

**LIST**

of the medicines recommended for the registration by the Center according to the meeting decision N 03-1/23 on March 15, 2023

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	Avonza	tenofovir disoproxil fumarate, lamivudine, efavirenz	tablets film-coated	300mg+300mg+ 400mg; (30) in plastic container, (90) in plastic container	Mylan Laboratories Limited, Plot No.11, 12 & 13, Indore SEZ, Pharma Zone, Phase-II, Sector-III, Pithampur-454775, Dist. Dhar, Madhya Pradesh	India	Mylan Laboratories Limited, Plot No. 564/A/22, Road No.92, Jubilee Hills, Hyderabad, Telangana, 500096	India	PoM	21224 15.03.2023
2	Panadol	paracetamol	tablets film-coated	500mg; (12/1x12/) in blister	GlaxoSmithKline Dungarvan Limited, Knockbrack, Dungarvan, Co Waterford	Ireland	GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	OTC	21225 15.03.2023
3	Feverach	paracetamol	solution for infusion	10mg/ml; 100ml glass bottle	Aculife Healthcare Private Limited, Unit-5, IDP, Village-Sachana, Tal.-Viramgam, Dist.-Ahmedabad, Gujarat, 382150	India	Aculife Healthcare Private Limited, Commerce House-V, Besides Vodafone House, Prahladnagar Corporate Road, Ahmedabad, Gujarat, 380051	India	PoM	21226 15.03.2023

4	Arlevert	cinnarizine, dimenhydrinate	tablets	20mg+40mg; (20/1x20/) in blister, (50/2x25/) in blister	Hennig Arzneimittel GmbH & Co. KG, Liebigstrasse 1-2, 65439 Floersheim-am-Main	Germany	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, 1611	Luxembourg	PoM	21227 15.03.2023
5	Dilaza	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3/) in blister	INDUSTRIA QUIMICA Y FARMACEUTICA VIR, S.A., C/ Laguna 66-68-70, Pol. Industrial Urtinsa II, Alcorcon, Madrid, 28923	Spain	INDUSTRIA QUIMICA Y FARMACEUTICA VIR, S.A., C/ Laguna 66-68-70, Pol. Industrial Urtinsa II, Alcorcon, Madrid, 28923	Spain	PoM	21228 15.03.2023
6	Nadroparin	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 15.03.2023

7	Nadroparin	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 15.03.2023
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## LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 03-1/23 on March 15, 2023

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; (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	21231 (000531) 15.03.2023
2	Diabeton MR	gliclazide	tablets modified-release	60mg; (28/2x14/) 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	21232 (000531) 15.03.2023
3	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	21233 (000531) 15.03.2023

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 03-1/23 on March 15, 2023

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	Ceftriaxone 500mg	ceftriaxone (ceftriaxone sodium)	powder for solution for injection/infusion	500mg; (10) glass vials	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building-secondary packager, quality control, batch releaser, Exir Pharmaceutical Company, 2nd km of Ring road-Boroujerd, 69189, Iran-bulk manufacturer, primary packager	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	21234 15.03.2023
2	Ceftriaxone 1000mg	ceftriaxone (ceftriaxone sodium)	powder for solution for injection/infusion	1000mg; (10) glass vials	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building-secondary packager, quality control, batch releaser, Exir Pharmaceutical Company, 2nd km of Ring road-Boroujerd, 69189, Iran-bulk manufacturer, primary packager	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	21235 15.03.2023

3	Lysobact	lysozyme (lysozyme hydrochloride), pyridoxine (pyridoxine hydrochloride)	lozenges compressed	20mg+10mg; (10/1x10/) in blister, (30/3x10/) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	21236 15.03.2023
4	Grammidin with anesthetic neo	gramicidin S (gramicidin S dihydrochloride), oxybuprocaine (oxybuprocaine hydrochloride), cetylpyridinium chloride (cetylpyridinium chloride monohydrate)	tablets to be sucked	3mg+0,2mg+1mg; (18/2x9/) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Centemo LTD, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	21237 15.03.2023
5	Moxiral	moxifloxacin (moxifloxacin hydrochloride)	tablets film-coated	400mg; (5/1x5/) in blister, (7/1x7/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	21238 15.03.2023
6	Ascorbic acid with glucose	ascorbic acid, dextrose	tablets	100mg+877mg; (10) in strip, (40) in plastic container	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	OTC	21239 15.03.2023
7	Lorazepam	lorazepam	tablets	1mg; (24/1x24/) 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	21240 15.03.2023

8	Lorazepam	lorazepam	tablets	2mg; (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	21241 15.03.2023
9	Doxycycline	doxycycline (doxycycline hyclate)	capsules	100mg; (10/1x10/) in blister, (1500/150x/1x10/) in blister	Belmedpreparaty RUE, Grodninsky region, Skidzyel, Kizevich str., 50-4	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	21242 15.03.2023
10	Atropine-Belmed	atropine (atropine sulfate)	solution for injection	1mg/ml; (5/1x5/) ampoules 1ml in blister, (10/2x5/) ampoules 1ml in blister, (10) ampoules 1ml label banderol	Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo St., 1/22 No7	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	21243 15.03.2023
11	Proctomed	phenylephrine (phenylephrine hydrochloride), cinchocaine, shark liver oil	cream rectal	2,5mg/g+10mg/g+30mg/g; 20g aluminium tube and applicator	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	21244 15.03.2023
12	Olanzapine	olanzapine	tablets film-coated	10mg; (30/3x10/) 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	21245 15.03.2023

13	Nitroglycerin-AM	nitroglycerin	tablets sublingual	0,5mg; (40) in plastic container	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PoM	21246 15.03.2023
14	Emsibel	methylethylpiridinol hydrochloride	drops eye (solution)	10mg/ml; 5ml vial-dropper	Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st. 1- quality control, batch releaser, Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st. 1/1, No 5, Republic of Belarus - bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	21247 15.03.2023
15	Detralex	diosmin, hesperidin	tablets film-coated	900mg+100mg; (18/2x9/) in blister, (30/3x10/) in blister, (60/6x10/) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	OTC	21248 15.03.2023
16	Risebon	risedronic acid (risedronate sodium)	tablets film-coated	35mg; (4/1x4/) 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, Pienkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	PoM	21249 15.03.2023



17	Levomicetin-Darnitsa	chloramphenicol	tablets	500mg; (10) in blister	PrJSC "Pharmaceutical firm "Darnitsa", 02093, Kyiv, Boryspilska Str.,13	Ukraine	PrJSC "Pharmaceutical firm "Darnitsa", 02093, Kyiv, Boryspilska Str.,13	Ukraine	PoM	21250 15.03.2023
18	Aciclovir-Belmed	aciclovir	tablets	200mg; (10/1x10/) in blister, (20/2x10/) 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	21251 15.03.2023
19	Lucetam	piracetam	tablets film-coated	800mg; (30) in glass bottle	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	21252 15.03.2023
20	Lucetam	piracetam	film-coated tablets	1200mg; (20) in glass bottle	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	21253 15.03.2023

21	Zyvox	linezolid	solution for infusion	2mg/ml; (10) plastic packs 300ml	Fresenius Kabi Norge AS, Svinesundsveien 80 HALDEN, NO-1788	Norway	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	PoM	21254 15.03.2023
22	Flixotide 50 micrograms Evohaler	fluticasone (fluticasone propionate)	suspension, pressurised inhalation	50mcg/dose; inhaler in aluminium container (120 doses)	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos	Spain	Glaxo Wellcome UK Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	PoM	21255 15.03.2023
23	Flixotide 125 micrograms Evohaler	fluticasone (fluticasone propionate)	suspension, pressurised inhalation	125mcg/dose; inhaler in aluminium container (120 doses)	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos	Spain	Glaxo Wellcome UK Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	PoM	21256 15.03.2023
24	Exoderil	naftifine (naftifine hydrochloride)	solution for external use	10mg/ml; glass vial 10ml, glass vial 20ml	Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl- batch releaser, Globopharm Pharmazeutische Produktions-und Handels GmbH., Breitenfurter Strasse 251, 1230 Wien, Austria- bulk manufacturer, packager, quality control	Austria	Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl	Austria	OTC	21257 15.03.2023

25	Wobenzym	pancreatin, trypsin, chymotrypsin, bromelain, papain, amylase, lipase, rutoside trihydrate	tablets gastro-resistant	300 prot.UA+360FIP-U+300FIP-U+225FIP-U+90FIP-U+50FIP-U+34FIP-U+50mg (40/2x20/) and (200/10x20/) in blister, (800) in plastic container	Mucos Emulsionsgesellschaft mbH, Miraustrasse 17, D-13509 Berlin	Germany	Mucos Pharma GmbH & Co. KG, Miraustrasse 17, D-13509 Berlin	Germany	OTC	21258 15.03.2023
26	Nimesubel	nimesulide	tablets	100mg; (20/2x10/) 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	21259 15.03.2023
27	Escadent dental drops	oleum menthae piperitae, camphor, valerianae radix	drops	31mg/ml+64mg/ml+48mg/ml; plastic vial-dropper 10ml	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	OTC	21260 15.03.2023
28	Lidocaine	lidocaine	spray, solution	50mg/ml; 15ml plastic container with pump dispenser	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	21261 15.03.2023

## LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 03-1/23 on March 15, 2023

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	Herticad	trastuzumab	powder lyophilized for concentrate for solution for infusion	150mg; (1) glass vial	<p>BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422- quality control, batch releaser,</p> <p>BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422, Russia- bulk manufacturer, packager</p>	Russia	<p>BIOCAD JSC, Intracity Municipality the Settlement of Strelna, the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515</p>	Russia	PoM	17890/2/2 15.03.2023
2	Herticad	trastuzumab	powder lyophilized for concentrate for solution for infusion	440mg; (1) glass vial and (1) glass vial with 20ml solvent	<p>BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422- quality control, batch releaser,</p> <p>BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422, Russia- bulk manufacturer, packager</p>	Russia	<p>BIOCAD JSC, Intracity Municipality the Settlement of Strelna, the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515</p>	Russia	PoM	17891/2/2 15.03.2023

3	Betiodine	povidone-iodine	soap liquid	75mg/ml; 80ml plastic bottle, 1l and 3l plastic container	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	17751/1/1 15.03.2023
4	Betiodine	povidone-iodine	solution for external use	100mg/ml; 30ml plastic container, 60ml plastic container, 100ml plastic container, 1l plastic container	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	17566/1/1 15.03.2023

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 03-1/23 on March 15, 2023

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	Carditon	levocarnitine	solution oral	100mg/ml; (10) glass vials 10ml	GM Pharmaceuticals Ltd, 65, Qyemo Phonichala str., 0165 Tbilisi- secondary packager, quality control, batch releaser, Anfarm Hellas S.A., Sximatari Viotias, 32009, Greece- bulk manufacturer, primary packager	Georgia	GM Pharmaceuticals Ltd, 65, Qyemo Phonichala str., 0165 Tbilisi	Georgia	PoM	19234/1 15.03.2023
2	Pimafucort	natamycin, neomycin (neomycin sulfate), hydrocortisone (hydrocortisone micronized)	ointment for external use	10mg/g+3500U/g+10mg/g; aluminium tube 15g	Temmler Italia S.r.L., Via delle Industrie 2, 20061 Carugate (MI)	Italy	LEO Pharma A/S, Industriparken 55, DK-2750 Ballerup	Denmark	PoM	19259/2 15.03.2023
3	Combilipen Tabs	benfotiamine, pyridoxine (pyridoxine hydrochloride), cyanocobalamin	tablets film-coated	100mg+100mg+ 2mcg; (15/1x15/) in blister, (30/2x15/) in blister, (60/4x15/) in blister	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	PoM	19783/1 15.03.2023

4	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	20222/1 15.03.2023
5	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	20223/1 15.03.2023
6	Crinone	progesterone	gel vaginal	80mg/g; (6) pre-filled plastic applicators 1,125g, (15) pre-filled plastic applicators 1,125g	Central Pharma (Contract Packing) Limited, Caxton Road, Bedford, Bedfordshire, MK41 0XZ - secondary packager, batch releaser, Dendron Brands Limited, 94 Rickmansworth Road, Watford, Hertfordshire, WD18 7JJ, UK - bulk manufacturer, Maropack AG, Industriestrasse Briseck 4, 6144 Zell, Switzerland-primary packager, Herd Mundy Richardson Limited, Oak House, Bredbury Parkway Ashton Road, Bredbury Stockport Cheshire SK62SN, UK- quality control	UK	Merck LLC, Valovaya Street 35, 115054 Moscow	Russia	PoM	18229/5/2 15.03.2023

7	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	18435/2 15.03.2023
8	Azithro-Denk 250mg	azithromycin (azithromycin monohydrate)	tablets film- coated	250mg; (6/1x6/) in blister	Artesan Pharma GmbH & Co. KG, Wendlandstrasse 1, 29439 Luechow	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	18435/2 15.03.2023
9	Lipertance	atorvastatin (atorvastatin calcium trihydrate), perindopril arginine, amlodipine (amlodipine besilate)	tablets film- coated	10mg+5mg+5mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	19848/2 15.03.2023
10	Lipertance	atorvastatin (atorvastatin calcium trihydrate), perindopril arginine, amlodipine (amlodipine besilate)	tablets film- coated	20mg+5mg+5mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	19849/2 15.03.2023
11	Lipertance	atorvastatin (atorvastatin calcium trihydrate), perindopril arginine, amlodipine (amlodipine besilate)	tablets film- coated	20mg+10mg+5mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	19850/2 15.03.2023



12	Lipertance	atorvastatin (atorvastatin calcium trihydrate), perindopril arginine, amlodipine (amlodipine besilate)	tablets film-coated	20mg+10mg+10mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	19851/2 15.03.2023
13	Lipertance	atorvastatin (atorvastatin calcium trihydrate), perindopril arginine, amlodipine (amlodipine besilate)	tablets film-coated	40mg+10mg+10mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	19852/2 15.03.2023
14	Kaptopril	captopril	tablets	25mg; (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	PoM	17979/1 15.03.2023
15	Kaptopril	captopril	tablets	50mg; (20/2x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, quality control, batch releaser, KRKA d.d., Novo mesto, Ulica Rada Pusenjaka 10, Ljutomer, 9240, Slovenia- packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	19558/1 15.03.2023
16	BacTRONN Forte	sulfamethoxazole, trimethoprim	tablets	800mg+160mg; (10/1x10/) in blister, (20/2x10/) in blister, (100/10x10/) in blister, (50) in jar, (100) in jar, (500) in jar	Medicon Pharmaceuticals Ltd, Industrial Plot No.17/A-1, Avenue 1, Block-D, Section-10, Mirpur, Dhaka-1216	Bangladesh	Medicon Pharmaceuticals Ltd, Industrial Plot No.17/A-1, Avenue 1, Block-D, Section-10, Mirpur, Dhaka-1216	Bangladesh	PoM	19092/1/1 15.03.2023

17	Cymbalta	duloxetine (duloxetine hydrochloride)	capsules gastro-resistant	30mg; (7/1x7/) in blister, (28/4x7/) in blister, (28/2x14/) in blister	Lilly S.A., Avda de la Industria 30, 28108 Alcobendas-Madrid-packager, batch releaser, Lilly del Caribe, Inc., Puerto Rico 00985, 12,6 km 65th Infantry Road, Carolina, USA- bulk manufacturer	Spain	Eli Lilly Nederland B.V.,Grootslag 1-5, NL-3991 RA,Houten	the Netherlands	PoM	18647/3/1 15.03.2023
18	Revolade	eltrombopag (eltrombopag olamine)	tablets film-coated	25mg; (28/4x7/) in blister	Novartis Pharma GmbH, Roonstrasse 25 und Obere Turnstrasse 8-10, Nuernberg, Bayern, 90429-batch releaser, Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona, Spain- bulk manufacturer, packager, quality control	Germany	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20450/1 15.03.2023
19	Revolade	eltrombopag (eltrombopag olamine)	tablets film-coated	50mg; (28/4x7/) in blister	Novartis Pharma GmbH, Roonstrasse 25 und Obere Turnstrasse 8-10, Nuernberg, Bayern, 90429-batch releaser, Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona, Spain- bulk manufacturer, packager, quality control	Germany	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20451/1 15.03.2023

20	Detralex	diosmin, hesperidin	tablets film-coated	900mg+100mg; (18/2x9/) in blister, (30/3x10/) in blister, (60/6x10/) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	OTC	17509/3 15.03.2023
21	Proctomed	phenylephrine (phenylephrine hydrochloride), cinchocaine, shark liver oil	cream rectal	2,5mg/g+10mg/g+30mg/g; 20g aluminium tube and applicator	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	17704/1 15.03.2023
22	Solution Potassium Chloride 4%	potassium chloride	solution for infusion	40mg/ml; 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	17693/1 15.03.2023
23	Risebon	risedronic acid (risedronate sodium)	tablets film-coated	35mg (4/1x4/) 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 Adamkiewicza St., 05-152 Czosnow	Poland	PoM	17213/3/1 15.03.2023
24	Drotaverine	drotaverine (drotaverine hydrochloride)	solution for i/v and i/m injection	20mg/ml; (10) ampoules 2ml, (10) ampoules 2ml label banderol, (10) ampoules 2ml dividella	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	21060/1 15.03.2023

25	Recreol	dexpanthenol	ointment	50mg/g; 30g and 50g aluminium tube	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	OTC	17714/2 15.03.2023
26	Cavinton Forte	vinpocetine	tablets	10mg; (30/2x15/) in blister, (90/6x15/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	19318/3 15.03.2023
27	Lucetam	piracetam	film-coated tablets	800mg; (30) in glass container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	17596/4 15.03.2023
28	Lucetam	piracetam	film-coated tablets	1200mg; (20) in glass container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	17597/4 15.03.2023
29	Kadcyla	trastuzumab emtansine	powder for concentrate for solution for infusion	100mg; glass vial 15ml	F. Hoffmann-La Roche Ltd. 4303 Kaiseraugst	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	20751/1 15.03.2023
30	Kadcyla	trastuzumab emtansine	powder for concentrate for solution for infusion	160mg; glass vial 20ml	F. Hoffmann-La Roche Ltd. 4303 Kaiseraugst	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	20750/1 15.03.2023

31	Testosteron depo	testosterone (testosterone enantate)	solution for i/m injection	250mg/ml; (5) ampoules 1ml	Galenika a.d., Batajnicket drum bb, 11080 Belgrade-secondary packager, quality control, batch releaser, Panpharma GmbH, Bunsenstrasse 4, 22946, Trittau, Germany-bulk manufacturer, primary packager	Serbia	Galenika a.d., Batajnicket drum bb, 11080 Belgrade	Serbia	PoM	16881/1 15.03.2023
32	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	5mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19013/1 15.03.2023
33	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	10mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19015/1 15.03.2023
34	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	15mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19016/1 15.03.2023

35	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	20mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19017/1 15.03.2023
36	Berotec N	fenoterol (fenoterol hydrobromide)	pressurised inhalation, solution	100mcg/dose; 10ml aluminium bottle and metering valve	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, 55216 Ingelheim am Rhein	Germany	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein	Germany	PoM	17602/2 15.03.2023
37	Colchicina Lirca	colchicine	tablets	1mg; (60/2x30/) in blister	Haupt Pharma Amareg GmbH, Donaustauer Strasse 378, 93055 Regensburg	Germany	Acarpia Farmaceutici S.r.l., Viale L. Majno 18, 20129 Milano	Italy	PoM	17457/2/1 15.03.2023
38	Trinomia	acetylsalicylic acid, atorvastatin, ramipril	capsules	100mg+20mg+ 2,5mg; (28/4x7/) in blister	Ferrer International, S.A., Joan Buscalla,1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer International, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	PoM	17967/3 15.03.2023
39	Trinomia	acetylsalicylic acid, atorvastatin, ramipril	capsules	100mg+20mg+5mg; (28/4x7/) in blister	Ferrer International, S.A., Joan Buscalla,1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer International, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	PoM	17965/3 15.03.2023

40	Trinomia	acetylsalicylic acid, atorvastatin, ramipril	capsules	100mg+20mg+10mg; (28/4x7/) in blister	Ferrer International, S.A., Joan Buscalla,1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer International, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	PoM	17966/3 15.03.2023
41	Ibuprofen	ibuprofen	tablets film-coated	200mg; (50/5x10/) in blister, (5000/500x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	OTC	20539/1 15.03.2023
42	Omnadren 250	testosterone (testosterone propionate), testosterone (testosterone phenylpropionate), testosterone (testosterone isocaproate), testosterone (testosterone decanoate)	oily solution for i/m injection	30mg/ml+60mg/ml+60mg/ml+100mg/ml; (5) ampoules 1ml	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	Bausch Health LLC., Shabolovka st. 31, building 5, 115162, Moscow	Russia	PoM	20734/2 15.03.2023
43	Flavamed cough tablets	ambroxol (ambroxol hydrochloride)	tablets	30mg; (20/2x10/) in blister	Berlin-Chemie AG, Glienicker Weg 125, D-12489 Berlin- packager, quality control, batch releaser, Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden, Germany- bulk manufacturer	Germany	Berlin-Chemie AG, Glienicker Weg 125, D-12489 Berlin	Germany	OTC	19190/2 15.03.2023

44	Nimesubel	nimesulide	tablets	100mg; (20/2x10/) in blister	Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo St., 1-quality control, batch releaser, Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st. 1/5, No6, Belarus- bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	PoM	17586/2/1 15.03.2023
45	Dynapar QPS	diclofenac (diclofenac diethylamine)	solution topical	40mg/ml; 15ml glass vial, 30ml glass vial	Troikaa Pharmaceuticals Ltd, Block No 2019, 2022, 2023, Virochannagar, Tal-Sanand, Ahmedabad, 382170, Gujarat	India	Troikaa Pharmaceuticals Ltd., Commerce House-1, Satya Marg, Bodakdev, Ahmedabad-380054	India	OTC	20757/1 15.03.2023
46	BC DentaHex Solution	chlorhexidine (chlorhexidine gluconate)	solution for external use	20mg/ml; (1) glass vial 100ml	Bio-Chem Ltd., 0046, Erevan, Manandyan str. 33, 1/1	Republic of Armenia	Bio-Chem Ltd., 0046, Erevan, Manandyan str. 33, 1/1	Republic of Armenia	OTC	19346/1 15.03.2023
47	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, Pienkow, Mariana Adamkiewicza St., 05-152 Czosnow	Poland	PoM	18263/3/1 15.03.2023



48	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, Pienkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	PoM	18264/3/2 15.03.2023
49	Clemastine	clemastine (clemastine fumarate)	solution for injection	1mg/ml; (10) ampoules 2ml label banderol, (10) ampoules 2ml dividella, (10) ampoules 2ml CAMA	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, No11/1, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	PoM	20934/1 15.03.2023
50	Escadent dental drops	oleum menthae piperitae, camphor, valerianae radix	drops	31mg/ml+64mg/ml+ 48mg/ml; plastic vial 10ml	Esco-Pharm LLC, Nor- Norq, Mikoyan 13, Yerevan	Republic of Armenia	Esco-Pharm LLC, Nor-Norq, Mikoyan 13, Yerevan	Republic of Armenia	OTC	18860/1 15.03.2023
51	Diflucan	fluconazole	capsules	50mg; (7/1x7/) in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur- Cisse	France	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	PoM	18201/6 15.03.2023
52	Diflucan	fluconazole	capsules	150mg; (1) blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur- Cisse	France	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	PoM	18202/6 15.03.2023

53	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, Industrial site of State Research Center of VB "Vector" city district Koltsovo work settlement, Koltsovo work settlement, building 104, office 201, Novosibirsk region, 630559	Russia	Vector-BiAlgam JSC, Industrial site of State Research Center of VB "Vector" city district Koltsovo work settlement, Koltsovo work settlement, building 104, office 201, Novosibirsk region, 630559	Russia	PoM	17229/1 15.03.2023
54	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, Industrial site of State Research Center of VB "Vector" city district Koltsovo work settlement, Koltsovo work settlement, building 104, office 201, Novosibirsk region, 630559	Russia	Vector-BiAlgam JSC, Industrial site of State Research Center of VB "Vector" city district Koltsovo work settlement, Koltsovo work settlement, building 104, office 201, Novosibirsk region, 630559	Russia	PoM	17230/1 15.03.2023

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 03-1/23 on March 15, 2023

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	Oncaspar	Pegaspargase	lyophilizate for solution for i/m injection and infusion	750IU/ml; glass vial 5ml	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy- quality control, batch releaser, Lyophilization Services of New England, Inc (LSNE),25 Commerce Drive, Bedford, New Hampshire (NH) 03110 , USA- bulk manufacturer, primary packager, Exelead Inc., 6925 Guion Road, Indianapolis, Indiana (IN) 46268, USA- secondary packager	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000545 15.03.2023