

## LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 09-3/24 on September 30, 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	Tecentriq	atezolizumab	concentrate for solution for infusion	60mg/ml; glass vial 20ml	F. Hoffmann-La Roche Ltd. 4303 Kaiser-augst- secondary packager, batch releaser, Roche Diagnostics GmbH, Sandhofer Strasse 116, Mannheim, 68305, Germany- bulk manufacturer, primary packager, quality control	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	22369 30.09.2024
2	Meriofert	menotropin	powder lyophilized for solution for i/m or s/c injection	75IU; (1) glass vial and (1) solvent in ampoule 1ml	IBSA Institut Biochimique S.A., Via Pian Scairolo 49, Pazzallo, 6912- secondary packager, quality control (physicochemical, microbiological, biological), batch releaser, ZAMBON S.P.A., VIA DELLA CHIMICA, 9, VICENZA, 36100, Italy- bulk manufacturer, primary packager, IBSA Institut Biochimique S.A., VIA Serta 12, Lamone, 6814, Switzerland- quality control (microbiological/sterility)	Switzerland	IBSA Institut Biochimique S.A., Via Pian Scairolo 49, Pazzallo, 6912	Switzerland	PoM	22370 30.09.2024

3	Meriofert	menotropin	powder lyophilized for solution for i/m or s/c injection	75IU; (1) glass vial and (1) solvent in ampoule 1ml	IBSA Institut Biochimique S.A., Via Pian Scairolo 49, Pazzallo, 6912- secondary packager, quality control (physicochemical, microbiological, biological), batch releaser, IBSA Institut Biochimique S.A., VIA Serta 12, Lamone, 6814, Switzerland- powder bulk manufacturer, powder primary packager, quality control (microbiological/sterility), ZAMBON S.P.A., VIA DELLA CHIMICA, 9, VICENZA, 36100, Italy- solvent bulk manufacturer, solvent primary packager	Switzerland	IBSA Institut Biochimique S.A., Via Pian Scairolo 49, Pazzallo, 6912	Switzerland	PoM	22371 30.09.2024
4	Meriofert	menotropin	powder lyophilized for solution for i/m or s/c injection	150IU; (1) glass vial and (1) solvent in ampoule 1ml	IBSA Institut Biochimique S.A., Via Pian Scairolo 49, Pazzallo, 6912- secondary packager, quality control (physicochemical, microbiological, biological), batch releaser, ZAMBON S.P.A., VIA DELLA CHIMICA, 9, VICENZA, 36100, Italy- bulk manufacturer, primary packager, IBSA Institut Biochimique S.A., VIA Serta 12, Lamone, 6814, Switzerland- quality control (microbiological/sterility)	Switzerland	IBSA Institut Biochimique S.A., Via Pian Scairolo 49, Pazzallo, 6912	Switzerland	PoM	22372 30.09.2024
5	Meriofert	menotropin	powder lyophilized for solution for i/m or s/c injection	150IU; (1) glass vial and (1) solvent in ampoule 1ml	IBSA Institut Biochimique S.A., Via Pian Scairolo 49, Pazzallo, 6912- secondary packager, quality control (physicochemical, microbiological, biological), batch releaser, IBSA Institut Biochimique S.A., VIA Serta 12, Lamone, 6814, Switzerland- powder bulk manufacturer, powder primary packager, quality control (microbiological/sterility), ZAMBON S.P.A., VIA DELLA CHIMICA, 9, VICENZA, 36100, Italy- solvent bulk manufacturer, solvent primary packager	Switzerland	IBSA Institut Biochimique S.A., Via Pian Scairolo 49, Pazzallo, 6912	Switzerland	PoM	22373 30.09.2024
6	Roxera Plus	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets film-coated	40mg+10mg; (30/3x10) in blister, (90/9x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22374 30.09.2024

7	Denk-Air Junior 4mg	montelukast (montelukast sodium)	tablets chewable	4mg; (28/2x14) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, quality control (physicochemical), batch releaser, Swiss Caps GmbH, Grassingerstr. 9, 83043 Bad Aibling, Germany- packager, LSSE & Co. KG, Mangelsfeld 4, 5, 6, 97708 Bad Bocklet-Grossenbrach, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	22375 30.09.2024
8	Denk-Air Junior 5mg	montelukast (montelukast sodium)	tablets chewable	5mg; (28/2x14) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, quality control (physicochemical), batch releaser, Swiss Caps GmbH, Grassingerstr. 9, 83043 Bad Aibling, Germany- packager, LSSE & Co. KG, Mangelsfeld 4, 5, 6, 97708 Bad Bocklet-Grossenbrach, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	22376 30.09.2024

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of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 09-3/24 on September 30, 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	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	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	22333 (005625) 30.09.2024
2	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	50mg; (30/3x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, packager, batch releaser, 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	22334 (005625) 30.09.2024

3	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	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	22335 (005625) 30.09.2024
4	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	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	22336 (005625) 30.09.2024
5	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	150mg; (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	22337 (005625) 30.09.2024

6	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	150mg: (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	22338 (005625) 30.09.2024
7	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	150mg: (30/3x10/) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, packager, batch releaser, 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	22339 (005625) 30.09.2024

8	Mydocalm	tolperisone (tolperisone hydrochloride)	tablets film-coated	150mg; (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	22340 (005625) 30.09.2024
9	Normodipine	amlodipine (amlodipine besilate)	tablets	5mg; (30/3x10') in blister	Gedeon Richter PLC, Gyomroi ut 19-21, H-1103 Budapest- bulk manufacturer, packager, batch releaser, Gedeon Richter PLC, Laboratory Quality Control Budapest 10, p/ya 27, H 1475, Hungary- quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22341 (000384) 30.09.2024
10	Normodipine	amlodipine (amlodipine besilate)	tablets	5mg; (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	22342 (000384) 30.09.2024

11	Normodipine	amlodipine (amlodipine besilate)	tablets	5mg; (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	22343 (000384) 30.09.2024
12	Normodipine	amlodipine (amlodipine besilate)	tablets	10mg; (30/3x10) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, H-1103 Budapest- bulk manufacturer, packager, batch releaser, Gedeon Richter PLC, Laboratory Quality Control Budapest 10, p/ya 27, H 1475, Hungary- quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22344 (000384) 30.09.2024
13	Normodipine	amlodipine (amlodipine besilate)	tablets	10mg; (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	22345 (000384) 30.09.2024



14	Normodipine	amlodipine (amlodipine besilate)	tablets	10mg; (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	22346 (000384) 30.09.2024
15	Omacor	omega-3 triglycerides	capsules soft	1000mg; (28) and (100) in plastic container	Abbott Laboratories GmbH, Justus-von-Liebig-Strasse 33, 31535 Neustadt- quality control, batch releaser, Patheon Softgels B.V., De Posthoornstraat 7, 5048 AS Tilburg, the Netherlands- bulk manufacturer, GMPack ApS, Plastvaenget 9, 9560 Hadsund, Denmark- packager	Germany	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	PoM	22347 (002376) 30.09.2024
16	Berlithion 600 capsules	thioctic acid	capsules soft	600mg; (30/3x10) in blister	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- packager, batch releaser, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany- bulk manufacturer, quality control (physicochemical), Gelita AG, Gammelsbacher Str. 2, Bau 11, 4. OG 69412 Eberbach Deutschland, Germany- quality control (microbiological)	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	PoM	22348 (006771) 30.09.2024
17	Flavamed cough solution	ambroxol (ambroxol hydrochloride)	solution oral	15mg/5ml; glass bottle 100ml and measuring spoon	Berlin-Chemie A.G., Glienicker Weg 125, D-12489 Berlin	Germany	Berlin-Chemie A.G., Glienicker Weg 125, D-12489 Berlin	Germany	OTC	22349 (006771) 30.09.2024

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of the medicines recommended for the re-registration by the Center according to the meeting decision N 09-3/24 on September 30, 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	Tadafort 20	tadalafil	tablets film-coated	20mg; (4/2x2) in blister	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansura-Aleppo	Syria	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansura-Aleppo	Syria	PoM	22350 30.09.2024
2	Co-trimoxazole	sulfamethoxazole, trimethoprim	suspension oral	40mg/ml+8mg/ml; glass bottle 120ml	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	22351 30.09.2024
3	Articaine with adrenaline forte	articaine (articaine hydrochloride), epinephrine (epinephrine hydrotartrate)	solution for injection	40mg/ml+0,01mg/ml; (50/5x10) glass cartridges 1.7ml, in blister	FKP «Armavirskaya biofabrika», 352212, Krasnodar reg., Novokubanskiy district, Progress settlement, str. Mechnikova, b. 11	Russia	«Binergia» JSC, 143930, Moscow region, Balashikha urban district, Balashikha, Saltykova microregion, Razinskoe avenue, 69, 1/41 fl./build., office 106A	Russia	PoM	22352 30.09.2024
4	Carbamazepine	carbamazepine	tablets	200mg; (40/4x10) in blister, (50/5x10) 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	22353 30.09.2024
5	Izigel-M	ibuprofen, levomenthol	gel for external use	50mg/g;+30mg/g; aluminium tube 40g	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi	Georgia	OTC	22354 30.09.2024

6	Influvac	A/Victoria/4897/2022 (H1N1) pdm09-like strain (A/Victoria/2570/2019, IVR-215), A/Thailand/8/2022 (H3N2)-like strain (A/California/122/2022, SAN-022), B/Austria/1359417/2021-like strain (B/Austria/1359417/2021, BVR-26)	suspension for injection	15mcg haemagglutinin/dose+15mcg haemagglutinin/dose+15mcg haemagglutinin/dose; pre-filled syringe 0,5ml	ABBOTT Biologicals B.V. Veerweg 12, 8121 AA Olst- packager, quality control (microbiological), batch releaser, Abbott Biologicals B.V., C.J. van Houtenlaan 36, WEESP, 1381CP, the Netherlands- bulk manufacturer, quality control (physicochemical)	the Netherlands	ABBOTT Biologicals B.V. C.J. van Houtenlaan 36, 1381 CP Weesp	the Netherlands	PoM	22355 30.09.2024
7	Sulfacyl-sodium	sulfacetamide (sulfacetamide sodium)	drops eye	300mg/ml; vial 5ml and dropper	Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st., 1- quality control, batch releaser, Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st., 1/1, N5, Republic of Belarus- bulk manufacturer, packager	Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	OTC	22356 30.09.2024
8	Vurdon-Neo	diclofenac (diclofenac sodium)	solution for injection	25mg/ml; (5) ampoules 3ml in blister	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorfofi, Attiki	Greece	PoM	22357 30.09.2024
9	Methotrexate	methotrexate	tablets film-coated	2,5mg; (20/2x10) in blister	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30- quality control, batch releaser, Belmedpreparaty RUE, 220007, Minsk, Fabritsius lane, 3/14 Republic of Belarus- bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	22358 30.09.2024
10	Methotrexate	methotrexate	tablets film-coated	5mg; (20/2x10) in blister	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30- quality control, batch releaser, Belmedpreparaty RUE, 220007, Minsk, Fabritsius lane, 3/14 Republic of Belarus- bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	22359 30.09.2024
11	Espumisan L	simeticone	emulsion oral	40mg/ml; glass vial-dropper 30ml	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	OTC	22360 30.09.2024
12	Espumisan	simeticone	capsules soft	40mg; (25/1x25) in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, quality control, batch releaser, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany- bulk manufacturer	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	OTC	22361 30.09.2024

13	Streptocid	sulfanilamide	powder for external use	300mg; (10) sachets	Esco-Pharm LLC, Nor-Norq, Mikoyan 13, Yerevan	Republic of Armenia	Esco-Pharm LLC, Nor-Norq, Mikoyan 13, Yerevan	Republic of Armenia	OTC	22362 30.09.2024
14	Artraxicam	meloxicam, peper siliculose fruits tincture	cream	30mg/g+100mg/g; aluminium or plastic tube 30g	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, build. 1	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st. 7	Russia	OTC	22363 30.09.2024

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of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 09-3/24 on September 30, 2024

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1	AMLODIPIN	amlodipine (amlodipine besilate)	tablets	5mg; (20/2x10) 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	22364 30.09.2024
2	AMLODIPIN	amlodipine (amlodipine besilate)	tablets	10mg; (20/2x10) 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	22365 30.09.2024
3	ATORVASTATIN	atorvastatin (atorvastatin calcium trihydrate)	tablets film-coated	10mg; (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	PoM	22366 30.09.2024
4	ATORVASTATIN	atorvastatin (atorvastatin calcium trihydrate)	tablets film-coated	40mg; (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	PoM	22367 30.09.2024

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of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 09-3/24 on September 30, 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	Polyoxidonium-Petrovax	azoximer bromide	tablets	12mg; (10/1x10) in blister, (20/2x10) in blister	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143- secondary packager, quality control and batch releaser, NPO Petrovax Pharm LLC, 1 Sosnovaya str., Bld.. 1, 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	19975/2/2 30.09.2024
2	Antiflu Kids	paracetamol, ascorbic acid, chlorpheniramine (chlorpheniramine maleate)	powder for oral solution with raspberry flavour	160mg+50mg+1mg; (5) sachets	Contract Pharmacal Corporation, 135 Adams avenue, Hauppauge, New York 11788- packager, quality qontrol, batch releaser, Contract Pharmacal Corporation, 150 Commerce Drive Hauppauge, New York 11788, USA- bulk manufacturer	USA	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	20056/3/1 30.09.2024

3	Regulax Picosulfate	sodium picosulfate (sodium picosulfate monohydrate)	drops oral	7,5mg/ml; glass bottle 20ml	Krewel Meuselbach GmbH, Xavier Vorbruggen str. 6, 98694 Ilmenau	Germany	Krewel Meuselbach GmbH, Krewel str. 2, 53783 Eitorf	Germany	OTC	22168/1/1 30.09.2024
4	Hedelix	ivy leaves extract	drops oral	40mg/ml; 50ml glass bottle	Krewel Meuselbach GmbH, Xavier Vorbruggen str. 6, 98694 Ilmenau- bulk manufacturer, packager, quality control (physicochemical), batch releaser, CUP Laboratorien Dr. Freitag GmbH, Carl-Eschebach str. 7, 01454 Radeberg Deutschland, Germany- quality control (microbiological)	Germany	Krewel Meuselbach GmbH, Krewel str. 2, 53783 Eitorf	Germany	OTC	21542/1/1 30.09.2024
5	Influvac	A/Victoria/4897/2022 (H1N1) pdm09-like strain (A/Victoria/2570/2019, IVR-215), A/Thailand/8/2022 (H3N2)-like strain (A/California/122/2022, SAN-022), B/Austria/1359417/2021-like strain (B/Austria/1359417/2021, BVR-26)	suspension for injection	15mcg haemagglutinin/dose+15mcg haemagglutinin/dose; pre-filled syringe 0,5ml	ABBOTT Biologicals B.V. Veerweg 12, 8121 AA Olst- packager, quality control (microbiological), batch releaser, Abbott Biologicals B.V., C.J. van Houtenlaan 36, WEESP, 1381CP, the Netherlands- bulk manufacturer, quality control (physicochemical)	the Netherlands	ABBOTT Biologicals B.V. C.J. van Houtenlaan 36, 1381 CP Weesp	the Netherlands	PoM	18823/3/2 30.09.2024
6	Ulcavis	bismuth tripotassium dicitrate (bismuth oxide)	tablets film-coated	120mg; (28/2x14) in blister, (56/4x14) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, 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	20462/1/1 30.09.2024

7	Salbutamol Pharmstandard VCH	salbutamol (salbutamol sulfate)	aerosol for inhalation dosed	100mcg/dose; 200 doses in aluminium container with metering valve and inhaler, 300 doses in aluminium container with metering valve and inhaler	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	PoM	20895/2/1 30.09.2024
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LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 09-3/24 on September 30, 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	Rotarix	human rotavirus vaccine live	suspension oral	not less than 10 <sup>6</sup> CCID <sub>50</sub> /dose; (50 plastic tube 1.5ml (1 dose)	GlaxoSmithKline Biologicals s.a., Rue de l' Institut, 89 B-1330 Rixensart-batch releaser, GlaxoSmith-Kline Biologicals SA, Parc de la Noire Epine Rue Fleming, 20,1300 Wavre, Belgium- bulk manufacturer, quality control, packager	Belgium	GlaxoSmithKline Biologicals s.a., Rue de l' Institut, 89 B-1330 Rixensart	Belgium	PoM	20908/2 30.09.2024
2	Vinorelbine Ebewe	vinorelbine (vinorelbine tartrate)	concentrate for solution for i/v infusion	10mg/ml; glass vial 1ml	Fareva Unterach GmbH, Mondseestrasse 11, A-4866 Unterach am Attersee- bulk manufacturer, packager, quality control (physicochemical), batch releaser, MPL Mikrobiologisches Pruflabor GmbH, Grabenweg 68, Innsbruck, 6020, Austria- quality control (microbiological)	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	19844/4/1 30.09.2024
3	Vinorelbine Ebewe	vinorelbine (vinorelbine tartrate)	concentrate for solution for i/v infusion	10mg/ml; glass vial 5ml	Fareva Unterach GmbH, Mondseestrasse 11, A-4866 Unterach am Attersee- bulk manufacturer, packager, quality control (physicochemical), batch releaser, MPL Mikrobiologisches Pruflabor GmbH, Grabenweg 68, Innsbruck, 6020, Austria- quality control (microbiological)	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	19845/4/1 30.09.2024
4	Winch	fluconazole	capsules hard	150mg; (2/1x2) in blister	LABORATORIO FARMACEUTICO C.T. S.R.L., VIA DANTE ALIGHIERI, 71, 18038 SANREMO (IM)	Italy	So.Se. Pharm S.r.l., Via dei Castelli Romani 22, 00071 Pomezia (Rome)	Italy	PoM	21730/2 30.09.2024
5	Arixtra	fondaparinux (fondaparinux sodium)	solution for injection	5mg/ml; (10/2x5) pre-filled syringes 0.5ml in blister	Aspen Notre Dame de Bondeville, 1 rue de l' Ab-baye, 76960 Notre Dame de Bondeville	France	Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24	Ireland	PoM	19118/5 30.09.2024

6	Co-trimoxazole	sulfamethoxazole, trimethoprim	suspension oral	40mg/ml+8mg/ml; glass bottle 120ml	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	18520/1 30.09.2024
7	Tadafort 20	tadalafil	tablets film-coated	20mg; (4/2x2) in blister	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansoura-Aleppo	Syria	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansoura-Aleppo	Syria	PoM	18789/1 30.09.2024
8	Carbamazepine	carbamazepine	tablets	200mg; (40/4x10) in blister, (50/5x10) 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	18809/1 30.09.2024
9	Articaine with adrenaline forte	articaine (articaine hydrochloride), epinephrine (epinephrine hydrotartrate)	solution for injection	40mg/ml+0.01mg/ml; (50/5x10) glass cartridges 1.7ml, in blister	FKP «Armavirskaya biofabrika», 352212, Krasnodar reg, Novokubanskiy district, Progress settlement, str. Mechnikova, b. 11	Russia	«Binergy» JSC, 143910, Moscow region, Balashikha, Krupeshina str., b. 1	Russia	PoM	18778/2/1 30.09.2024
10	Solu-Medrol	methylprednisolone (methylprednisolone sodium succinate)	powder lyophilized for solution for i/m and i/v injection	250mg; (1) Act-O-Vial (250mg powder and 4ml solvent)	Pfizer Manufacturing Belgium N.V., Rijksweg 12, B-2870 Puurs	Belgium	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	PoM	19887/2 30.09.2024
11	Solu-Medrol	methylprednisolone (methylprednisolone sodium succinate)	powder lyophilized for solution for i/m and i/v injection	500mg; (1) glass vial with powder and (1) glass vial with solvent 7,8ml	Pfizer Manufacturing Belgium N.V., Rijksweg 12, B-2870 Puurs	Belgium	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	PoM	19888/2 30.09.2024
12	Solu-Medrol	methylprednisolone (methylprednisolone sodium succinate)	powder lyophilized for solution for i/m and i/v injection	1000mg; (1) glass vial with powder and (1) glass vial with solvent 15,6ml	Pfizer Manufacturing Belgium N.V., Rijksweg 12, B-2870 Puurs for	Belgium	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	PoM	19889/2 30.09.2024
13	AMLODIPIN	amlodipine (amlodipine besilate)	tablets	5mg; (20/2x10) 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	18573/1 30.09.2024
14	AMLODIPIN	amlodipine (amlodipine besilate)	tablets	10mg; (20/2x10) 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	18574/1 30.09.2024
15	ATORVASTATIN	atorvastatin (atorvastatin calcium trihydrate)	tablets film-coated	10mg; (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	PoM	18688/1 30.09.2024

16	ATORVASTATIN	atorvastatin (atorvastatin calcium trihydrate)	tablets film-coated	20mg; (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	PoM	18689/1 30.09.2024
17	ATORVASTATIN	atorvastatin (atorvastatin calcium trihydrate)	tablets film-coated	40mg; (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	PoM	18690/1 30.09.2024
18	Captopril	captopril	tablets	25mg; (40/4x10) 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	21296/1 30.09.2024
19	L-Thyroxin 25 Berlin-Chemie	levothyroxine sodium	tablets	25mcg; (100/4x25) in blister	Berlin-Chemie A.G., 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 A.G., Glienicker Weg 125, 12489 Berlin, Germany- quality control (physicochemical)	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	PoM	21167/2 30.09.2024
20	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	22234/1 30.09.2024
21	Hartil-D	ramipril, hydrochlorothiazide	tablets	5mg+25mg; (28/2x14) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	21512/1 30.09.2024
22	Upsarin Upsa	acetylsalicylic acid	tablets effervescent	500mg; (16/4x4) in strip	UPSA SAS, 979, Avenue des Pyrenees, 47520 Le Passage	France	UPSA SAS, 3, rue Joseph Monier- 92500 Rueil- Malmaison	France	OTC	21010/2 30.09.2024
23	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	18716/7/1 30.09.2024

24	Sulfacyl-sodium	sulfacetamide (sulfacetamide sodium)	drops eye	300mg/ml; vial 5ml and dropper	Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st., 1- quality control, batch releaser, Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st., 1/1, N5, Republic of Belarus -bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	OTC	18697/2/1 30.09.2024
25	Lecrolyn	cromoglicic acid (sodium cromoglicate)	drops eye	40mg/ml; 5ml plastic vial-dropper	Santen Oy, Kelloportinkatu 1, Tampere, 33100-batch releaser, NextPharma Oy, Niittyhaankatu 20, Tampere, 33720, 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, Niittyhaankatu 20, 33720 Tampere	Finland	OTC	19529/2 30.09.2024
26	Almigen	almotriptan (almotriptan malate)	tablets film-coated	12,5mg; (2/1x2) in blister	Chanelle Medical Unlimited Company, Dublin Road, Loughrea, Co Galway, 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	PoM	19659/2/1 30.09.2024
27	Strepsils Intensive	flurbiprofen	spray dosed for topical use with cherry and mint flavour	8,75mg; (1) plastic container with dosing device, 15ml (at least 15 dose)	Reckitt Benckiser Healthcare Manufacturing (Thailand) Ltd, 65 Lardkrabang-Bangplee Road Moo 12, Bangplee, Samutprakarn, 10540	Thailand	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	OTC	20726/3/1 30.09.2024
28	L-Thyroxin 50 Berlin-Chemie	levothyroxine sodium	tablets	50mcg; (100/4x25) 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	PoM	20790/2/1 30.09.2024

29	L-Thyroxin 75 Berlin-Chemie	levothyroxine sodium	tablets	75mcg; (100/4x25/) 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	PoM	20791/2/1 30.09.2024
30	L-Thyroxin 100 Berlin-Chemie	levothyroxine sodium	tablets	100mcg; (100/4x25/) 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	PoM	20792/2/1 30.09.2024
31	L-Thyroxin 125 Berlin-Chemie	levothyroxine sodium	tablets	125mcg; (100/4x25/) 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	PoM	20793/2/1 30.09.2024
32	L-Thyroxin 150 Berlin-Chemie	levothyroxine sodium	tablets	150mcg; (100/4x25/) 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	PoM	20794/2/1 30.09.2024
33	Streptocid	sulfanilamide	powder for external use	300mg; (10) sachets	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	18434/2 30.09.2024
34	Artraxicam	meloxicam, peper siliculose fruits tincture	cream	30mg/g+100mg/g; aluminium or plastic tube 30g	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, build. 1	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st. 7	Russia	OTC	18481/3/1 30.09.2024

35	Coldrex HotRem	paracetamol, phenylephrine (phenylephrine hydrochloride), ascorbic acid	powder for oral solution with lemon flavour	750mg+10mg+60mg; (10) sachets 5g	SmithKline Beecham S.A. Ctra. de Ajalvir, KM-2500-28806, Alcala de Henares, Madrid	Spain	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	OTC	19506/2/1 30.09.2024
36	Coldrex HotRem	paracetamol, phenylephrine (phenylephrine hydrochloride), ascorbic acid	powder for oral solution with honey and lemon flavour	750mg+10mg+60mg; (10) sachets 5g	SmithKline Beecham S.A. Ctra. de Ajalvir, KM-2500-28806, Alcala de Henares, Madrid	Spain	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	OTC	19633/2/1 30.09.2024

## LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting  
decision N 09-3/24 on September 30, 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 30.09.2024
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 30.09.2024
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 30.09.2024

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	000880 30.09.2024
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	000880 30.09.2024
6	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 30.09.2024
7	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 30.09.2024
8	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 30.09.2024