality control, batch releaser, Unichem Laboratories Limited, Plots 15, 16, 17, 17A,18, Pilerne Industrial Estate, Pilerne, Bardez GoA, 40351, India- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	21905 (000567) 31.01.2024
7	Nalgesin forte	naproxen (naproxen sodium)	tablets film-coated	550mg; (10/1x10/) in blister, (20/2x10/) in blister, (60/6x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	21906 (000568) 31.01.2024
8	Nalgesin forte	naproxen (naproxen sodium)	tablets film-coated	550mg; (10/1x10/) in blister, (20/2x10/) in blister, (60/6x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- packager, quality control, batch releaser, Unichem Laboratories Limited, Plots 15, 16, 17, 17A,18, Pilerne Industrial Estate, Pilerne, Bardez GoA, 40351, India- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	21907 (000568) 31.01.2024
9	Sea Buckthorn Oil	hippopheae oil	suppositories rectal	500mg; (10/2x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	21908 (004936) 31.01.2024
10	Alzepil	donepezil (donepezil hydrochloride)	tablets film-coated	5mg; (28/2x14/) in blister, (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	21909 (000979) 31.01.2024

11	Alzepil	donepezil (donepezil hydrochloride)	tablets film-coated	10mg; (28/2x14/) in blister, (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	21910 (000979) 31.01.2024
12	Sulid	nimesulide	granules for oral suspension	100mg; (30) sachets 2g	AVVA RUS JSC, 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	21898 (005436) 31.01.2024
13	ZEToptic-N	timolol (timolol maleate), brinzolamide	drops eye (suspension)	5mg/ml+10mg/ml; plastic vial 5ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	21899 (005440) 31.01.2024

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of the medicines recommended for the re-registration by the Center according to the meeting decision 01-2/24 on January 31, 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	Fluconazole	fluconazole	tablets coated	150mg; (2/1x2) in blister	PJSC «Technolog», 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PJSC «Technolog», 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PoM	21911 31.01.2024
2	Sevorane	sevoflurane	liquid for inhalation	100%; 250ml plastic container with Quik fil closure system	AbbVie S.r.l., S.R. 148 Pontina KM 52, SNC 04011 Campoverde di Aprilia (LT)	Italy	AbbVie Biopharmaceuticals GmbH, Alte Steinhäuserstrasse 14, 6330 Cham	Switzerland	PoM	21912 31.01.2024
3	Ketonal	ketoprofen	suppositories rectal	100mg; (12/2x6)	Genveon Ilac Sanayi ve Ticaret A.S., Inoenue Mahallesi, Gebze Plastikciler Organize Sanayi Boelgesi, Mahallesi 9, Cadde No.2, 41400, Kocaeli	Turkey	Lek d.d., Verovskova str. 57,1526 Ljubljana	Slovenia	PoM	21913 31.01.2024
4	Prednisolone-Belmed	prednisolone	tablets	5mg; (10/1x10) in blister, (50/5x10) in blister	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30- quality control, batch releaser, Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 3, No4, Republic of Belarus- bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	21914 31.01.2024
5	Fluconazole 0,2%	fluconazole	solution for i/v infusion	2mg/ml; 50ml plastic pack, 100ml plastic pack, 200ml plastic pack	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	21915 31.01.2024
6	Ariprazol	aripiprazole	tablets	10mg; (30/3x10) in blister, (60/6x10) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	21916 31.01.2024
7	Ariprazol	aripiprazole	tablets	15mg; (30/3x10) in blister, (60/6x10) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	21917 31.01.2024

8	Diclofenac	diclofenac (diclofenac sodium)	tablets film-coated prolonged-release	100mg; (20/2x10) in blister	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	PoM	21918 31.01.2024
9	Chondroxid Artra	chondroitin sulfate (chondroitin sulfate sodium)	gel for external use	50mg/g; 30g aluminium tube, 30g plastic tube	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	21919 31.01.2024
10	Chondroxid Artra	chondroitin sulfate (chondroitin sulfate sodium)	ointment for external use	50mg/g; 30g aluminium tube, 30g plastic tube	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	21920 31.01.2024
11	Ceraxon	citicoline (citicoline sodium)	solution for i/m and i/v injection	500mg/4ml; (5) ampoules 4ml	Ferrer International, S.A., Joan Busscalla, 1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer International, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	PoM	21921 31.01.2024
12	Ceraxon	citicoline (citicoline sodium)	solution for i/m and i/v injection	1000mg/4ml; (5) ampoules 4ml	Ferrer International, S.A., Joan Busscalla, 1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer International, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	PoM	21922 31.01.2024
13	Ceraxon	citicoline (citicoline sodium)	solution oral	100mg/ml; glass bottle 30ml and measuring syringe, (6) sachets 10ml, (10) sachets 10ml, (30) sachets 10ml	Ferrer International, S.A., Joan Busscalla, 1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer International, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	PoM	21923 31.01.2024
14	Sentor	losartan (losartan potassium)	tablets film-coated	50mg; (10/1x10) in blister, (30/3x10) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35,Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager, Gedeon Richter Polska Sp. z o.o. ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825, Poland- quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	21924 31.01.2024
15	Sentor	losartan (losartan potassium)	tablets film-coated	100mg; (10/1x10) in blister, (30/3x10) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35,Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager, Gedeon Richter Polska Sp. z o.o. ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825, Poland- quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	21925 31.01.2024

16	Metformin	metformin (metformin hydrochloride)	tablets	1000mg; (30/2x15/) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Arme- nia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	21926 31.01.2024
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of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 01-2/24 on January 31,  
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	Ketorolac	ketorolac (ketorolac trometamol)	tablets film-coated	10mg; (10), (20/2x10) in blister	Open joint stock company «Borisovskiy zavod medicinskikh preparatov» 64A, 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	19964/1/1 31.01.2024
2	Neoton	phosphocreatine (phosphocreatine sodium)	powder for solution for injection/infusion	1000mg; glass vial	Alfasigma S.p.A., Via Enrico Fermi, 1-65020, Alanno (Pescara)	Italy	Alfasigma S.p.A., Via Ragazzi del, 99, 5-40133 Bologna (BO)	Italy	PoM	19216/3/1 31.01.2024



3	Magne B6	magnesium lactate dihydrate, pyridoxine hydrochloride	tablets coated	470mg+5mg; (60/3x20) in blister	Opella Healthcare Hungary Limited Liability Company (Opella Healthcare Hungary Ltd.), Levai u. 5., Veres-egyhazi, 2112- bulk manufacturer, packager, quality control (physico-chemical), batch releaser, CHINOIN Private Co. Ltd.- Ujpest site, To utca 1-5., Budapest, 1045, Hungary- quality control (microbiological)	Hungary	Opella Healthcare Commercial Ltd, 1138 Budapest, Vaci ut 133. E. ep. 3 em.	Hungary	OTC	20826/2/1 31.01.2024
4	Paracetamol-Pharmstandard	paracetamol	tablets	500mg; (10/1x10) in blister, (20/2x10) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	18975/4/2 31.01.2024
5	Carvedilol-Mic	carvedilol	capsules	6,25mg; (30/3x10) in blister	Minskintercaps U.V., 26/3 bild. No2, Inzhenernaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Republic of Belarus	PoM	18380/1/1 31.01.2024
6	Carvedilol-Mic	carvedilol	capsules	12,5mg; (30/3x10) in blister	Minskintercaps U.V., 26/3 bild. No2, Inzhenernaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Republic of Belarus	PoM	18381/1/1 31.01.2024

7	Carvedilol-Mic	carvedilol	capsules	25mg; (30/3x10) in blister	Minskintercaps U.V., 26/3 bild. No2, Inzhenernaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Republic of Belarus	PoM	18382/1/1 31.01.2024
8	Tetram-Pharmstandard	disulfiram	tablets	150mg; (30/3x10) in blister, (30/2x15) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	PoM	21282/1/1 31.01.2024
9	Grammidin with anesthetic	gramicidin S (gramicidin S dihydrochloride), oxybuprocaine (oxybuprocaine hydrochloride), cetylpyridinium chloride	spray dosed	0,06mg/dose+0,15mg/dose+0,1mg/dose; aluminium bottle (112 dose) with pump dispenser	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2- secondary packager, quality control (physicochemical), batch releaser, Delpharm Bladel B.V., Industrieweg 1, 5531 AD Bladel, the Netherlands- bulk manufacturer, primary packager, Centemo LTD, Moscow Region, Shchelkovo, Fabrichnaya St., 2, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	21282/1/1 31.01.2024
10	Grammidin for kids	gramicidin S (gramicidin S dihydrochloride), cetylpyridinium chloride	spray dosed for topical use	0.03mg+0.1mg; aluminium bottle 112 dose with dosing device	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2- secondary packager, quality control (physicochemical), batch releaser, Delpharm Bladel B.V., Industrieweg 1, 5531 AD Bladel, the Netherlands- bulk manufacturer, primary packager, Centemo LTD, Moscow Region, Shchelkovo, Fabrichnaya St., 2, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	20732/2/1 31.01.2024

11	Tadalafil Genericon	tadalafil	tablets film-coated	20mg; (4/1x4) in blister	<p>Genericon Pharma Gesellschaft m.b.H., Hafnerstrasse 211, 8054, Graz, Styria- quality control (phiscochem- ical), batch releaser, Humanis Saglik JSC, Cerkezkoy Organize Sanayi Bolgesi Karaagac, Mah. Fatih Bulv. N32, Kapakli, Tekirdag, Turkey- bulk manufacturer, packager, AGES Graz IMED, Beethovenstrasse 6, Graz, 8010, Austria- quality control (microbio- logical)</p>	Austria	<p>Genericon Pharma Gesellschaft m.b.H., Hafnerstrasse 211, 8054, Graz, Styria</p>	Austria	PoM	<p>21272/2/2 31.01.2024</p>
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of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 01-2/24 on January 31,  
2024

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1	Amoxicillin	amoxicillin	granules for oral suspension	250mg/5ml; 40g granules in 100ml glass bottle and measuring spoon 5ml	Hemofarm A.D. 26300, Vrsac, Beogradskii put bb- batch releaser, Hemofarm A.D., Vrsac, 26224, Dubovac, str. Cara Lazara bb, Serbia- bulk manufacturer, packager, quality control	Serbia	Hemofarm A.D. 26300, Vrsac, Beogradskii put bb	Serbia	PoM	20384/3 31.01.2024
2	Prospan cough drops	hedera helix	drops oral	20mg/ml; 20ml glass vial-dropper	Engelhard Arzneimittel GmbH& Co. KG, Herzbergstrasse 3, 61138 Niederdorfelden	Germany	Engelhard Arzneimittel GmbH& Co. KG, Herzbergstrasse 3, 61138 Niederdorfelden	Germany	OTC	19612/1 31.01.2024
3	Neiromidin	ipidacrine (ipidacrine hydrochloride)	tablets	20mg; (50/5x10/), in blister	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	PoM	19930/1 31.01.2024
4	Elonva	corifollitropin alfa	solution for injection	100mcg/0,5ml; (1) pre-filled syringe 0,5ml and needle	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, 1.Vetter Pharma-Fertigung GmbH & Co. KG, Schutzenstrasse 87 and 99/101, D-88212 Ravensburg, Germany, 2.N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands- quality control	the Netherlands	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	20962/1 31.01.2024

5	Elonva	corifollitropin alfa	solution for injection	150mcg/0,5ml; (1) pre-filled syringe 0,5ml and needle	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, 1.Vetter Pharma-Fertigung GmbH & Co. KG, Schutzenstrasse 87 and 99/101, D-88212 Ravensburg, Germany, 2.N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands- quality control	the Netherlands	Organon Central East GmbH, Weystasse 20, 6006 Luzern	Switzerland	PoM	20963/1 31.01.2024
6	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	500mg+125mg; (14/2x7) in blister	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	PoM	21463/1 31.01.2024
7	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	875mg+125mg; (14/2x7) in blister	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	PoM	21464/1 31.01.2024
8	Monox	etoricoxib	tablets film-coated	60mg; (30/3x10) in blister	Synthon Hispania,S.L., C/ Castello, N 1, Sant Boi de Llobregat, Barcelona, 08830	Spain	Family Pharm Group LLC., 85 Marshal Baghramyan ave., 0033, Yerevan	Republic of Armenia	PoM	20604/1 31.01.2024
9	Monox	etoricoxib	tablets film-coated	90mg; (30/3x10) in blister	Synthon Hispania,S.L., C/ Castello, N 1, Sant Boi de Llobregat, Barcelona, 08830	Spain	Family Pharm Group LLC., 85 Marshal Baghramyan ave., 0033, Yerevan	Republic of Armenia	PoM	20605/1 31.01.2024
10	Monox	etoricoxib	tablets film-coated	120mg; (28/4x7) in blister	Synthon Hispania,S.L., C/ Castello, N 1, Sant Boi de Llobregat, Barcelona, 08830	Spain	Family Pharm Group LLC., 85 Marshal Baghramyan ave., 0033, Yerevan	Republic of Armenia	PoM	20606/1 31.01.2024
11	Sevorane	sevoflurane	liquid for inhalation	100%; 250ml plastic container with Quik fil closure system	AbbVie S.r.l, S.R. 148 Pontina KM 52, SNC 04011 Campoverde di Aprilia (LT)	Italy	AbbVie Biopharmaceuticals GmbH, Alte Steinhäuserstrasse 14, 6330 Cham	Switzerland	PoM	18306/2/1 31.01.2024

12	Priorix	live attenuated measles virus(Schwarz strain), live attenuated mumps virus(RIT 4385 strain), live attenuated rubella virus(Wistar RA 27/3 strain)	powder and solvent for solution for injection	not less than 103.0CCID50/dose+not less than 103.7CCID50/dose+not less than 103.0CCID50/dose; (100/200 dose) glass vial, (100) solvent in ampoule 1ml	GlaxoSmithkline Biologicals SA, Belgium, Parc de la Noire Epine, Avenue Fleming 20, Wavre, 1300-secondary packager, batch releaser, Fidia Farmaceutici S.P.A., Via Ponte Della Fabbrica 3/A-35031 Abano Terme (PD), Italy-bulk manufacturer, primary packager, Delpharm Tours Rue Paul Langevin BP 90241, 37172 Chambray-les-Tours, France-solvent manufacturer	Belgium	GlaxoSmithKline Biologicals s.a., Rue de l Institut, 89 B-1330 Rixensart	Belgium	PoM	18627/2 31.01.2024
13	SmofKabiven Central	I camera: L-alanine, L-arginine, glycine, L-histidine, L-isoleucine, L-leucine, L-lysine (lysine acetate), L-methionine, L-phenylalanine, L-proline, L-serine, taurine, L-threonine, L-tryptophan, L-tyrosine, L-valine, calcium chloride (calcium chloride dihydrate), sodium glycerophosphate (sodium glycerophosphate hydrate), magnesium sulphate (magnesium sulphate heptahydrate), potassium chloride, sodium acetate (sodium acetate trihydrate), zinc sulphate (zinc sulphate heptahydrate), II camera: glucose (glucose monohydrate), III camera: soya-bean oil, triglycerides, olive oil, fish oil (rich in omega-3 acids)	emulsion for infusion	I camera: 14mg/ml+12mg/ml+11mg/ml+3mg/ml+5mg/ml+7,4mg/ml+6,6mg/ml+4,3mg/ml+5,1mg/ml+11,2mg/ml+6,5mg/ml+1mg/ml+4,4mg/ml+2mg/ml+0,4mg/ml+6,2mg/ml+0,56mg/ml+4,2mg/ml+1,2mg/ml+3,4mg/ml+0,013mg/ml, II camera: 419,5mg/ml, III camera: 60mg/ml+60mg/ml+50mg/ml+30mg/ml; (4/4x1/) plastic camera set 986ml (camera I 500ml+camera II 298ml+camera III 188ml), (4/4x1/) plastic camera set 1477ml (camera I 750ml+camera II 446ml+camera III 281ml), (4/4x1/) plastic camera set 1970ml (camera I 1000ml+camera II 595ml+camera III 375ml)	Fresenius Kabi AB, Rapskatan 7 Uppsala, 75174	Sweden	Fresenius Kabi Deutschland GmbH, 61346 Bad Homburg, v.d.H	Germany	PoM	19754/2 31.01.2024

14	Prednisolone- Belmed	prednisolone	tablets	5mg; (10/1x10/) in blister, (50/5x10/) in blister	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30- quality control, batch releaser, Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 3, No4, Republic of Belarus- bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	18272/1 31.01.2024
15	Uperio 24mg/26mg	sacubitril, valsartan (valsartan sodium)	tablets film-coated	24,3mg+25,7mg; (28/2x14) in blister	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata, (NA)	Italy	Novartis Pharma Services AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19728/4 31.01.2024
16	Uperio 97mg/103mg	sacubitril, valsartan (valsartan sodium)	tablets film-coated	97.2mg+102.8mg; (28/2x14) in blister	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata, (NA)	Italy	Novartis Pharma Services AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19730/4 31.01.2024
17	Bronchobos	carbocisteine	capsules	375mg; (30/3x10) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	19990/5 31.01.2024
18	Nebilet Plus 5/12,5	nebivolol (nebivolol hydrochloride), hydrochlorothiazide	tablets film-coated	5mg+12,5mg; (28/2x14) in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1. Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany, 2. Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin, Germany- quality control (phisicochemical), Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin, Germany- quality control (microbiological)	Germany	Menarini International Operations Luxembourg S.A., 1, avenue de la Gare, 1611	Luxembourg	PoM	20199/2 31.01.2024
19	Fluconazole	fluconazole	tablets coated	150mg; (2/1x2) in blister	PJSC «Technolog», 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PJSC «Technolog», 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PoM	18390/2 31.01.2024
20	Fluconazole 0.2%	fluconazole	solution for i/v infusion	2mg/ml; 50ml, 100ml and 200ml plastic pack	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	18316/1 31.01.2024

21	Bisacodyl-Hemofarm	bisacodyl	tablets gastro-resistant	5mg; (30/3x10) in blister	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb- packager, quality control (microbiological), batch releaser, Hemofarm d.o.o., Novakovici bb, Banja Luka 78000, Bosnia and Herzegovina- bulk manufacturer, quality control (physicochemical)	Serbia	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	OTC	20528/1 31.01.2024
22	Bisacodyl-Hemofarm	bisacodyl	tablets gastro-resistant	5mg; (30/3x10) in blister	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	OTC	20802/1 31.01.2024
23	Amiksin	tilorone	tablets film-coated	60mg; (6/1x6) in blister, (10/1x10) in blister, (12/2x6) in blister, (20/2x10) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTCPharm JSC, Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	20916/1 31.01.2024
24	Amiksin	tilorone	tablets film-coated	125mg; (3/1x3) in blister, (6/1x6) in blister, (6/2x3) in blister, (10/1x10) in blister, (12/2x6) in blister, (20/2x10) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTCPharm JSC, Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	20917/1 31.01.2024
25	Midazolam Kalceks	midazolam	solution for injection/infusion	5mg/ml; (5) ampoules 1ml, (10) ampoules 1ml	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	19203/3/2 31.01.2024
26	Midazolam Kalceks	midazolam	solution for injection/infusion	5mg/ml; (5) ampoules 3ml, (10) ampoules 3ml	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	19204/3/2 31.01.2024
27	Bronchomunal P	lyophilized bacterial lysate	capsules hard	3,5mg; (10/1x10) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- packager, quality control, batch releaser, OM Pharma SA, 22, rue du Bois-du-Lan, 1217 Meyrin 2/ Geneva, Switzerland- bulk manufacturer	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19713/4 31.01.2024



28	Broncho-munal	lyophilized bacterial lysate	capsules hard	7mg; (10/1x10) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- packager, quality control, batch releaser, OM Pharma SA, 22, rue du Bois-du-Lan, 1217 Meyrin 2/ Geneva, Switzerland- bulk manufacturer	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19712/4 31.01.2024
29	Venosmil	hidrosmin	capsules	200mg; (60/6x10) in blister	FAES FARMA S.A., C/Maximo Aguirre, 14, 48940 Lejona/Leioa (Vizcaya/Bizkaia)	Spain	FAES FARMA S.A., C/Maximo Aguirre, 14, 48940 Lejona/Leioa (Vizcaya/Bizkaia)	Spain	PoM	21132/1 31.01.2024
30	Avamigran	propyphenazone, caffeine, camylofin (camylofin hydrochloride), mecloxamine (mecloxamine citrate), ergotamine (ergotamine tartrate)	tablets film-coated	200mg+80mg+25mg+20mg+0,75mg; (10) in plastic container	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	PoM	21047/3 31.01.2024
31	Levicitam	levetiracetam	tablets film-coated	250mg (30/3x10) in blister, (60/6x10) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	18675/4/1 31.01.2024
32	Levicitam	levetiracetam	tablets film-coated	500mg (30/3x10) in blister, (60/6x10) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	18676/4/1 31.01.2024
33	Ermucin	erdosteine	capsules hard	300mg; (10/1x10) in blister, (20/2x10) in blister	Edmond Pharma S.r.l., Strada Statale dei Giovi 131- 20037 Paderno Dugnano (MI)- bulk manufacturer, quality control, batch releaser, Lamp San Prospero S.p.A., Via della Pace, 25/A-41030 San Prospero (MO), Italy- packager	Italy	UAB «MRA», Totoriu str. 20-9, LT-01121 Vilnius	Republic of Lithuania	PoM	21851/1 31.01.2024

## LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 01-2/24 on January 31, 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	Diabeton MR	gliclazide	tablets modified-release	60mg; (30/1x30) in blister, (60/2x30) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000531 31.01.2024
2	Diabeton MR	gliclazide	tablets modified-release	60mg; (28/2x14) in blister, (30/2x15) in blister, (60/4x15) 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	000531 31.01.2024
3	Diabeton MR	gliclazide	tablets modified-release	60mg; (28/2x14) in blister, (30/2x15) in blister, (30/1x30) in blister, (60/2x30) in blister, (60/4x15) in blister	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	000531 31.01.2024