

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 02-1/24 on February 15, 2024

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Ondansetron	ondansetron	solution for injection	2mg/ml; (5/1x5) ampoules 4ml 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	21929 15.02.2024
2	Cerucal	metoclopramide (metoclopramide hydrochloride monohydrate)	tablets	10mg; (50) in glass bottle	PLIVA Hrvatska d.o.o., Prilaz baruna Filipovica 25, 10000 Zagreb	Croatia	Teva Pharmaceutical Industries Ltd., 124 Dvora HaNevi's St., Tel Aviv 6944020	Israel	PoM	21930 15.02.2024

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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	Regulon	desogestrel, ethinylestradiol	tablets film-coated	0,15mg+0,03mg; (21/1x21) in blister, (63/3x21) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	21935 (000383, 006623) 15.02.2024
2	Panangin	potassium asparaginate (potassium asparaginate hemihydrate), magnesium asparaginate (magnesium asparaginate tetrahydrate)	concentrate for solution for infusion	45,2mg/ml+40mg/ml; (5/1x5) ampoules 10ml in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	21936 (004109, 004108) 15.02.2024
3	Panangin	potassium asparaginate (potassium asparaginate hemihydrate), magnesium asparaginate (magnesium asparaginate tetrahydrate)	concentrate for solution for infusion	45,2mg/ml+40mg/ml; (5/1x5) ampoules 10ml in blister	SotexPharmFirm» CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region- quality control, batch releaser, «Sotex»PharmFirm» CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, Russia- bulk manufacturer, packager	Hungary	Gedeon Richter Plc., Gyomroi ut 19-21, Budapest, 1103	Hungary	PoM	21937 (004109, 004108) 15.02.2024
4	MOXONIDIN-ALIMUM	moxonidine	tablets film-coated	0,2mg; (30/3x10) in blister	Alium AO, build. 1, No: 2, Quarter A, Obolensk working settlement, Serpukhov city, 142279, Moscow reg.- quality control, batch releaser, Alium AO, No: 2, Quarter A, Obolensk working settlement, Serpukhov city, 142279, Moscow region, Russia- bulk manufacturer, packager	Russia	Alium AO, No: 2, Quarter A, Obolensk working settlement, Serpukhov city, 142279, Moscow region	Russia	PoM	21938 (000421) 15.02.2024

5	MOXONIDIN- ALIMUM	moxonidine	tablets film-coated	0,4mg; (30/3x10) in blister	Alium AO, build. 1, No: 2, Quarter A, Obolensk working settlement, Serpukhov city, 142279, Moscow reg.- quality control, batch releaser, Alium AO, No: 2, Quarter A, Obolensk working settlement, Serpukhov city, 142279, Moscow region, Russia- bulk manufacturer, packager	Russia	Alium AO, No: 2, Quarter A, Obolensk working settlement, Serpukhov city, 142279, Moscow region	Russia	PoM	21939 (000421) 15.02.2024
6	Cerotex	choline alfoscerate polyhydrate	solution for i/m and i/v injection	250mg/ml; (3) ampoules 4ml, (5) ampoules 4ml, (6) ampoules 4ml, (10) ampoules 4ml	SotexPharmFirm» CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region- quality control, batch releaser, «Sotex»PharmFirm» CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, Russia- bulk manufacturer, packager	Russia	«Sotex»PharmFirm» CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	PoM	21940 (002262) 15.02.2024
7	Valdocef	cefadroxil(cefadroxil monohydrate)	capsules hard	500mg; (16/2x8) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- quality control, batch releaser, Alkaloid AD Skopje, Blvd. Partizanski odredi 98A, 1000 Skopje, Republic of North Macedonia- bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	21933 (006398) 15.02.2024
8	Valdocef	cefadroxil (cefadroxil monohydrate)	granules for oral suspension	250mg/5ml; 65g granules for preparation 100ml oral suspension in 150ml glass bottle and plastic oral syringe	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- quality control, batch releaser, Alkaloid AD Skopje, Blvd. Partizanski odredi 98A, 1000 Skopje, Republic of North Macedonia- bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	21934 (006903) 15.02.2024
9	Trifas 5	torasemide	tablets	5mg; (30/3x10) in blister	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie A.G., Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1. Berlin-Chemie A.G., Tempelhofer Weg 83, 12347 Berlin, Germany, 2. Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin, Germany- quality control (phiscochemical)	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	21931 (007305) 15.02.2024

10	Trifas 10	torasemide	tablets	10mg; (30/3x10) in blister	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie A.G., Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1. Berlin-Chemie A.G., Tempelhofer Weg 83, 12347 Berlin, Germany, 2. Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin, Germany- quality control (phiscochemical)	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	21932 (007305) 15.02.2024
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LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 02-1/24 on February 15, 2024

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Ergoferon	affinity purified antibodies to human interferon gamma, affinity purified antibodies to histamine, affinity purified antibodies to CD4	tablets	10000MAU+10000MAU+10000MAU; (20/1x20) in blister	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	21942 15.02.2024
2	Pilfud	minoxidil	spray cutaneous, solution	20mg/ml; 60ml plastic vial	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	21943 15.02.2024
3	Pilfud	minoxidil	spray cutaneous, solution	50mg/ml; 60ml plastic vial	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	21944 15.02.2024
4	Cepiton	cefepime (cefepime dihydrochloride monohydrate)	powder for solution for injection/infusion	1000mg; glass vial 15ml	Medochemie Ltd (Factory C), 2 Michael Erakleous street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupoles street, 3011 Limassol	Cyprus	PoM	21945 15.02.2024
5	Mexidol	ethylmethylhydroxypyridine succinate	tablets film-coated	125mg; (30/3x10) in blister, (50/5x10) in blister	CJSC «ZiO-Zdorovie», 142103, Moscow region, Podolsk, str. Zheleznodorozhnaya, 2	Russia	LLC «RPC «PHARMASOFT», 115407, Moscow, Sudostroitel'naya str., bld. 41, floor 1, premises 12	Russia	PoM	21946 15.02.2024
6	Warfarin Orion	warfarin (warfarin sodium)	tablets	3mg; (30) in plastic container, (100) in plastic container	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	PoM	21947 15.02.2024
7	Warfarin Orion	warfarin (warfarin sodium)	tablets	5mg; (30) in plastic container, (100) in plastic container	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	PoM	21948 15.02.2024

8	Kanamycin	kanamycin (kanamycin sulfate)	powder for solution for i/m injection	1000mg; (40) glass vials	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	PoM	21949 15.02.2024
9	Stresam	etifoxine (etifoxine hydrochloride)	capsules	50mg; (60/3x20/) in blister	Biocodex, 1 avenue Blaise Pascal, 60000 Beauvais	France	Biocodex, 7 avenue Gallieni 94250 Gentilly	France	PoM	21950 15.02.2024
10	Neuromultivit	vitamin B1, vitamin B6, vitamin B12	tablets film-coated	100mg+200mg+0,2mg; (20/2x10) in blister, (100/10x10) in blister	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach- batch releaser, G.L. Pharma GmbH, Industriestrasse 1, 8502 Lannach, Austria- bulk manufacturer, packager, quality control	Austria	Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	OTC	21951 15.02.2024
11	Diazepam	diazepam	tablets	5mg; (24/1x24) 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	21952 15.02.2024
12	Diazepam	diazepam	tablets	10mg; (24/1x24) 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	21953 15.02.2024
13	Nakom	levodopa, carbidopa	tablets	250mg+25mg; (100/10x10) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	21954 15.02.2024
14	Arthrinol	tenoxicam	tablets film-coated	20mg; (10/1x10) blister	Remedica Ltd., Limassol Industrial Estate, Aharnon street, 3056 Limassol	Cyprus	Remedica Ltd., Limassol Industrial Estate, Aharnon street, 3056 Limassol	Cyprus	PoM	21955 15.02.2024
15	Diflucan	fluconazole	solution for i/v infusion	2mg/ml; glass vial 50ml	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse or	France	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	PoM	21956 15.02.2024
16	Physiotens	moxonidine	tablets film-coated	0,2mg; (14/1x14) in blister	Mylan Laboratories SAS, Route de Belleville, Lieu dit Maillard, 01400 Chatillon sur Chalaronne	France	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	PoM	21957 15.02.2024
17	Physiotens	moxonidine	tablets film-coated	0,4mg; (14/1x14) in blister	Mylan Laboratories SAS, Route de Belleville, Lieu dit Maillard, 01400 Chatillon sur Chalaronne	France	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	PoM	21958 15.02.2024
18	NOSH-ARPI	drotaverine (drotaverine hydrochloride)	tablets	40mg; (24/1x24) 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	OTC	21959 15.02.2024

19	Betaklav	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	500mg+125mg; (14/2x7/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- batch releaser, Micro Lab Limited, 16, Veersandra Industrial Area, Anekal Taluk, Bangalore-560100, India- bulk manufacturer, packager, KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto, Slovenia- quality control (microbiological), 1. KRKA d.d., Novo mesto, Povahova ulica 5, 8501 Novo Mesto, Slovenia, 2.KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	21960 15.02.2024
20	Betaklav	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	875mg+125mg; (14/2x7/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- batch releaser, Micro Lab Limited, 16, Veersandra Industrial Area, Anekal Taluk, Bangalore, 560100, India- bulk manufacturer, packager, KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto, Slovenia- quality control (microbiological), 1. KRKA d.d., Novo mesto, Povahova ulica 5, 8501 Novo Mesto, Slovenia, 2.KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	21961 15.02.2024
21	Phosphogliv	phospholipids (lipoid C 100), glycyrrhizinic acid (glycyrrhizinic acid trisodium)	powder lyophilized for solution for i/v injection	500mg+200mg; (5) glass vials 2,5g and (5) solvent in ampoules 10ml	Pharmstandard-Ufa VITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	Pharmstandard-Ufa VITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	PoM	21962 15.02.2024

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 02-1/24 on February 15,
2024

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Izoconazol-M	isozonazole (isozonazole nitrate)	cream	10mg/g; aluminium tube 25g	Esco-Pharm LLC, Nor-Norq, Mikoyan 13, Yerevan	Republic of Armenia	Medical Horizon LLC, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	PoM	18961/1/1 15.02.2024
2	Utrogestan	progesterone	capsules soft	100mg; (28/2x14) in blister	Cyndea Pharma SL, Poligono Industrial Emiliano Revilla Sanz, Avenida de Agreda, 31, Olvega 42110(Soria)	Spain	Besins Healthcare SA, Rue Washington 80, Ixelles 1050	Belgium	PoM	20013/1/1 15.02.2024

3	Utrogestan	progesterone	capsules soft	200mg; (14/2x7) in blister	Cyndea Pharma SL, Poligono Industrial Emiliano Revilla Sanz, Avenida de Agreda, 31, Olvega 42110(Soria)	Spain	Besins Healthcare SA, Rue Washington 80, Ixelles 1050	Belgium	PoM	20014/1/1 15.02.2024
4	Diazepam	diazepam	tablets	5mg; (24/1x24) 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	18606/1/1 15.02.2024
5	Diazepam	diazepam	tablets	10mg; (24/1x24) 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	18607/1/1 15.02.2024
6	Elocom	mometasone (mometasone furoate)	cream	1mg/g; 15g aluminium tube	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	20463/1/1 15.02.2024

7	Charcoal activated-Pharmstandard	charcoal activated	tablets	250mg; (10) in blister, (10/1x10) in blister, (30/3x10) in blister, (50/5x10) in blister	Pharmstandard-Leksredstva OJSC, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva OJSC, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	19163/2/2 15.02.2024
8	NOSH-ARPI	drotaverine (drotaverine hydrochloride)	tablets	40mg; (24/1x24) 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	OTC	18610/1/1 15.02.2024
9	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	18903/1/1 15.02.2024

LIST

of the variations (reformulation) under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 02-1/24 on February 15, 2024

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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 15.02.2024
2	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 15.02.2024
3	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 15.02.2024
4	Midazem	midazolam	solution for injection	5mg/ml; (5) ampoules 3ml	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	PoM	000619 15.02.2024

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 02-1/24 on February 15,
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1	Ergoferon	affinity purified antibodies to human interferon gamma, affinity purified antibodies to histamine, affinity purified antibodies to CD4	tablets	10000MAU+10000MAU+10000MAU; (20/1x20) in blister	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	17550/2 15.02.2024
2	Pilfud	minoxidil	spray cutaneous, solution	20mg/ml; 60ml plastic vial	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	17711/3 15.02.2024
3	Prograf	tacrolimus	capsules hard	0,5mg; (50/5x10) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry, V93 FC86	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	PoM	20195/3/1 15.02.2024
4	Prograf	tacrolimus	capsules hard	1mg; (50/5x10) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry, V93 FC86	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	PoM	20196/3/1 15.02.2024
5	Prograf	tacrolimus	capsules hard	5mg; (50/5x10) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry, V93 FC86	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	PoM	20197/3/1 15.02.2024

6	Cepiton	cefepime (cefepime dihydrochloride monohydrate)	powder for solution for injection/infusion	1000mg glass vial 15ml	Medochemie Ltd (Factory C), 2 Michael Erakleous street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupolos street, 3011 Limassol	Cyprus	PoM	18215/1 15.02.2024
7	Hemomycin	azithromycin (azithromycin dihydrate)	powder for oral suspension	200mg/5ml; 60ml glass bottle with 10g powder and measuring spoon 5ml	Hemofarm A.D., 26300 Vrsac, Beogradskii put bb- batch releaser, Hemofarm A.D. Vrsac, branch plant Sabac, 15000, Sabac, Hajduk Veljkova str. No: bb, Serbia- bulk manufacturer, packager, quality control	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradskii put bb	Serbia	PoM	20633/2 15.02.2024
8	Hemomycin	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3) in blister	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	PoM	19397/1 15.02.2024
9	Hemomycin	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3) in blister	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb- packager, quality control, batch releaser, Hemofarm d.o.o., Novakovici bb, Banja Luka 78000, Bosnia and Herzegovina- bulk manufacturer	Serbia	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	PoM	21642/1 15.02.2024
10	Niperten	bisoprolol (bisoprolol fumarate)	tablets film-coated	2,5mg; (30/3x10) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	PoM	20042/1 15.02.2024
11	Niperten	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (30/3x10) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	PoM	20043/1 15.02.2024
12	Niperten	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg; (30/3x10) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	PoM	20044/1 15.02.2024
13	Furacilin Tatpharm	nitrofurantoin	tablets for solution for local and external use	20mg; (10/1x10) in strip, (10/1x10) in blister	Tatchempharmpreparaty JSC, 420091 Kazan, str. Belomorskaya 260	Russia	Tatchempharm-preparaty JSC, 420091 Kazan, str. Belomorskaya 260	Russia	OTC	18271/1 15.02.2024

14	Stresam	etifoxine (etifoxine hydrochloride)	capsules	50mg; (60/3x20) in blister	Biocodex, 1 avenue Blaise Pascal, 60000 Beauvais	France	Biocodex, 7 avenue Gallieni 94250 Gentilly	France	PoM	17646/3 15.02.2024
15	Ketonal	ketoprofen	cream for external use	50mg/g; aluminium tube 30g	Salutas Pharma GmbH, Lange Goehren 3, 39171 Osterweddingen	Germany	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19812/2 15.02.2024
16	GalvusMet	vildagliptin, metformin (metformin hydrochloride)	tablets film-coated	50mg+850mg; (30/3x10) in blister, (60/6x10) in blister	Novartis Saglik, Gida ve Tarim Urunleri San.Ve Tic. A.S., Yenisehir Mahallesi, Ihlara Vadisi Sokak,N2. Pendik,Istambul 34912	Turkey	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	21799/1 15.02.2024
17	GalvusMet	vildagliptin, metformin (metformin hydrochloride)	tablets film-coated	50mg+1000mg; (30/3x10) in blister, (60/6x10) in blister	Novartis Saglik, Gida ve Tarim Urunleri San.Ve Tic. A.S., Yenisehir Mahallesi, Ihlara Vadisi Sokak,N2. Pendik,Istambul 34912	Turkey	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	21800/1 15.02.2024
18	Floxaton	levofloxacin (levofloxacin hemihydrate)	tablets film-coated	500mg (10/1x10) in blister	Medochemie Ltd., (Central Factory), 1-10 Constantinoupoleos street, 3011 Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupoleos street, 3011 Limassol	Cyprus	PoM	18249/3 15.02.2024
19	Kreon 10000	pancreatin (lipase 10000PhEU, amylase 8000 PhEU, protease 600 PhEU)	capsules gastro-resistant	150mg (20/2x10) in blister, (20) in plastic container	Abbott Laboratories GmbH, Justus-von-Liebig-Strasse 33, 31535 Neustadt	Germany	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	OTC	19458/1 15.02.2024
20	Kreon 25000	pancreatin (lipase 25000PhEU, amylase 18000 PhEU, protease 1000 PhEU)	capsules gastro-resistant	300mg (20/2x10) in blister, (20) in plastic container	Abbott Laboratories GmbH, Justus-von-Liebig-Strasse 33, 31535 Neustadt	Germany	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	OTC	19459/1 15.02.2024
21	Kreon 40000	pancreatin (lipase 40000PhEU, amylase 25000 PhEU, protease 1600 PhEU)	capsules gastro-resistant	400mg (20/2x10) in blister, (20) in plastic container	Abbott Laboratories GmbH, Justus-von-Liebig-Strasse 33, 31535 Neustadt	Germany	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	OTC	19460/1 15.02.2024
22	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	18662/4/1 15.02.2024

23	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	21913/1 15.02.2024
24	Numeta G13%E Preterm	alanine, arginine, aspartic acid, cysteine, glutamic acid, glycine, histidine, Isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenyl- alanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, potassium acetate, calcium chloride dehydrate, magnesium glyc- erophosphate hydrated, glucose monohydrate, refined olive oil + refined soya bean oil	emulsion for infusion	0,75g+0,78g+0,56g+0,18g+0,93g +0,37g+0,35g+0,62g+0,93g+1,15 g+0,22g+0,30g+0,39g+0,28g+0,3 7g+0,06g+0,35g+0,19g+0,07g+0 ,71g+0,61g+0,55g+0,10g+0,98g+ 44g+7,5g; (10) bags 300ml	Baxter SA., Boulevard Rene Branquart 80, Lessines, 7860	Belgium	Baxter Healthcare Ltd, Caxton Way, Thretford, Nor- folk, IP24 3SE	UK	PoM	19411/2 15.02.2024
25	Numeta G16%E	alanine, arginine, aspartic acid, cysteine, glutamic acid, glycine, histidine, Isoleucine, leucine, lysine monohydrate, methi- onine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, sodium chloride, potassium acetate, calcium chloride dehydrate, magnesium acetate tetrahydrate, sodium glyc- erophosphate hydrated, glucose monohydrate, refined olive oil + refined soya bean oil	emulsion for infusion	1,03g+1,08g+0,77g+0,24g+1,2 9g+0,51g+0,49g+0,86g+1,29g+ 1,59g+0,31g+0,41g+0,54g+0,39 g+0,51g+0,08g+0,48g+0,26g+0, 10g+0,98g+0,30g+1,12g+0,46g +0,33g+0,98g+85,25+15,5g (6) bags 500ml	Baxter SA., Boulevard Rene Branquart 80, Lessines, 7860	Belgium	Baxter Healthcare Ltd, Caxton Way, Thretford, Nor- folk, IP24 3SE	UK	PoM	19412/2 15.02.2024

26	Numeta G19%E	alanine, arginine, aspartic acid, cysteine, glutamic acid, glycine, histidine, Isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, sodium chloride, potassium acetate, calcium chloride dehydrate, magnesium acetate tetrahydrate, sodium glycerophosphate hydrated, glucose monohydrate, refined olive oil + refined soya bean oil	emulsion for infusion	1,83g+1,9g+1,37g+0,43g+2,29g+0,91g+0,87g+1,53g+2,29g+2,82g+0,55g+0,73g+0,96g+0,69g+0,91g+0,14g+0,85g+0,46g+0,18g+1,74g+1,79g+3,14g+0,56g+0,55g+2,21g+210,65+28,1g; (6) bags 1000ml	Baxter SA., Boulevard Rene Branquart 80, Lessines, 7860	Belgium	Baxter Healthcare Ltd, Caxton Way, Thretford, Norfolk, IP24 3SE	UK	PoM	19413/2 15.02.2024
27	Nimesil	nimesulide	granules for oral suspension	100mg; (30) sachets 2g	Fine Foods and Pharmaceuticals N.T.M. S.P.A., Via Grignano 43-24041 Brembate(Bergamo)	Italy	Laboratori Guidotti S.p.A., Via Livornese, 897 56122 La Vettola(Pisa)	Italy	PoM	18894/1 15.02.2024
28	Nimesil	nimesulide	granules for oral suspension	100mg; (30) sachets 2g	Laboratorios Menarini S.A., str. Alfonso XII, 587 08918 Badalona (Barcelona)	Spain	Laboratori Guidotti S.p.A., Via Livornese, 897 56122 La Vettola(Pisa)	Italy	PoM	18895/1 15.02.2024
29	Betaklav	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	powder for oral suspension	400mg/5ml+57mg/5ml; 100ml glass bottle and measuring syringe	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto-batch releaser, Micro Lab Limited, 16, Veersandra Industrial Area, Anekal Taluk, Bangalore-560100, India-bulk manufacturer, packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	18247/1 15.02.2024
30	Betaklav	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	500mg+125mg; (14/2x7) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto-batch releaser, Micro Lab Limited, 16, Veersandra Industrial Area, Anekal Taluk, Bangalore-560100, India-bulk manufacturer, packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	18163/1 15.02.2024

31	Algavak M	inactivated antigen of hepatitis A	suspension for i/m injection	not less than 50 ELISA U/1ml (1 dose for adult or 2 dose for children); (10/2x5/) ampoules 1ml (10 doses) or (10/2x5/) ampoules 1ml (20 doses)	Vector-BiAlgam JSC, Industrial site of State Research Center of VB «Vector», building N104, Koltsovo, Novosibirsk oblast, 630559	Russia	Vector-BiAlgam JSC, Industrial site of State Research Center of VB «Vector», building N104, Koltsovo, Novosibirsk oblast, 630559	Russia	PoM	17230/2 15.02.2024
32	Algavak M	inactivated antigen of hepatitis A	suspension for i/m injection	not less than 25 ELISA U/0,5ml (1 dose for children); (10/2x5/) ampoules 0.5ml (10 doses)	Vector-BiAlgam JSC, Industrial site of State Research Center of VB «Vector», building N104, Koltsovo, Novosibirsk oblast, 630559	Russia	Vector-BiAlgam JSC, Industrial site of State Research Center of VB «Vector», building N104, Koltsovo, Novosibirsk oblast, 630559	Russia	PoM	17229/2 15.02.2024
33	Scandonest	mepivacaine (mepivacaine hydrochloride)	solution for injection	30mg/ml; (50) cartridges 1,7ml	Septodont, 58 rue du Pont de Creteil, 94100 Saint- Maur- des- Fosses	France	Septodont, 58 rue du Pont de Creteil, 94100 Saint- Maur- des- Fosses	France	PoM	18169/1 15.02.2024

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 02-1/24 on February 15, 2024

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	SIMBRINZA	brinzolamide, brimonidine (brimonidine tartrate)	drops eye, suspension	10mg/ml+2mg/ml, 5ml plastic vial-dropper	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	000013 15.02.2024
2	Prestarium A	perindopril (perindopril arginine)	tablets film-coated	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	000574 15.02.2024
3	Prestarium A	perindopril (perindopril arginine)	tablets film-coated	5mg; (30) in plastic container, (90/3x30) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000574 15.02.2024
4	Prestarium A	perindopril (perindopril arginine)	tablets film-coated	5mg; (14) in plastic container, (30) in plastic container, (90/3x30) 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	000574 15.02.2024
5	Prestarium A	perindopril (perindopril arginine)	tablets film-coated	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	000574 15.02.2024
6	Prestarium A	perindopril (perindopril arginine)	tablets film-coated	10mg; (30) in plastic container, (90/3x30) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000574 15.02.2024

7	Prestarium A	perindopril (perindopril arginine)	tablets film-coated	10mg; (30) in plastic container, (90/3x30) 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	000574 15.02.2024
8	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	5mg+5mg; (29) in plastic container, (30) in plastic container, (90/3x30) 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	000575 15.02.2024
9	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	5mg+10mg; (29) in plastic container, (30) in plastic container, (90/3x30) 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	000575 15.02.2024
10	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	10mg+5mg; (29) in plastic container, (30) in plastic container, (90/3x30) 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	000575 15.02.2024
11	Prestance	amlodipine (amlodipine besilate), perindopril (perindopril arginine)	tablets	10mg+10mg; (29) in plastic container, (30) in plastic container, (90/3x30) 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	000575 15.02.2024
12	Prestilol 5mg/5mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	5mg+5mg; (30) in plastic container, (90/3x30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284-batch releaser, packager, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000569 15.02.2024
13	Prestilol 5mg/10mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	5mg+10mg; (30) in plastic container, (90/3x30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284-batch releaser, packager, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000569 15.02.2024
14	Prestilol 10mg/5mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	10mg+5mg; (30) in plastic container, (90/3x30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284-batch releaser, packager, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000569 15.02.2024

15	Prestilol 10mg/10mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	10mg+10mg; (30) in plastic container, (90/3x30/) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284- batch releaser, packager, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000569 15.02.2024
16	Prestilol 5mg/5mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	5mg+5mg; (30) in plastic container, (90/3x30/) 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	000569 15.02.2024
17	Prestilol 5mg/10mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	5mg+10mg; (30) in plastic container, (90/3x30/) 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	000569 15.02.2024
18	Prestilol 10mg/5mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	10mg+5mg; (30) in plastic container, (90/3x30/) 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	000569 15.02.2024
19	Prestilol 10mg/10mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	10mg+10mg; (30) in plastic container, (90/3x30/) 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	000569 15.02.2024