

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 10-2/24 on October 31, 2024

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Perinam Denk 4/5	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate)	tablets	4mg+5mg; (30/2x15) in blister	Actavis Ltd., BLB015, BLB016, Bulebel Industrial Estate, Zejtun, ZTN 3000	Malta	Denk Pharma GmbH & Co. KG, Prinzregentenstr.79, 81675 Muenchen	Germany	PoM	22409 31.10.2024
2	Perinam Denk 4/10	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate)	tablets	4mg+10mg; (30/2x15) in blister	Actavis Ltd., BLB015, BLB016, Bulebel Industrial Estate, Zejtun, ZTN 3000	Malta	Denk Pharma GmbH & Co. KG, Prinzregentenstr.79, 81675 Muenchen	Germany	PoM	22410 31.10.2024
3	Perinam Denk 8/10	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate)	tablets	8mg+10mg; (30/2x15) in blister	Actavis Ltd., BLB015, BLB016, Bulebel Industrial Estate, Zejtun, ZTN 3000	Malta	Denk Pharma GmbH & Co. KG, Prinzregentenstr.79, 81675 Muenchen	Germany	PoM	2211 31.10.2024
4	KISQALI	ribociclib (ribociclib succinate)	tablets film-coated	200mg; (21/1x21) in PA/AL/PVC blister, (21/1x21) in PVC/PCTFE blister, (63/3x21) in PA/AL/PVC blister, (63/3x21) in PVC/PCTFE blister	Novartis Pharmaceutical Manufacturing LLC, Verovskova Ulica 57, Ljubljana 1000	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22412 31.10.2024

5	Tranexamic acid	tranexamic acid	solution for i/v injection	50mg/ml; (5/1x5) ampoules 5ml in blister, (10/2x5) ampoules 5ml in blister	B-PHARM LLC, Kaluga region, Borovskiy municipal district, Vorsino rural settlement of the village, hamlet Dobrino, 1-st Vostochniy proezd, building 4, structure 1- bulk manufacturer, packager, quality control (physicochemical), batch releaser, VIFITEH CJSC, Moscow region, Serpukhov district, Obolensk v., Obolensk shosse, building 16/1, Russia- quality control (microbiological)	Russia	B-PHarm LLC, 143026, Moscow region, urban district Odintsovskiy, working settlement Novoivanovskoe, Agrokhimikov street, building 2A, room 2	Russia	PoM	22413 31.10.2024
---	-----------------	-----------------	----------------------------	--	---	--------	--	--------	-----	---------------------

LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision 10-2/24 on October 31,
2024

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Xalkori	crizotinib	capsules	200mg; (10/1x10) in blister, (60/6x10) in blister	Pfizer Manufacturing Deutschland GmbH, Mosswaldalee 1, 79090 Freiburg	Germany	Pfizer Inc., 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	22417 (009281) 31.10.2024
2	Xalkori	crizotinib	capsules	250mg; (10/1x10) in blister, (60/6x10) in blister	Pfizer Manufacturing Deutschland GmbH, Mosswaldalee 1, 79090 Freiburg	Germany	Pfizer Inc., 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	22418 (009281) 31.10.2024
3	Lamal	lamotrigine	tablets	25mg; (30/3x10) 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	22419 (000725) 31.10.2024
4	Lamal	lamotrigine	tablets	50mg; (30/3x10) 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	22420 (000725) 31.10.2024
5	Lamal	lamotrigine	tablets	100mg; (30/2x15) 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	22421 (000725) 31.10.2024
6	Lamal	lamotrigine	tablets	200mg; (30/2x15) 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	22422 (000725) 31.10.2024
7	Dioxydine	dioxidine	drops ear	2,5mg/ml; 10ml plastic vial-dropper	Grotex LLC, Industrialniy av. 71, bld. 2, lit. A, Saint Petersburg, 195279	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	PoM	22423 (000725) 31.10.2024

8	Quamatel	famotidine	tablets film-coated	20mg; (28/2x14) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- bulk manufacturer, packager, quality control (physicochemical), Gedeon Richter Plc., 2510 Dorog, Esztergomi st. 27, Hungary- quality control (microbiological)	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22424 (003093) 31.10.2024
9	Quamatel	famotidine	tablets film-coated	40mg; (14/1x14) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- bulk manufacturer, packager, quality control (physicochemical), Gedeon Richter Plc., 2510 Dorog, Esztergomi st. 27, Hungary- quality control (microbiological)	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22425 (003093) 31.10.2024
10	Quamatel	famotidine	tablets film-coated	20mg; (28/2x14) in blister	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	22426 (003093) 31.10.2024

11	Quamatel	famotidine	tablets film-coated	40mg; (14/1x14) in blister	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	22427 (003093) 31.10.2024
12	Verospiron	spironolactone	capsules	50mg; (30/3x10) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22428 (003093) 31.10.2024
13	Verospiron	spironolactone	capsules	50mg; (30/3x10) in blister	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	22429 (003093) 31.10.2024

14	Verospiron	spironolactone	capsules	50mg; (30/3x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest, Hungary- 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	22430 (003093) 31.10.2024
15	Verospiron	spironolactone	capsules	100mg; (30/3x10) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22431 (003093) 31.10.2024
16	Verospiron	spironolactone	capsules	100mg; (30/3x10) in blister	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	22432 (003093) 31.10.2024

17	Verospiron	spironolactone	capsules	100mg; (30/3x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest, Hungary- 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	22433 (003093) 31.10.2024
18	Massido	neбиволол (neбиволол hydrochloride)	tablets	5mg; (28/2x14) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- batch releaser, CADILA PHARMACEUTICALS LTD. PLOT NO. 1389 TRASAD ROAD, DHOLKA- 382225, Dist: AHMED-ABAD,GUJARAT STATE, India- bulk manufacturer, packager, quality control	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	22416 (007304) 31.10.2024
19	Flavamed cough tablets	ambroxol (ambroxol hydrochloride)	tablets	30mg; (20/2x10) in blister	Berlin-Chemie AG, Glienicker Weg 125, 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, 12489 Berlin	Germany	OTC	22414 (009473) 31.10.2024
20	Flavamed cough tablets	ambroxol (ambroxol hydrochloride)	tablets	30mg; (20/2x10) in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, 12347, Berlin, Germany- bulk manufacturer, 1. Berlin-Chemie AG,Tempelhofer Weg 83, 12347, Berlin, Germany, 2. Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin, Germany- quality control (physicochemical)	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	OTC	22415 (009473) 31.10.2024

LIST

of the medicines recommended for the registration (new packaging) procedure by the Center according to the meeting decision N10-2/24 on October 31, 2024

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Phosphogliv	phospholipids, sodium glycyrrhizinate (glycyrrhizinic acid trisodium)	capsules	65mg+35mg; (50/5x10) in blister, (96/8x12) in blister	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	19211/1/2 31.10.2024

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N10-2/24 on October 31, 2024

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Furosemide	furosemide	tablets	40mg; (50/5x10) in blister	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64A, No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	22434 31.10.2024
2	Furadonin	nitrofurantoin (nitrofurantoin monohydrate)	tablets	50mg; (10) in strip	Irbitskiy himfarmzavod OJSC, 124a, K. Marksa str., Irbit, St. Sverdlovsk, 623856	Russia	Irbitskiy himfarmzavod OJSC, 172, Kirova str., Irbit, St. Sverdlovsk, 623856	Russia	PoM	22435 31.10.2024
3	Analgin-Pharmstandard	metamizole (metamizole sodium)	tablets	500mg; (10/1x10) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	22436 31.10.2024
4	Korold-Asteria	paracetamol, pseudoephedrine (pseudoephedrine hydrochloride), chlorphenamine (chlorphenamine maleate)	tablets film-coated	500mg+30mg+2mg; (20/2x10) in blister, (100/10x10) in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-Si, Chungcheongbuk-do	Republic of Korea	Asteria LLC, 72/3 Nairi Zaryan, 0051 Yerevan	Republic of Armenia	OTC	22437 31.10.2024
5	Ceftriaxone-Asteria Inj. 1g	ceftriaxone (ceftriaxone sodium)	powder for solution for i/m injection	1000mg; (1) glass vial and 3,5ml solvent in ampoule	Hankook Korus Pharm Co., Ltd, 78 Daepungsandan-ro, Daeso-myeon, Eumseong-gun, Chungcheongbuk-do	Republic of Korea	Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan	Republic of Armenia	PoM	22438 31.10.2024
6	Suaron	nimesulide	tablets	100mg; (20/2x10) in blister	GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi	Georgia	PoM	22439 31.10.2024
7	Suaron	nimesulide	powder for oral suspension	100mg; (10) sachets	GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi	Georgia	PoM	22440 31.10.2024

8	Edarbi	azilsartan medoxomil	tablets	40mg; (28/2x14) in blister	Takeda Ireland Ltd., Bray Business Park Kilruddery Co. Wicklow- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Almac Sciences Ireland Ltd, IDA Business & Technology Park, Garrycastle, Athlone, Co. Westmeath, Ireland- quality control (microbiological)	Ireland	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	22441 31.10.2024
9	Edarbi	azilsartan medoxomil	tablets	80mg; (28/2x14) in blister	Takeda Ireland Ltd., Bray Business Park Kilruddery Co. Wicklow- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Almac Sciences Ireland Ltd, IDA Business & Technology Park, Garrycastle, Athlone, Co. Westmeath, Ireland- quality control (microbiological)	Ireland	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	22442 31.10.2024
10	Psilo-Balsam	diphenhydramine (diphenhydramine hydrochloride)	gel	10mg/g; aluminium tube 20g	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	22443 31.10.2024
11	Gonadotropin chorionic	gonadotrophin chorionic	powder lyophilized for solution for i/m injection	5000IU; (5) glass vials and (5) solvent in ampoules 1ml	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	22444 31.10.2024
12	Actovegin	deproteinised haemoderivate of calf blood	solution for injection	40mg/ml; (5) ampoules 5ml	Takeda Austria GmbH, St. Peter strasse 25, 4020 Linz	Austria	Takeda Pharmaceuticals LLC, Usatcheva str 2 bld. 1, Moscow 119048	Russia	PoM	22445 31.10.2024
13	Actovegin	deproteinised haemoderivate of calf blood	solution for injection	40mg/ml; (5) ampoules 10ml	Takeda Austria GmbH, St. Peter strasse 25, 4020 Linz	Austria	Takeda Pharmaceuticals LLC, Usatcheva str 2 bld. 1, Moscow 119048	Russia	PoM	22446 31.10.2024
14	CORVALOL	alfa-bromisovalerianic acid ethyl ether, phenobarbital, peppermint oil	drops oral	20mg/ml+18,26mg/ml+1,42mg/ml; glass bottle 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	22447 31.10.2024

15	Doxycycline	doxycycline (doxycycline hyclate)	capsules	100mg; (10) in blister, (20/2x10/) in blister	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, No3/3, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	22448 31.10.2024
16	Femoston 2/10	pink tablet- estradiol, yellow tablet- estradiol + dydrogesterone	tablets film-coated	2mg+2mg+10mg; (28/14pink tablets + 14yellow tablets/) in blister	ABBOTT Biologicals B.V., Veerweg 12, 8121 AA Olst	the Netherlands	ABBOTT Healthcare Products B.V., C.J. van Houtenlaan 36, NL-1381 CP Weesp	the Netherlands	PoM	22449 31.10.2024
17	Trifazine	trifluoperazine (trifluoperazine hydrochloride)	tablets coated	5mg; (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	22450 31.10.2024
18	Azimac	azithromycin (azithromycin dihydrate)	powder for oral suspension	200mg/5ml; glass bottle 37,5ml and measuring syringe	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	22451 31.10.2024
19	Mexidol	ethylmethylhydroxypyridine succinate	solution for i/v and i/m injection	50mg/ml; (10/2x5) ampoules 2ml in blister	FSE «Armavirskaya biofabrika», 352212, Krasnodar reg., Novokubanskiy district, Progress settlement, str. Mechnikova, b. 11	Russia	LLC «RPC «PHARMASOFT», 115407, Moscow, Sudostroitel'naya str., bld. 41, floor 1, premises 12	Russia	PoM	22452 31.10.2024
20	Mexidol	ethylmethylhydroxypyridine succinate	solution for i/v and i/m injection	50mg/ml; (5/1x5) ampoules 5ml in blister	FSE «Armavirskaya biofabrika», 352212, Krasnodar reg., Novokubanskiy district, Progress settlement, str. Mechnikova, b. 11	Russia	LLC «RPC «PHARMASOFT», 115407, Moscow, Sudostroitel'naya str., bld. 41, floor 1, premises 12	Russia	PoM	22453 31.10.2024
21	¹³¹ I-sodium-iodide ThyroTop 38-7400 MBq hard capsules	¹³¹ I sodium iodide	capsules hard	38-7400MBq; (1) in container	Institute of Isotopes Co. Ltd., Konkoly Thege Miklos str.29-33, Budapest 1121	Hungary	Institute of Isotopes Co. Ltd., Konkoly Thege Miklos str.29-33, Budapest 1121	Hungary	PoM	22454 31.10.2024

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N10-2/24 on October 31, 2024

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	ACC200mg Hot Drink	acetylcysteine	powder for oral solution	200mg; (20) sachets 3g	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben- batch releaser, Lindopharm GmbH, Neustrasse 82, 40721 Hilden, Nordrhein-Westfalen, Germany- bulk manufacturer, packager, quality control (physicochemical), IMQ- Institut für mikrobiologische Qualitätssicherung GmbH, Benninghofer Weg 2, Mettmann, 40822, Germany- quality control (microbiological)	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	22455 31.10.2024
2	ARMENICUM	iodine, potassium iodide, lithium chloride, polyvinyl alcohol, dextrin, sodium chloride	capsules	28,76mg+43,14mg+0,72 mg+10,79mg+359,53mg+32,36mg; (40/4x10) in blister	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	'Armenicum+' CJSC, 37 Nalbandyan, Yerevan 0001	Republic of Armenia	PoM	22456 31.10.2024
3	ACC 200	acetylcysteine	tablets effervescent	200mg; (20) in plastic container	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben- batch releaser, Hermes Pharma Ges.m.b.H, Schwimmschulweg 1a, Wolfsberg, 9400, Austria- bulk manufacturer, packager, quality control	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	22457 31.10.2024

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N10-2/24 on October 31, 2024

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Phosphogliv URSO-Pharmstandard	ursodeoxycholic acid, sodium glycyrrhizinate (glycyrrhizinic acid trisodium)	capsules	250mg+35mg; (50/5x10) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	PoM	20358/2/1 31.10.2024
2	Polyoxidonium-Petrovax	azoximer bromide	suppositories rectal and vaginal	6mg; (10/2x5/)	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143- secondary packager, batch releaser, quality control, NPO Petrovax Pharm LLC, 1/1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143, Russia - bulk manufacturer, primary packager	Russia	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	OTC	20351/2/2 31.10.2024

3	Polyoxidonium- Petrovax	azoximer bromide	suppositories rectal and vaginal	12mg; (10/2x5)	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143- secondary packager, batch releaser, quality control, NPO Petrovax Pharm LLC, 1/1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143, Russia - bulk manufacturer, primary packager	Russia	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	OTC	20352/2/2 31.10.2024
4	Persen Day	valeriana officinalis extract, melissa officinalis extract, mentha piperita extract	tablets coated	35mg+17,5mg+17,5mg; (40/4x10) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Zentiva, k.s., U kabelovny 130, 102 37 Praha 10, Dolni Mecholupy	Czech Republic	OTC	22202/1/1 31.10.2024
5	Persen Night	valeriana officinalis extract, melissa officinalis extract, mentha piperita extract	capsules	87,5mg+17,5mg+17,5mg; (20/2x10) in blister	ADIPHARM EAD, 130 Simeonovsko shose Blvd., Sofia 1700	Bulgaria	Zentiva, k.s., U kabelovny 130, 102 37 Praha 10, Dolni Mecholupy	Czech Republic	OTC	22201/1/1 31.10.2024
6	Klimaktoplan	cimicifuga Trit. D2, sepia Trit. D2, ignatia Trit. D3, sanguinaria Trit. D6	tablets	25mg+25mg+25mg+25mg; (60/3x20) in blister	Dr. Gustav Klein GmbH & Co. KG, Steinenfeld 3, 77736 Zell am Harmersbach- bulk manufacturer, packager, quality control (physicochemical), batch releaser, GBA Pharma GmbH, Ernst-Abbe-Str. 40, Ulm, Baden-Wuerttemberg, 89079, Germany- quality control (microbiological)	Germany	Alpen Pharma GmbH, Steinenfeld 3 Zell am Harmersbach, 77736	Germany	OTC	19628/2/1 31.10.2024

7	Trifazine	trifluoperazine (trifluoperazine hydrochloride)	tablets coated	5mg; (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	18933/1/1 31.10.2024
---	-----------	---	----------------	---------------------------	--	---------------------	--	---------------------	-----	-------------------------

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting
decision N10-2/24 on October 31, 2024

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Tantum Verde	benzydamine (benzydamine hydrochloride)	spray for local use	0,255mg/dose; 30ml (176 doses) plastic container with pump dispenser	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. Via Vecchia Del Pinocchio, 22, 60100 Ancona	Italy	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. Viale Amelia, 70, Rome	Italy	OTC	000747 31.10.2024
2	Detraproct	lidocaine (lidocaine hydrochloride monohydrate), fluocinolone acetonide	cream rectal	21,2mg/g+0,1mg/g; 15g aluminium tube and applicator	Galenica Pharmaceutical Industry S.A. Asklipeion 4-6, Kryoneri (Attiki), 14568	Greece	Servier JSC, 125196, Lesnaya str., 7, floor 7/8/9, Moscow	Russia	PoM	000915 31.10.2024

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N10-2/24 on October 31, 2024

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Mexiprim	ethylmethylhydroxypyridine succinate	solution for i/m and i/v injection	50mg/ml; (10/2x5) ampoules 2ml in blister	Scientific Technological Pharmaceutical Firm POLISAN LLC, lit. A, building 2, Salova st. 72, Saint- Petersburg, 192102	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	19584/2/1 31.10.2024
2	Mexiprim	ethylmethylhydroxypyridine succinate	solution for i/m and i/v injection	50mg/ml; (5/1x5) ampoules 5ml in blister	Scientific Technological Pharmaceutical Firm POLISAN LLC, lit. A, building 2, Salova st. 72, Saint- Petersburg, 192102	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	19585/2/1 31.10.2024
3	Lysobact Complete Spray	lysozyme (lysozyme hydrochloride), cetylpyridinium chloride, lidocaine (lidocaine hydrochloride)	spray	20mg/ml+1,5mg/ml+0,5mg/ml; 30ml glass bottle with spraying pump and spray applicator	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	21489/1 31.10.2024
4	Lysobact DUO	lysozyme (lysozyme hydrochloride), cetylpyridinium (cetylpyridinium chloride)	lozenges compressed	20mg+1,5mg; (20/2x10) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	21369/1 31.10.2024
5	Lysobact Spray with Peppermint flavour	lysozyme (lysozyme hydrochloride), cetylpyridinium chloride	spray	20mg/ml+1,5mg/ml; 30ml glass bottle with spraying pump and spray applicator	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	21490/1 31.10.2024

6	Bonjigar	eclipta alba, picrorrhiza kurrooa, solanum nigrum, cichorium intybus, glycyrrhiza glabra, tamarix gallica, raphanus sativus, berberis aristata, silbyum marianum, spherantus indica, boerhavia diffusa	syrup	83mg/10ml+33mg/10ml+17mg/10ml+58mg/10ml+67mg/10ml+33mg/10ml+17mg/10ml+50mg/10ml+67mg/10ml+17mg/10ml+33mg/10ml; (90) glass bottle, (120) glass bottle, (150) glass bottle	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	PoM	18983/1 31.10.2024
7	Thiotriazolin	thiotriazoline (tiazotic acid morpholinate)	tablets	200mg; (90/9x10) in blister, (90/6x15) in blister	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	22028/3/1 31.10.2024
8	Respero Myrtol forte	distillate of a mixture of rectified essential oils of eucalyptus, sweet orange, myrtle and lemon	capsules gastro-resistant, soft	300mg; (20/2x10) in blister, (50/5x10) in blister, (100/10x10) in blister	G. Pohl-Boskamp GmbH & Co.KG, Kieler Strasse 11, 25551, Hohenlockstedt- quality control (microbiological), batch releaser, G. Pohl-Boskamp GmbH & Co.KG, Kaddenbusch, 25578, Daegeling, Germany- bulk manufacturer, packager, quality control (physicochemical)	Germany	G. Pohl-Boskamp GmbH & Co.KG, Kieler Strasse 11, 25551, Hohenlockstedt	Germany	OTC	20614/2/1 31.10.2024
9	Furosemide	furosemide	tablets	40mg; (50/5x10) in blister	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64A, No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	18847/3/1 31.10.2024
10	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	21236/1 31.10.2024
11	Votrient	pazopanib	tablets film-coated	400mg; (30) in plastic container	Novartis Pharmaceutical Manufacturing LLC, Verovskova Str. 57, Ljubljana, 1000- packager, batch releaser, Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona, Spain- bulk manufacturer, quality control	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	21644/2/1 31.10.2024

12	Furadonin	nitrofurantoin (nitrofurantoin monohydrate)	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	18491/2 31.10.2024
13	Verapress MR 240 Tablets	verapamil (verapamil hydrochloride)	tablets modified-release	240mg; (28/2x14) in blister	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields Industrial Estate, Daventry, NN11 8PB- batch releaser, Dexcel Ltd., 1 Dexcel Street, Or-Akiva 3060000, Israel- bulk manufacturer, packager, quality control (physico-chemical), 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 Industrial Estate, Daventry, NN11 8PB	UK	PoM	21533/2 31.10.2024
14	Numeta G13%E Preterm	alanine, arginine, aspartic acid, cysteine, glutamic acid, glycine, histidine, Isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, potassium acetate, calcium chloride dehydrate, magnesium acetate tetrahydrate, sodium glycerophosphate 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+1,15g+0,22g+0,30g+0,39g+0,28g+0,37g+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, Norfolk, IP24 3SE	UK	PoM	19411/4 31.10.2024

15	Numeta G16%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	1,03g+1,08g+0,77g+0,24g+1,29g+0,51g+0,49g+0,86g+1,29g+1,59g+0,31g+0,41g+0,54g+0,39g+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, Norfolk, IP24 3SE	UK	PoM	19412/4 31.10.2024
16	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	19413/4 31.10.2024
17	Ermucin	erdosteine	granules for oral suspension	225mg; (10) sachets 4,425mg	Fine Foods & Pharmaceuticals N.T.M. S.p.A., Via Grignano, 43, 24041, Brembate (BG)	Italy	UAB «MRA», Totoriu str. 20-9, LT-01121 Vilnius	Republic of Lithuania	PoM	21749/1 31.10.2024
18	Ermucin	erdosteine	capsules hard	300mg; (10/1x10) in blister, (20/2x10) in blister	Edmond Pharma S.r.l., Strada Statale dei Giovi 131- 20037 Paderno Dugnano (MI)- bulk manufacturer, quality control, batch releaser, Lamp San Prospero S.p.A., Via della Pace, 25/A-41030 San Prospero (MO), Italy-packager	Italy	UAB «MRA», Totoriu str. 20-9, LT-01121 Vilnius	Republic of Lithuania	PoM	21851/2 31.10.2024

19	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	21532/1 31.10.2024
20	Cetirizine	cetirizine (cetirizine dihydrochloride)	tablets film-coated	10mg; (20/2x10) in blister	Chanelle Medical Unlimited Company, Dublin Road, Loughrea, H62 FH90 - bulk manufacturer, packager, quality control (physicochemical), batch releaser, Complete Laboratory Solutions, Units 3A & 8, Small Business Park, Tuam Road, Galway, Ireland- quality control (microbiological)	Ireland	ARGO-PHARM LLC, 13/9 Sundukyan str., 0012 Yerevan	Republic of Armenia	OTC	20862/3/1 31.10.2024
21	Ofan Dexamethason	dexamethasone (dexamethasone sodium phosphate)	drops eye	1mg/ml; 5ml plastic bottle-dropper	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, NextPharma Oy, Niityhaankatu 20, 33720 Tampere, Finland- bulk manufacturer, primary packager, quality control, Manufacturing Packaging Farmaca (MPF) B.V., Neptunus 12, HEERENVEEN, 8448 CN, the Netherlands- secondary packager	Finland	Santen Oy, Niityhaankatu 20, 33720 Tampere	Finland	PoM	19337/3 31.10.2024
22	Dibase 10,000IU/ ml oral drops, solution	colecalfiferol (vitamin D3)	drops oral, solution	10000IU/ml; glass bottle 10ml and dropper	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	PoM	22178/1 31.10.2024

23	Nucleo CMP Forte	cytidine-5-disodium monophosphate + (uridine-5-trisodium triphosphate, uridine-5-disodium diphosphate, uridine-5-disodium monophosphate)	capsules	5mg+3mg; (30/2x15) 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	OTC	21319/1 31.10.2024
24	Actrapid	insulin human (recombinant DNA)	solution for injection	100IU/ml; glass vial 10ml	Novo Nordisk Production SAS, 45 avenue d' Orleans, F-28000, Chartres	France	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	21316/2 31.10.2024
25	Insulatard	insulin human (recombinant DNA)	suspension for injection	100IU/ml; (1) glass vial 10ml	Novo Nordisk Production SAS, 45 avenue d' Orleans, F-28000, Chartres	France	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	21089/2 31.10.2024
26	Levemir FlexPen	insulin detemir (recombinant)	solution for injection	100U/ml; (5) pre-filled pen 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	21637/2 31.10.2024
27	Mixtard 30	insulin human (recombinant DNA)	suspension for injection	100IU/ml; (1) glass vial 10ml	Novo Nordisk Production SAS, 45 avenue d' Orleans, F-28000, Chartres	France	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	21088/2 31.10.2024
28	NovoMix 30 FlexPen	insulin aspart (recombinant)	suspension for injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	21703/2 31.10.2024
29	NovoRapid FlexPen	insulin aspart	solution for s/c or i/v injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd- bulk manufacturer, primary packager, batch releaser, Novo Nordisk A/S, Brennum Park, DK-3400 Hillerod, Denmark- secondary packager, quality control	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	20594/4 31.10.2024

30	Tresiba FlexTouch	insulin degludec	solution for injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd- bulk manufacturer, primary packager, batch releaser, Novo Nordisk A/S, Brennum Park, Hillerod,3400, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	20828/3 31.10.2024
31	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	20181/4 31.10.2024
32	ARMENICUM	iodine, potassium iodide, lithium chloride, polyvinyl alcohol, dextrin, sodium chloride	capsules	28,76mg+43,14mg+0,72mg+10,79mg+359,53mg+32,36mg; (40/4x10) in blister, (40) in plastic container	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	«Armenicum+» CJSC, 37 Nalbandayan, Yerevan 0001	Republic of Armenia	PoM	19467/1 31.10.2024
33	Ceftriaxone-Asteria Inj, 1g	ceftriaxone (ceftriaxone sodium)	powder for solution for i/m injection	1000mg; (1) glass vial and 3,5ml solvent in ampoule	Hankook Korus Pharm Co., Ltd, 78 Daepungsandan-ro, Daeso-myeon, Eumseong-gun, Chungcheongbuk-do	Republic of Korea	Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan	Republic of Armenia	PoM	18679/2/1 31.10.2024
34	Suaron	nimesulide	tablets	100mg; (20/2x10) in blister	GM Pharmaceuticals Ltd, Rustavi Highway 52,Tbilisi	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52,Tbilisi	Georgia	PoM	18936/2/1 31.10.2024
35	Suaron	nimesulide	powder for oral suspension	100mg; (10) sachets	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52,Tbilisi	Georgia	PoM	18937/2/1 31.10.2024
36	Mekinist	trametinib (trametinib dimethyl sulfoxide)	tablets film-coated	2mg; (30) in plastic container	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos- packager, batch releaser, GlaxoSmithKline Manufacturing S.p.A., Strada Provinciale Asolana, 90, 43056 San Polo di Torrile, Parma, Italy- bulk manufacturer, quality control	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18988/6/1 31.10.2024

37	Mekinist	trametinib (trametinib dimethyl sulfoxide)	tablets film-coated	2mg; (30) in plastic container	Novartis Pharmaceuticals Manufacturing LLC, Verovskova Ulica 57, 1000, Ljubljana- packager, batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, 4332, Switzerland- bulk manufacturer, quality control	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22162/1 31.10.2024
38	Medrol	methylprednisolone	tablets	4mg; (30/3x10) in blister	Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno	Italy	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	21351/1 31.10.2024
39	Duphalac	lactulose	syrup	667mg/ml; plastic bottle 200ml, plastic bottle 500ml, plastic bottle 1000ml	ABBOTT Biologicals B.V., Veerweg 12, 8121 AA Olst	the Netherlands	ABBOTT Healthcare Products B.V., C.J. van Houtenlaan 36, NL-1381 CP Weesp	the Netherlands	OTC	19721/1 31.10.2024
40	Duphalac	lactulose	syrup	667mg/ml; (10) sachets 15ml	ABBOTT Biologicals B.V., Veerweg 12, 8121 AA Olst	the Netherlands	ABBOTT Healthcare Products B.V., C.J. van Houtenlaan 36, NL-1381 CP Weesp	the Netherlands	OTC	19722/1 31.10.2024
41	CORVALOL	alfa-bromisovalerianic acid ethyl ether, phenobarbital, peppermint oil	drops oral	20mg/ml+18,26mg/ml+1,42mg/ml; glass bottle 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	19009/1 31.10.2024
42	Diprospan	betamethasone (betamethasone dipropionate), betamethasone (betamethasone sodium phosphate)	suspension for injection	5mg/ml+2mg/ml; (5) ampoules 1ml	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	19021/7/2 31.10.2024
43	¹³¹ I-sodium-iodide ThyroTop 38-7400 MBq hard capsules	¹³¹ I sodium iodide	capsules hard	38-7400MBq; (1) in container	Institute of Isotopes Co. Ltd., Konkoly Thege Miklos str.29-33, Budapest 1121	Hungary	Institute of Isotopes Co. Ltd., Konkoly Thege Miklos str.29-33, Budapest 1121	Hungary	PoM	18841/1 31.10.2024

44	Korold-Asteria	paracetamol, pseudoephedrine (pseudoephedrine hydrochloride), chlorphenamine (chlorphenamine maleate)	tablets film-coated	500mg+30mg+2mg (20/2x10) and (100/10x10) in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-Si, Chungcheongbuk-do	Republic of Korea	Asteria LLC, 72/3 Nairi Zaryan, 0051 Yerevan	Republic of Armenia	OTC	18757/3/1 31.10.2024
----	----------------	---	---------------------	---	---	-------------------	--	---------------------	-----	-------------------------

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting
decision N10-2/24 on October 31, 2024

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	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 31.10.2024
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	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	OTC	000822 31.10.2024
3	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 31.10.2024
4	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 31.10.2024

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	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	OTC	000880 31.10.2024
6	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	000880 31.10.2024
7	Coraxan 5mg	ivabradine	tablets film-coated	5mg; (14/1x14) in blister, (28/2x14) in blister, (52/2x26) in blister, (56/4x14) in blister, (1000-300000) 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	000306 31.10.2024
8	Coraxan 5mg	ivabradine	tablets film-coated	5mg; (14/1x14) in blister, (28/2x14) in blister, (52/2x26) in blister, (56/4x14) in blister, (1000-300000) 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	000306 31.10.2024
9	Coraxan 5mg	ivabradine	tablets film-coated	5mg; (14/1x14) in blister, (28/2x14) in blister, (52/2x26) in blister, (56/4x14) in blister, (1000-300000) in plastic container	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	PoM	000306 31.10.2024
10	Coraxan 7,5mg	ivabradine	tablets film-coated	7,5mg; (14/1x14) in blister, (28/2x14) in blister, (52/2x26) in blister, (56/4x14) in blister, (1000-300000) 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	000306 31.10.2024
11	Coraxan 7,5mg	ivabradine	tablets film-coated	7,5mg; (14/1x14) in blister, (28/2x14) in blister, (52/2x26) in blister, (56/4x14) in blister, (1000-300000) 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	000306 31.10.2024

12	Coraxan 7,5mg	ivabradine	tablets film-coated	7,5mg; (14/1x14) in blister, (28/2x14) in blister, (52/2x26) in blister, (56/4x14) in blister, (1000-300000) in plastic container	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	PoM	000306 31.10.2024
----	---------------	------------	---------------------	---	---	--------	--	--------	-----	----------------------