

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 08-1/24 on August 16, 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	Rinocil	dimethindene maleate, phenylephrine (phenylephrine hydrochloride)	spray nasal	0,25mg/ml+2,5mg/ml; 10ml plastic vial with metering pump	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	OTC	22257 16.08.2024
2	Telaxel	timolol (timolol maleate)	drops eye (solution)	5mg/ml; plastic vial 5ml	Pharmatech CJSC, 111 Raffi str., Yerevan, 0064	Republic of Armenia	Pharmatech CJSC, 111 Raffi str., Yerevan, 0064	Republic of Armenia	PoM	22258 16.08.2024
3	Milgamma	benfotiamine, pyridoxine (pyridoxine hydrochloride)	tablets coated	100mg+100mg; (30/2x15) in blister, (60/4x15) in blister	Mauermann-Arzneimittel KG, Gewerbealle 1, Poecking, 82343- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Grossenbrach, Bad Bocklet, Bavaria, 97708, Germany- quality control (microbiological)	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen	Germany	PoM	22259 16.08.2024

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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	Stopdiar	nifuroxazide	suspension oral	220mg/5ml; glass bottle 90ml and dual measuring spoon (2,5ml/5ml)	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- batch releaser, Gedeon Richter Romania S.A., 99-105 Guza Voda str., 540306, Targu-Mures, Romania- bulk manufacturer, packager, quality control	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22249 (000864) 16.08.2024
2	Elmucin	erdosteine	capsules	300mg; (10/1x10) 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	OTC	22250 (005655) 16.08.2024
3	Suprastinex	levocetirizine (levocetirizine dihydrochloride)	drops oral	5mg/ml; glass vial with dropper 20ml	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	OTC	22251 (001957) 16.08.2024
4	Natalsid	sodium alginate	suppositories rectal	250mg; (10/2x5)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, c.1- quality control, batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia- bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	22252 (002743) 16.08.2024

5	Mydocalm Long	tolperisone (tolperisone hydrochloride)	tablets film-coated prolonged release	450mg; (10/1x10) in blister, (30/3x10) in blister, (bag) 10,5-18,5 kg x 1(box)	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22253 (000118) 16.08.2024
6	Mydocalm Long	tolperisone (tolperisone hydrochloride)	tablets film-coated prolonged release	450mg; (10/1x10) in blister, (30/3x10) in blister, (bag) 10,5-18,5 kg x 1(box)	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, batch releaser, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22254 (000118) 16.08.2024
7	Mydocalm Long	tolperisone (tolperisone hydrochloride)	film-coated tablets prolonged release	450mg; (10/1x10) in blister, (30/3x10) in blister, (bag) 10,5-18,5 kg x 1(box)	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22255 (000118) 16.08.2024

8	Trifas	torasemide	solution for injection	10mg/2ml; (5) ampoules 2ml	A. Menarini Manufacturing Logistics and Services S.r.l., Via Sette Santi, 3 50131 Florence	Italy	Menarini International Operations Luxembourg S.A., 1, avenue de la Gare, 1611	Luxembourg	PoM	22256 (009425) 16.08.2024
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LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 08-1/24 on August 16, 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	Hypomed	lisinopril (lisinopril dihydrate), amlodipine (amlodipine besilate)	tablets	10mg+5mg; (40/1x40) in blister	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	22233 16.08.2024
2	Co-Diovan	valsartan, hydrochlorothiazide	tablets film-coated	80mg+12,5mg; (14/1x14) in blister, (28/2x14) in blister	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22234 16.08.2024
3	Co-Diovan	valsartan, hydrochlorothiazide	tablets film-coated	160mg+12,5mg; (14/1x14) in blister	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22235 16.08.2024
4	Anaferon kids	affinity purified antibodies to human interferon gamma	drops oral	10000UMA/ml; 25ml glass vial-dropper	NPF Materia Medica Holding LLC, 54, Buguruslanskaya st., Chelyabinsk 454139	Russia	NPF Materia Medica Holding LLC, 9 bld., 3rd Samotyochny per., Moscow 127473	Russia	OTC	22236 16.08.2024
5	Dexamethason	dexamethasone	tablets	0,5mg; (10/1x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, quality control, batch releaser, KRKA d.d., Novo mesto, Novomeskacesta 22, Sentjernej 8310, Slovenia- packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22237 16.08.2024
6	Furazolidon	furazolidone	tablets	50mg; (10) in strip	Irbitskiy himfarmzavod OJSC, 124-a, K. Marksa str., Irbit, St. Sverdlovsk, 623856	Russia	Irbitskiy himfarmzavod OJSC, 172, Kirova str., Irbit, St. Sverdlovsk, 623856	Russia	PoM	22238 16.08.2024
7	Azaleptine	clozapine	tablets	100mg; (40/4x10) in blister, (50/5x10) 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	22239 16.08.2024

8	Amlodipine	amlodipine (amlodipine besilate)	tablets	10mg; (30/3x10) in blister	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	22240 16.08.2024
9	DONORMYL	doxylamine (doxylamine succinate)	tablets coated	15mg; (10) in plastic container, (30) in plastic container	UPSA SAS, 304, avenue du Docteur Jean Bru, 47000 AGEN	France	UPSA SAS, 3, rue Joseph Monier- 92500 Rueil- Malmaison	France	PoM	22241 16.08.2024
10	Cyclodol	trihexyphenidyl (trihexyphenidyl hydrochloride)	tablets	2mg; (40/1x40) in blister, (48/2x24) in blister	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	22242 16.08.2024
11	Rispaxol	risperidone	tablets film-coated	2mg; (20/2x10) in blister, (60/6x10) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	22243 16.08.2024
12	Rispaxol	risperidone	tablets film-coated	4mg; (20/2x10) in blister, (60/6x10) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	22244 16.08.2024
13	TRAMETALIN	tramadol (tramadol hydrochloride)	solution for injection	50mg/ml; (5/1x5) ampoules 2ml in blister	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	22245 16.08.2024
14	Zometa	zoledronic acid (zoledronic acid monohydrate)	concentrate for solution for infusion	0,8mg/ml; glass vial 5ml	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein- secondary packager, quality control, batch releaser, Fresenius Kabi Austria GmbH, Hafnerstrasse 36, Graz, 8055, Austria- bulk manufacturer, primary packager	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22246 16.08.2024
15	Trimethosulfá Orale	sulfadiazine, trimethoprim	solution oral	40mg/ml+200mg/ml; plastic bottle 1000ml, plastic container 5l, plastic container 10l, plastic pack 10l	Industria Italiana Integratori Trei S.p.A., Via Affarosa, 4, Rio Saliceto (RE), 42010	Italy	Industria Italiana Integratori Trei S.p.A., Viale Corassori, 62-41100 Modena	Italy	PoM	22247 16.08.2024
16	Antilice	pyrethrins (permethrin+tetramethrin), piperonyl butoxide	shampoo	1,65mg/ml+16,5mg/ml; plastic bottle 90ml	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	22248 16.08.2024

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 08-1/24 on August 16, 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	Zidin	chlorhexidine (chlorhexidine bigluconate)	suppositories vaginal	16mg; (10/2x5/)	Medical Horizon LLC, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	Medical Horizon LLC, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	OTC	22229 16.08.2024
2	Bisoprolol	bisoprolol (bisoprolol fumarate)	tablets film-coated	2,5mg; (30/3x10) in blister	Replek Farm Ltd.-Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	Replek Farm Ltd.-Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	PoM	22230 16.08.2024
3	Bisoprolol	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (30/3x10) in blister	REPLEK FARM Ltd.-Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	Replek Farm Ltd.-Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	PoM	22231 16.08.2024
4	Ibuprofen AKTIV	ibuprofen	tablets film-coated	400mg; (30/3x10) in blister	REPLEK FARM Ltd. Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	Esculap Ltd., 17/2, 1 block, Davidashen, 0054, Yerevan	Republic of Armenia	OTC	22232 16.08.2024

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 08-1/24 on August 16, 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	Nuroton	ibuprofen	suspension oral	100mg/5ml; 100ml plastic bottle and measuring syringe 5ml	Pharmtechnology LLC, Korzhenevskogo str., 22, 220024, Minsk	Republic of Belarus	Giga Farm LLC, Gogunca str.3/5, Gyumri	Republic of Armenia	OTC	20960/1/1 16.08.2024
2	Nuroton Zero	ibuprofen	suspension oral	100mg/5ml; 100ml plastic bottle and measuring syringe 5ml	Pharmtechnology LLC, Korzhenevskogo str., 22, 220024, Minsk	Republic of Belarus	Giga Farm LLC, Gogunca str.3/5, Gyumri	Republic of Armenia	OTC	20804/1/1 16.08.2024

3	Sulfocamphocaine-Darnytsia	DL-sulfocamphoric acid, procaine base	solution for injection	49,6mg/ml+50,4mg/ml (10/2x5) ampoules 2ml in blister	PrJSC «Pharmaceutical firm «Darnytsia», 13 Boryspilska Street, Kyiv, 02093	Ukraine	PrJSC «Pharmaceutical firm «Darnytsia», 13 Boryspilska Street, Kyiv, 02093	Ukraine	PoM	19582/1/1 16.08.2024
4	Lasolvan	ambroxol (ambroxol hydrochloride)	tablets	30mg; (20/2x10) in blister	Delpharm Reims, 10 rue Colonel Charbonneaux, Reims, 51100	France	A. Nattermann & Cie. GmbH, Industriepark Hoechst, Bruningstrasse 50, D-65926, Frankfurt am Main	Germany	OTC	20868/1/1 16.08.2024
5	Loperamide hydrochloride	loperamide (loperamide hydrochloride)	capsules	2mg; (10/1x10) in blister, (20/2x10) in blister	Open joint stock company «Borisovskiy zavod medicinskikh preparatov», 64A, No4, 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	OTC	18703/1/1 16.08.2024
6	Lopraxer-Neo	citalopram (citalopram hydrochloride)	drops oral (solution)	40mg/ml; 15ml glass bottle	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorfofi, Attiki	Greece	PoM	21094/1/1 16.08.2024

7	SYBRAVA	inclisiran	solution for subcutaneous injection	189mg/ml; 1.5ml pre-filled syringe	Novartis Pharmaceutical Manufacturing GmbH, Biochemiestrasse 10, Langkampfen, 6336- batch releaser, Corden Pharma S.p.A., Reparto UP3, Via G. Galilei, 17, Caponago (MB), 20867, Italy- bulk manufacturer, primary packager, quality control, Corden Pharma S.p.A., viale dell Industria, 3, Caponago (MB), 20867, Italy- secondary packager	Austria	Novartis Overseas Investments AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20914/1/1 16.08.2024
8	Bronchoton	glaucine (glaucine hydrobromide), ephedrine (ephedrine hydrochloride)	syrup	5,75mg/5ml+4,6mg/5ml; 125g (109,6ml) plastic container	Vetprom AD, Otets Paisiy str. 26, Radomir 2400	Bulgaria	Danhson-BG, Otets Paisiy str. 26, Radomir 2400	Bulgaria	PoM	21514/1/1 16.08.2024
9	Nakom	levodopa, carbidopa	tablets	250mg+25mg; (100/10x10) in blister	Lek Pharmaceuticals d.d., Verovskova Ulica 57, 1000, Ljubljana - quality control (microbiological), batch releaser, Novartis Pharmaceutical Manufacturing LLC, Verovskova Ulica 57, 1000, Ljubljana, Slovenia- bulk manufacturer, packager, quality control (physicochemical)	Slovenia	Lek Pharmaceuticals d.d., Verovskova Ulica 57, Ljubljana	Slovenia	PoM	21954/1/1 16.08.2024
10	Dimedrol-Damytsia	diphenhydramine (diphenhydramine hydrochloride)	tablets	50mg; (10) in blister, (10/1x10) in blister	PrJSC «Pharmaceutical firm» Darnytsia», 02093, Kyiv, Boryspilska Str.,13	Ukraine	PrJSC «Pharmaceutical firm» Darnytsia», 02093, Kyiv, Boryspilska Str.,13	Ukraine	PoM	21124/2/1 16.08.2024
11	Metronidazole	metronidazole	tablets	250mg; (10) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	PoM	20949/1/1 16.08.2024

12	Camphor oil	camphor	solution for external use	100mg/ml; glass bottle 30ml, plastic vial 30ml	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	OTC	22055/1/1 16.08.2024
13	Amlodipine	amlodipine (amlodipine besilate)	tablets	5mg; (30/3x10) in blister	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	19293/2/1 16.08.2024
14	Amlodipine	amlodipine (amlodipine besilate)	tablets	10mg; (30/3x10) in blister	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	18611/2/1 16.08.2024
15	Ciprofloxacin	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	250mg; (10/1x10) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	PoM	20736/1/1 16.08.2024
16	Ciprofloxacin	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	500mg; (10/1x10) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	PoM	20737/1/1 16.08.2024

17	Cyclodol	trihexyphenidyl (trihexyphenidyl hydrochloride)	tablets	2mg; (40/1x40) in blister, (48/2x24) in blister	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Mi- cro-District, 19 Building	Republic of Armenia	PoM	18827/2/1 16.08.2024
18	KOXIKEA	etoricoxib	tablets film- coated	60mg; (28/4x7) in blister	Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa	Greece	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	20346/3/1 16.08.2024
19	KOXIKEA	etoricoxib	tablets film- coated	90mg; (28/4x7) in blister	Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa	Greece	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	20347/3/1 16.08.2024
20	KOXIKEA	etoricoxib	tablets film- coated	120mg; (7/1x7) in blister	Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa	Greece	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	20348/3/1 16.08.2024
21	Spazmaton	metamizole (metamizole sodium), pitofenone (pitofenone hydrochloride), fempiverinium bromide	tablets	500mg+5mg+0,1mg; (20/2x10) in blister, (50/5x10) in blister	Open joint stock company «Borisovskiy zavod medicinskikh preparatov», 64A, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinski- kh preparatov», 64, ul. Chapaeva, Borisov, 222518, Minsk region	Republic of Belarus	OTC	18827/2/1 16.08.2024

22	Antilice	pyrethrins (permethrin+tetramethrin), piperonyl butoxide	shampoo	1,65mg/ml+16,5mg/ml; plastic bottle 90ml	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	18682/3/2 16.08.2024
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LIST

of variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting decision N
08-1/24 on August 16, 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	Sodium bicarbonate	sodium bicarbonate	solution for infusion	84mg/ml; glass vial 20ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	001605 16.08.2024

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 08-1/24 on August 16, 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	Para-Denk 500	paracetamol	tablets	500mg; (20/2x10) in blister	bene-Arzneimittel GmbH Herterichstrasse 1-3, Muenchen, Bayern, 81479- bulk manufacturer, packager, batch releaser, bene-Arzneimittel GmbH Bayerwaldstrasse 7-9, Geretsried, Bayern, 82538, Germany- quality control (physicochemical), Labor für analytische und pharmazeutische Chemie Dr. Graner & Partner GmbH, Lochhausener Str. 205 81249 Muenchen, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	OTC	21270/1 16.08.2024
2	Euthyrox	levothyroxine (levothyroxine sodium)	tablets	25mcg; (100/4x25) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, 35 Valovaya Street, Moscow 115054	Russia	PoM	20404/2/1 16.08.2024
3	Euthyrox	levothyroxine (levothyroxine sodium)	tablets	50mcg; (100/4x25) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, 35 Valovaya Street, Moscow 115054	Russia	PoM	20405/2/1 16.08.2024
4	Euthyrox	levothyroxine (levothyroxine sodium)	tablets	75mcg; (100/4x25) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, 35 Valovaya Street, Moscow 115054	Russia	PoM	20406/2/1 16.08.2024
5	Euthyrox	levothyroxine (levothyroxine sodium)	tablets	100mcg; (100/4x25) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, 35 Valovaya Street, Moscow 115054	Russia	PoM	20407/2/1 16.08.2024
6	Euthyrox	levothyroxine (levothyroxine sodium)	tablets	125mcg; (100/4x25) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, 35 Valovaya Street, Moscow 115054	Russia	PoM	20408/2/1 16.08.2024
7	Euthyrox	levothyroxine (levothyroxine sodium)	tablets	150mcg; (100/4x25) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, 35 Valovaya Street, Moscow 115054	Russia	PoM	20409/2/1 16.08.2024

8	Hypomed	lisinopril (lisinopril dihydrate), amlodipine (amlodipine besilate)	tablets	10mg+5mg; (40/1x40) in blister	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	18636/1 16.08.2024
9	Sulphaprim	sulfamethoxazole, trimethoprim	suspension oral	200mg/5ml+40mg/5ml; glass bottle 100ml and measuring cup	Medical Horizon Ltd, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	Medical Horizon Ltd, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	PoM	18891/1 16.08.2024
10	Fenkarol	quifenadine (quifenadine hydrochloride)	tablets	50mg; (15/1x15) in blister, (30/2x15) in blister	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	OTC	19973/1 16.08.2024
11	Folacin	folic acid	tablets	5mg; (30/3x10) in blister	JADRAN-GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	JADRAN-GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	PoM	20205/2 16.08.2024
12	Tonopenem	meropenem (meropenem trihydrate)	powder for solution for i/v injection	500mg; (36) glass vials 10ml	Tonus-Les LLC, N1 Laboratory complex, 6th str., v. Nor Gyugh, com. Akunk, Kotayk marz- batch releaser, TriplePharm, Minsk Region, Logoisk, Minskaya str., house 2B, Republic of Belarus- bulk manufacturer, packager, quality control	Republic of Armenia	Tonus-Les LLC, Yerevan, 1 Yervand Kochar str., 0070	Republic of Armenia	PoM	21677/2/1 16.08.2024
13	Klimalanin	beta-alanine	tablets	400mg; (30/3x10) in blister, (30/2x15) in blister	Laboratoires Bouchara-Recordati, Parc Mecatronic 03410 Saint Victor	France	Laboratoires Bouchara-Recordati, Immeuble le Wilson, 70 avenue du General de Gaulle, 92800 Puteaux	France	OTC	19321/1 16.08.2024
14	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, Weystrasse 20, 6006 Luzern	Switzerland	PoM	20962/2 16.08.2024

15	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, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	20963/2 16.08.2024
16	Urolesan	abies oil, mentha piperita oil, daucus carota fluid extract, humulus lupulus fluid extract, origanum fluid extract	drops oral	67,6mg/ml+16,9mg/ml+194,35mg/ml+278,8mg/ml+192,95mg/ml; bottle-dropper 25ml	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	OTC	20963/2 16.08.2024
17	Diclone	diclofenac (diclofenac sodium)	suppositories rectal	12,5mg; (10/2x5)	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	PoM	18897/1 16.08.2024
18	Diclone	diclofenac (diclofenac sodium)	suppositories rectal	25mg; (10/2x5)	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	PoM	18898/1 16.08.2024
19	Diclone	diclofenac (diclofenac sodium)	suppositories rectal	50mg; (10/2x5)	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	PoM	18899/1 16.08.2024
20	Diclone	diclofenac (diclofenac sodium)	suppositories rectal	100mg; (10/2x5)	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	PoM	18900/1 16.08.2024
21	Co-Diovan	valsartan, hydrochlorothiazide	tablets film-coated	80mg+12,5mg; (14/1x14) in blister, (28/2x14) in blister	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18660/5 16.08.2024
22	Co-Diovan	valsartan, hydrochlorothiazide	tablets film-coated	160mg+12,5mg; (14/1x14) in blister	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18661/5 16.08.2024
23	Acetylsalicylic acid	acetylsalicylic acid	tablets	500mg; (10) in blister, (10) in strip	Irbitskiy himfarmzavod OJSC, 124-a, K. Marksa str., Irbit, St. Sverdlovsk, 623856	Russia	Irbitskiy himfarmzavod OJSC, 172, Kirova str., Irbit, St. Sverdlovsk, 623856	Russia	OTC	18487/1 16.08.2024

24	Acnamino MR 100mg Capsules	minocycline (minocycline hydrochloride)	capsules hard	100mg; (56/8x7) in blister	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB- batch releaser, Dexcel Ltd., 1 Dexcel Street, Or-Akiva 3060000, Israel- bulk manufacturer, packager, quality control (physicochemical), The Institute for Food Microbiology and Consumer Goods Ltd.,9 HaShalom Road, Neshet, Israel- quality control (microbiological)	UK	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB	UK	PoM	21674/2 16.08.2024
25	Bisoprolol	bisoprolol (bisoprolol fumarate)	tablets film- coated	2,5mg; (30/3x10) in blister	REPLEK FARM Ltd.-Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	REPLEK FARM Ltd.-Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	PoM	18888/1 16.08.2024
26	Bisoprolol	bisoprolol (bisoprolol fumarate)	tablets film- coated	5mg; (30/3x10) in blister	REPLEK FARM Ltd.-Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	REPLEK FARM Ltd.-Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	PoM	18889/1 16.08.2024
27	Azaleptine	clozapine	tablets	100mg; (40/4x10) in blister, (50/5x10) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Mi- cro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	18729/1 16.08.2024
28	Zidin	chlorhexidine (chlorhexidine bigluconate)	suppositories vaginal	16mg; (10/2x5)	Medical Horizon LLC, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	Medical Horizon LLC, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	OTC	18903/2/1 16.08.2024
29	Dexamethason	dexamethasone	tablets	0,5mg; (10/1x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto-bulk manufacturer, batch releaser, KRKA, d.d. Novo mesto, Novomeskacesta 22, Sent- jemej 8310, Slovenia-packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	18556/3 16.08.2024
30	Suprostilin	chloropyramine (chloropyramine hydrochloride)	tablets	25mg; (10/1x10) in blister, (20/2x10) 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	OTC	21782/2 16.08.2024
31	Tot` Hema	iron (iron gluconate), manganese (manganese gluconate), copper (copper gluconate)	solution oral	50mg/10ml+1,33mg/10m- l+0,7mg/10ml; (20/2x10) ampoules 10ml in blister	Innothera Chouzy, Rue Rene Chantereau, Chouzy- sur-Cisse, Valloire-sur-Cisse, 41150	France	Laboratoire Innotech Inter- national, 22, Avenue Aristide Briand, 94110 Arcueil	France	PoM	19991/1 16.08.2024
32	TRAMETALIN	tramadol (tramadol hydrochloride)	solution for injection	50mg/ml; (5/1x5) ampoules 2ml in blister	Moscow Endocrine Plant FSUE, 25, bld. 1, Novok- hokhlovskaya 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	18265/3 16.08.2024

33	Rispaxol	risperidone	tablets film-coated	2mg; (20/2x10) in blister, (60/6x10) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	18273/3 16.08.2024
34	Rispaxol	risperidone	tablets film-coated	4mg; (20/2x10) in blister, (60/6x10) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	18274/3 16.08.2024
35	Zometa	zoledronic acid (zoledronic acid monohydrate)	concentrate for solution for infusion	0.8mg/ml; (1) glass vial 5ml	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein- batch releaser, secondary packager, Fresenius Kabi Austria GmbH, Hafnerstrasse 36, Graz, 8055, Austria- bulk manufacturer, primary packager	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	18667/5 16.08.2024
36	Donormyl	doxylamine (doxylamine succinate)	tablets coated	15mg; (10) in plastic container, (30) in plastic container	UPSA SAS, 304, avenue du Docteur Jean Bru, 47000 AGEN	France	UPSA SAS, 3, rue Joseph Monier- 92500 Rueil- Malmaison	France	PoM	18512/3 16.08.2024
37	Ibuprofen AKTIV	ibuprofen	tablets film-coated	400mg; (30/3x10) in blister	REPLEK FARM Ltd. Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	Esculap Ltd., 17/2, 1 block, Davidashen, 0054, Yerevan	Republic of Armenia	OTC	18929/1 16.08.2024
38	Heparin-Belmed	heparin (heparin sodium)	solution for i/v and s/c injection	5000UU/ml; (1) glass vial 5ml, (5) glass vials 5ml	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30, No2	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	18991/1 16.08.2024
39	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	20181/3 16.08.2024

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 08-1/24 on August 16, 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	Detralex	diosmin, hesperidin	tablets film-coated	450mg+50mg; (28/2x14) in blister, (30/2x15) in blister, (36/3x12) in blister, (56/4x14) in blister, (60/4x15) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	OTC	000822 16.08.2024
2	Detralex	diosmin, hesperidin	tablets film-coated	450mg+50mg; (28/2x14) in blister, (30/2x15) in blister, (36/3x12) in blister, (56/4x14) 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	OTC	000822 16.08.2024
3	Detralex	diosmin, hesperidin	tablets film-coated	450mg+50mg; (30/2x15) in blister, (36/3x12) in blister, (60/4x15) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, quality control, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	OTC	000822 16.08.2024
4	Detralex	diosmin, hesperidin	tablets film-coated	900mg+100mg; (18/2x9) in blister, (27/3x9) 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	000822 16.08.2024
5	Detralex	diosmin, hesperidin	tablets film-coated	900mg+100mg; (18/2x9) in blister, (27/3x9) in blister, (30/3x10) in blister, (60/6x10) 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	OTC	000822 16.08.2024
6	Bro-mocriptin-Richter	bromocriptine (bromocriptine mesilate)	tablets	2,5mg; (30) glass bottle	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	002402 16.08.2024

7	Skudexa	tramadol (tramadol hydrochloride), dexketoprofen	tablets film-coated	75mg+25mg; (15/1x15) in blister	Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden	Germany	Menarini International Operations Luxembourg S.A., 1, avenue de la Gare, 1611	Luxembourg	PoM	002976 16.08.2024
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