

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 09-2/24 on September 16, 2024

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Magnerot	magnesium orotate (magnesium orotate dihydrate)	tablets	500mg; (20/2x10) in blister, (50/5x10) in blister	Mauermann-Arzneimittel KG, Gewerbealle 1, Poecking, 82343- bulk manufacturer, packager, quality control (physico-chemical), batch releaser, Labor LSSE & Co. KG, Mangelsfeld 4, 5, 6, Grossenbrach, Bad Bocklet, Bavaria, 97708, Germany- quality control (microbiological)	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen	Germany	OTC	22293 16.09.2024
2	IBUPROFEN 400mg film-coated tablets	ibuprofen	tablets film-coated	400mg; (100/10x10) in blister	M/s Medopharm, No. 34-B, Industrial Area, Malur-563 160, Kolar District, Karnataka	India	Troge Scientific Research I. PVT.LTD., Tower C, Unit No-A-12-A, 2nd floor, Alphathum, sector-90, Noida 201305, Gautam Buddh Nagar, Uttar Pradesh	India	OTC	22294 16.09.2024
3	Letiram	levetiracetam	tablets coated	250mg; (30/3x10) in blister, (60/6x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, PharOS MT Ltd, HF62X, Hal Far Industrial Estate, Birzebbugia BBG, 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22295 16.09.2024
4	Letiram	levetiracetam	tablets coated	500mg; (30/3x10) in blister, (60/6x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, PharOS MT Ltd, HF62X, Hal Far Industrial Estate, Birzebbugia BBG, 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22296 16.09.2024

5	Letiram	levetiracetam	tablets coated	750mg; (30/3x10) in blister, (60/6x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, PharOS MT Ltd, HF62X, Hal Far In- dustrial Estate, Birzebbugia BBG, 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22297 16.09.2024
6	Letiram	levetiracetam	tablets coated	1000mg; (30/3x10) in blister, (60/6x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, PharOS MT Ltd, HF62X, Hal Far In- dustrial Estate, Birzebbugia BBG, 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22298 16.09.2024

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of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 09-2/24 on September 16, 2024

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Diroton	lisinopril (lisinopril dihydrate)	tablets	5mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22299 (002345) 16.09.2024
2	Diroton	lisinopril (lisinopril dihydrate)	tablets	5mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) 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	22300 (002345) 16.09.2024

3	Diroton	lisinopril (lisinopril dihydrate)	tablets	5mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- bulk manufacturer, pri- mary packager, batch releaser, GEDEON RICHTER JSC - RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- secondary 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)	Hungary	Gedeon Richter PLC, Gyom- roi ut 19-21, 1103 Budapest	Hungary	PoM	22301 (002345) 16.09.2024
4	Diroton	lisinopril (lisinopril dihydrate)	tablets	5mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegori- yevsky district, 140342- batch releaser, Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest, Hungary- bulk manufac- turer, GEDEON RICHTER JSC- RUS, Le- snaya 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, Gyom- roi ut 19-21, 1103 Budapest	Hungary	PoM	22302 (002345) 16.09.2024
5	Diroton	lisinopril (lisinopril dihydrate)	tablets	10mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyom- roi ut 19-21, 1103 Budapest	Hungary	PoM	22303 (002345) 16.09.2024

6	Diroton	lisinopril (lisinopril dihydrate)	tablets	10mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoje, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, batch releaser, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoje, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoje, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoje, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22304 (002345) 16.09.2024
7	Diroton	lisinopril (lisinopril dihydrate)	tablets	10mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- bulk manufacturer, primary packager, batch releaser, GEDEON RICHTER JSC - RUS, Lesnaya St. 43/5., Shuvoje, Moscow region, Yegoriyevsky district, 140342, Russia- secondary packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoje, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoje, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22305 (002345) 16.09.2024

8	Diroton	lisinopril (lisinopril dihydrate)	tablets	10mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) 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	22306 (002345) 16.09.2024
9	Diroton	lisinopril (lisinopril dihydrate)	tablets	20mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22307 (002345) 16.09.2024
10	Diroton	lisinopril (lisinopril dihydrate)	tablets	20mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) 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	22308 (002345) 16.09.2024

11	Diroton	lisinopril (lisinopril dihydrate)	tablets	20mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- bulk manufacturer, primary packager, batch releaser, GEDEON RICHTER JSC - RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- secondary 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)	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22309 (002345) 16.09.2024
12	Diroton	lisinopril (lisinopril dihydrate)	tablets	20mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) 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	22310 (002345) 16.09.2024
13	Trichopol Polpharma	metronidazole	tablets	250mg; (20/2x10) in blister	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	PoM	22311 (003265) 16.09.2024
14	Cytotec	misoprostol	tablets	200mcg; (60/6x10) in blister	Piramal Healthcare UK Limited, Whalton Road Morpeth, Northumberland, NE61 3YA	UK	Pfizer H.C.P. Corporation, 66 Hudson Boulevard East, New York, NY 10001-2192	USA	PoM	22312 (006386) 16.09.2024

15	Zemplar	paricalcitol	solution for injection	5mcg/ml; (5/1x5/) glass vials 1ml in carton tray, (10/2x5/) glass vials 1ml in carton tray, (5/1x5/) glass vials 1ml in plastic tray, (10/2x5/) glass vials 1ml in plastic tray	AbbVie S.r.l., S.R. 148 Pontina KM 52, S.N.C.- Campoverde di Aprilia 04011- batch releaser, AVARA LISCATE PHARMACEUTICAL SERVICES S.p.A., VIA FOSSE ARDEATINE, 2, LISCATE, 20050, Italy- bulk manufacturer, packager, quality control	Italy	AbbVie LLC, 125196, Lesnaya str, 7, floor 4, room 1, Moscow	Russia	PoM	22313 (006219) 16.09.2024
16	Zemplar	paricalcitol	solution for injection	5mcg/ml; (5/1x5/) glass vials 1ml in carton tray, (10/2x5/) glass vials 1ml in carton tray, (5/1x5/) glass vials 1ml in plastic tray, (10/2x5/) glass vials 1ml in plastic tray	ORTAT JSC, Kostromskaya distr., Susaninsky region, vil. Severnoe, microdistr. Kharitonovo, 157092- secondary packager, batch releaser, AVARA LISCATE PHARMACEUTICAL SERVICES S.p.A., VIA FOSSE ARDEATINE, 2, LISCATE, 20050, Italy- bulk manufacturer, primary packager, quality control for «ORTAT» JSC, Kostromskaya distr., Susaninsky region, vil. Severnoe, microdistr. Kharitonovo, 157092- secondary packager, batch releaser, AVARA LISCATE PHARMACEUTICAL SERVICES S.p.A., VIA FOSSE ARDEATINE, 2, LISCATE, 20050, Italy- bulk manufacturer, primary packager, quality control	Russia	AbbVie LLC, 125196, Lesnaya str, 7, floor 4, room 1, Moscow	Russia	PoM	22314 (006219) 16.09.2024
17	Allergostin	ebastine	tablets film-coated	10mg; (10/1x10) in blister	Scientific Technological Pharmaceutical Firm "POLYSAN" Ltd, lit. A, 2 building, 72 Salova st., Saint- Petersburg, 192102	Russia	Scientific Technological Pharmaceutical Firm "POLYSAN" Ltd, lit. A, 2 building, 72 Salova st., Saint- Petersburg, 192102	Russia	OTC	22315 (001230) 16.09.2024
18	Allergostin	ebastine	tablets film-coated	20mg; (10/1x10) in blister	Scientific Technological Pharmaceutical Firm "POLYSAN" Ltd, lit. A, 2 building, 72 Salova st., Saint- Petersburg, 192102	Russia	Scientific Technological Pharmaceutical Firm "POLYSAN" Ltd, lit. A, 2 building, 72 Salova st., Saint- Petersburg, 192102	Russia	OTC	22316 (001230) 16.09.2024

19	Dexalfen	dexketoprofen (dexketoprofen trometamol)	solution for i/m and i/v injection	25mg/ml; (5/1x5/) ampoules 2ml in blister; (10/2x5/) ampoules 2ml in PVC/polimer film blister; (5/1x5/) ampoules 2ml in PVC/polimer film blister; (10/2x5/) ampoules 2ml in PVC/polimer film blister	SotexPharmFirm» CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region- quality control, batch releaser, «Sotex»PharmFirm» CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, Russia- bulk manufacturer, packager	Russia	«Sotex»PharmFirm» CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	PoM	22317 (001098) 16.09.2024
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of the medicines recommended for the re-registration by the Center according to the meeting decision N 09-2/24 on September 16, 2024

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1	Afala	antibodies to prostatospecific antigen affinity purified	tablets to be sucked	10000UMA; (100/5x20) in blister	NPF Materia Medica Holding LLC, 54, Buguruslanskaya st., Chelyabinsk 454139	Russia	NPF Materia Medica Holding LLC, 9 bld., 3rd Samotyochny per., Moscow 127473	Russia	OTC	22318 16.09.2024
2	Atracurium Besylate 10mg/ml Solution for Injection/Infusion	atracurium (atracurium besylate)	solution for injection/infusion	10mg/ml; (5) ampoules 2,5ml	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	22319 16.09.2024
3	Atracurium Besylate 10mg/ml Solution for Injection/Infusion	atracurium (atracurium besylate)	solution for injection/infusion	10mg/ml; (5) ampoules 5ml	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	22320 16.09.2024
4	Evica	saraca indica, symplocos racemosa, valeriana wallichii, matricaria chamomilla, vitex agnus castus, areca catechu	capsules	150mg+50mg+50mg+50mg+50mg+50mg; (20) in plastic container, (60) in plastic container	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	22321 16.09.2024
5	Andipal	metamizole (metamizole sodium), phenobarbital, bendazol (bendazol hydrochloride), papaverine (papaverine hydrochloride)	tablets	250mg+20mg+20mg+20mg; (10/1x10) in blister	Irbitskiy himfarmzavod OJSC, 124-a, K. Marksa str., Irbit, St. Sverdlovsk, 623856	Russia	Irbitskiy himfarmzavod OJSC, 172, Kirova str., Irbit, St. Sverdlovsk, 623856	Russia	OTC	22322 16.09.2024

6	ALBUCID	sulfacetamide (sulfacetamide sodium)	powder for external use	500mg; (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	22323 16.09.2024
7	Levomecol	chloramphenicol, 6-methyluracil	ointment	7,5mg/g+40mg/g; aluminium tube 30g, aluminium tube 40g	SIC «Borshchahivskiy Chemical-Pharmaceutical Plant» PJSC, 17, Mira St, Kyiv, 03134	Ukraine	SIC «Borshchahivskiy Chemical-Pharmaceutical Plant» PJSC, 17, Mira St, Kyiv, 03134	Ukraine	OTC	22324 16.09.2024
8	Acne Wash	salicylic acid	soap liquid	20mg/ml; plastic container 100ml	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	22325 16.09.2024
9	CETRIWINA	cetirizine (cetirizine hydrochloride)	tablets film-coated	10mg; (10/1x10) in blister	Akriti Pharmaceuticals Pvt. Ltd., Plot No. D-10, D-11, M.I.D.C. Indl. Estate, Nira Road, Jejuri, Tal. Purandar (Saswad), Dist. Pune-412 303, Maharashtra	India	Akriti Pharmaceuticals Pvt. Ltd., 117, Block No. 2, Emerald Plaza, Hiranandani Meadows, Barrister Nath Pai Road, Thane (West) 400 610	India	OTC	22326 16.09.2024
10	Folic Acid	folic acid	tablets	1mg; (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	22327 16.09.2024
11	Paracetamol-Pharmstandard	paracetamol	tablets	500mg; (10/1x10) in blister, (20/2x10) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	22328 16.09.2024
12	Dexmedetomidine	dexmedetomidine (dexmedetomidine hydrochloride)	concentrate for solution for infusion	100mcg/ml; (5) ampoules 2ml	EVER Pharma Jena GmbH, Otto-Schott-Strasse 15, 07745 Jena	Germany	EVER Valinject GmbH, Oberburgau 3, 4866 Unterach am Attersee	Austria	PoM	22329 16.09.2024
13	Combilipen Tabs	benfotiamine, pyridoxine (pyridoxine hydrochloride), cyanocobalamin	tablets film-coated	100mg+100mg+2mcg; (15/1x15) in blister, (30/2x15) in blister, (60/4x15) in blister	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	PoM	22330 16.09.2024
14	Deep Heat	methyl salicylate, menthol (racemic), eucalyptus oil, turpentine oil	cream for external use	128mg/g+59,1mg/g+19,7mg/g+14,7mg/g; 15g aluminium tube, 67g aluminium tube	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	OTC	22331 16.09.2024

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1	SIMBRINZA	brinzolamide, brimonidine (brimonidine tartrate)	drops eye, suspension	10mg/ml+2mg/ml; 5ml plastic vial-dropper	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22332 (013327) 16.09.2024

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of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 09-2/24 on September 16, 2024

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1	Enzix Duo	I-enalapril (enalapril maleate), II-indapamide	tablets and tablets film-coated	I-10mg, II-2,5mg; (45/3x15// (10)-I tablets + (5)-II film-coated tablets) in blister	Hemofarm LLC, 249035, Obninsk, Kaluga Region, 62 Kievskoye highway-bulk manufacturer, packager, quality control (physicochemical), batch releaser, Farmoborona Test Center, Ltd., 141074, Korolyov, Moscow Region, Gagarin St., 46A, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	PoM	21112/3/2 16.09.2024
2	Enzix Duo Forte	I-enalapril (enalapril maleate), II-indapamide	tablets and tablets film-coated	I-20mg, II-2,5mg; (45/3x15// (10)-I tablets + (5)-II film coated tablets) in blister	Hemofarm LLC, 249035, Obninsk, Kaluga Region, 62 Kievskoye highway-bulk manufacturer, packager, quality control (physicochemical), batch releaser, Farmoborona Test Center, Ltd., 141074, Korolyov, Moscow Region, Gagarin St., 46A, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	PoM	21113/3/2 16.09.2024

3	Acne Wash	salicylic acid	soap liquid	20mg/ml; plastic container 100ml	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	18713/1/1 16.09.2024
4	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, Rus- tavi Highway 52, Tbilisi	Georgia	OTC	18813/3/1 16.09.2024
5	Folic Acid	folic acid	tablets	1mg; (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	18720/1/1 16.09.2024
6	Combilipen	thiamine (thiamine hydrochloride), pyridoxine (pyridoxine hydrochloride), cyanocobalamin, lidocaine (lidocaine hydrochloride)	solution for i/m injection	50mg/ml+50mg/ml+0,5mg/ ml+10mg/ml (5/1x5/ ampoules 2ml in blister, (10/2x5) ampoules 2ml in blister	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	PoM	19507/1/1 16.09.2024

7	Rivarox	rivaroxaban	tablets film-coated	2,5mg; (56/4x14) in blister	Combino Pharm (Malta) Ltd., HF60, Hal Far Industrial Estate Hal Far BBG3000, Warehouse No.1 and No.2, Hal Farrug Road, Luqa LQA9040- bulk manufacturer, packager, quality control (physico-chemical), batch releaser, BioDNA Laboratory Services Ltd., LS2.1.1 and LS2.1.2, Malta Life Sciences Park, San Gwann Industrial Estate, San Gwann, SGN3000, Malta- quality control (microbiological)	Malta	GM Pharmaceuticals Ltd, 52, Rustavi Highway 52, Tbilisi	Georgia	PoM	21118/1/1 16.09.2024
8	Rivarox	rivaroxaban	tablets film-coated	10mg; (10/1x10) in blister	Combino Pharm (Malta) Ltd., HF60, Hal Far Industrial Estate Hal Far BBG3000, Warehouse No.1 and No.2, Hal Farrug Road, Luqa LQA9040- bulk manufacturer, packager, quality control (physico-chemical), batch releaser, BioDNA Laboratory Services Ltd., LS2.1.1 and LS2.1.2, Malta Life Sciences Park, San Gwann Industrial Estate, San Gwann, SGN3000, Malta- quality control (microbiological)	Malta	GM Pharmaceuticals Ltd, 52, Rustavi Highway 52, Tbilisi	Georgia	PoM	21119/1/1 16.09.2024
9	Rivarox	rivaroxaban	tablets film-coated	15mg; (28/2x14) in blister	Combino Pharm (Malta) Ltd., HF60, Hal Far Industrial Estate Hal Far BBG3000, Warehouse No.1 and No.2, Hal Farrug Road, Luqa LQA9040- bulk manufacturer, packager, quality control (physico-chemical), batch releaser, BioDNA Laboratory Services Ltd., LS2.1.1 and LS2.1.2, Malta Life Sciences Park, San Gwann Industrial Estate, San Gwann, SGN3000, Malta- quality control (microbiological)	Malta	GM Pharmaceuticals Ltd, 52, Rustavi Highway 52, Tbilisi	Georgia	PoM	21120/1/1 16.09.2024
10	Rivarox	rivaroxaban	tablets film-coated	20mg; (28/2x14) in blister	Combino Pharm (Malta) Ltd., HF60, Hal Far Industrial Estate Hal Far BBG3000, Warehouse No.1 and No.2, Hal Farrug Road, Luqa LQA9040- bulk manufacturer, packager, quality control (physico-chemical), batch releaser, BioDNA Laboratory Services Ltd., LS2.1.1 and LS2.1.2, Malta Life Sciences Park, San Gwann Industrial Estate, San Gwann, SGN3000, Malta- quality control (microbiological)	Malta	GM Pharmaceuticals Ltd, 52, Rustavi Highway 52, Tbilisi	Georgia	PoM	21121/1/1 16.09.2024

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1	Prestarium A	perindopril (perindopril arginine)	tablets film-coated	5mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000574 16.09.2024
2	Prestarium A	perindopril (perindopril arginine)	tablets film-coated	5mg; (14) in plastic container, (30) in plastic container, (90/3x30) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000574 16.09.2024
3	Prestarium A	perindopril (perindopril arginine)	tablets film-coated	5mg; (14) in plastic container, (30) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000574 16.09.2024
4	Prestarium A	perindopril (perindopril arginine)	tablets film-coated	5mg; (14) in plastic container, (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284- packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000574 16.09.2024
5	Prestarium A	perindopril (perindopril arginine)	tablets film-coated	10mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000574 16.09.2024
6	Prestarium A	perindopril (perindopril arginine)	tablets film-coated	10mg; (30) in plastic container, (90/3x30) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000574 16.09.2024

7	Prestarium A	perindopril (perindopril arginine)	tablets film-coated	10mg; (30) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000574 16.09.2024
8	Prestarium A	perindopril (perindopril arginine)	tablets film-coated	10mg; (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284- packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000574 16.09.2024

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N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Gadovist	gadobutrol	solution for injection	604,72mg/ml; (5) glass vials 15ml	Bayer AG, Mullerstrasse 178, 13353, Berlin	Germany	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	PoM	19743/3 16.09.2024
2	Liprimar ST	atorvastatin (atorvastatin calcium)	tablets film-coated	80mg; (30/3x10) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieburg Im Breisgau - packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	21152/2/1 16.09.2024
3	Zyvox	linezolid	solution for infusion	2mg/ml; (10) plastic packs 300ml	Fresenius Kabi Norge AS, Svinesundsveien 80 HALDEN, NO-1788	Norway	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	PoM	21254/1 16.09.2024
4	Zyvox	linezolid	tablets film-coated	600mg; (10/1x10) in blister	Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693	USA	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York, 10017	USA	PoM	19288/4 16.09.2024
5	Levocom	levodopa, carbidopa	tablets	250mg+25mg; (30/3x10) in blister, (100/10x10) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	22003/1 16.09.2024
6	Levomecol	chloramphenicol, 6-methyluracil	ointment	7,5mg/g+40mg/g aluminium tube 30g, aluminium tube 40g	SIC «Borshchahivskiy Chemical-Pharmaceutical Plant» PJSC, 17, Mira St, Kyiv, 03134	Ukraine	SIC «Borshchahivskiy Chemical-Pharmaceutical Plant» PJSC, 17, Mira St, Kyiv, 03134	Ukraine	OTC	18510/2 16.09.2024
7	Ketonal DUO	ketoprofen	capsules modified-release	150mg; (20/2x10) in blister, (30/3x10) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19541/6 16.09.2024
8	Glucophage XR	metformin (metformin hydrochloride)	tablets prolonged-release	500mg; (30/2x15) in blister, (60/4x15) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400, Semoy	France	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	19451/4/1 16.09.2024

9	Glucophage XR	metformin (metformin hydrochloride)	tablets prolonged-release	1000mg; (60/6x10) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400, Semoy- packager, batch releaser, Merck Healthcare KGaA, Frankfurter Strasse 250, 64 293 Darmstadt, Germany- bulk manufacturer, quality control	France	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	19452/4/1 16.09.2024
10	Urolesan	abies oil, mentha piperita oil, daucus carota fluid extract, humulus lupulus fluid extract, origanum fluid extract	drops oral	67,6mg/ml+16,9mg/ml+194,35mg/ml+278,8mg/ml+192,95mg/ml; bottle-drop- per 25ml	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	OTC	21144/2 16.09.2024
11	Paracetamol- Pharmstandard	paracetamol	tablets	500mg; (10/1x10) in blister, (20/2x10) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	18975/5/2 16.09.2024
12	Cetriwina	cetirizine (cetirizine hydrochloride)	tablets film-coated	10mg; (10/1x10) in blister	Akriti Pharmaceuticals Pvt. Ltd., Plot No. D-10, D-11, M.I.D.C. Incl. Estate, Nira Road, Jejuri, Tal. Purandar (Saswad), Dist. Pune-412 303, Maharashtra	India	Akriti Pharmaceuticals Pvt. Ltd., 117, Block No. 2, Emerald Plaza, Hiranandani Meadows, Barrister Nath Pai Road, Thane (West) 400 610	India	OTC	17834/1 16.09.2024
13	Rufixalo	rivaroxaban	tablets film-coated	2,5mg; (56/4x14) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- batch releaser, PharOS MT Ltd, HF62X, Hal Far Industrial Estate, Birzebbugia BGC, 3000, Malta- bulk manufacturer, packager, quality control	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	20753/3 16.09.2024
14	Combilipen Tabs	benfotiamine, pyridoxine (pyridoxine hydrochloride), cyanocobalamin	tablets film-coated	100mg+100mg+2mcg; (15/1x15) in blister, (30/2x15) in blister, (60/4x15) in blister	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	PoM	19783/2/1 16.09.2024
15	Polyoxidonium	azoximer bromide	powder lyophilized for solution for injection and local use	6mg; (5) glass vials 3ml	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	PoM	22132/1 16.09.2024
16	Amorolfine Lacquer	amorolfine (amorolfine hydrochloride)	medicated nail lacquer	50mg/ml; 2,5ml glass vial, (10) spatulas, (30) nail files, (30) cleansing swabs	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	20727/2/1 16.09.2024

17	Panangin	magnesium aspartate (magnesium aspartate tetrahydrate), potassium aspartate (potassium aspartate hemihydrate)	tablets film-coated	140mg+158mg; (50) in plastic container, (60/3x20/) in blister, (100/5x20/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	OTC	19515/2/1 16.09.2024
18	KISQALI	ribociclib (ribociclib succinate)	tablets film-coated	200mg; (21/1x21/) in blister, (63/3x21/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein AG, 4332- packager, batch releaser, Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd., 10 Tuas Bay Lane, 637461 Singapore, Singapore- bulk manufacturer, quality control	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20278/3 16.09.2024
19	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 Metamorphosis, Attica	Greece	PoM	18724/2 16.09.2024

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1	ARIFON Retard	indapamide	tablets film-coated prolonged-release	1,5mg; (30/1x30) in blister, (90/3x30) 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	000156 16.09.2024
2	Visanne	dienogest (micronised)	tablets	2mg; (28/2x14) in blister, (84/6x14) in blister	Bayer Weimar GmbH & Co. KG, Dobereinerstrasse 20, 99427 Weimar	Germany	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	PoM	001547 16.09.2024
3	Sitadiab	sitagliptin (sitagliptin hydrochloride monohydrate)	tablets film-coated	100mg; (28/2x14) in blister	Gedeon Richter-RUS JSC, Lesnaya st. 40, Shuvoye, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, quality control, batch releaser, Gedeon Richter-RUS JSC, Lesnaya st. 43/5, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	000724 16.09.2024
4	Sitadiab	sitagliptin (sitagliptin hydrochloride monohydrate)	tablets film-coated	100mg; (28/2x14) in blister	Gedeon Richter-RUS JSC, Lesnaya st. 40, Shuvoye, Moscow region, Yegoriyevsky district, 140342- quality control, batch releaser, Gedeon Richter Romania S.A., Guza Voda str. 99-105, Targu-Mures, 540306, Romania- bulk manufacturer, Gedeon Richter-RUS JSC, Lesnaya st. 43/5, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	000724 16.09.2024

5	Sitadiab	sitagliptin (sitagliptin hydrochloride monohydrate)	tablets film-coated	100mg; (28/2x14) in blister	Gedeon Richter Romania S.A., Guza Voda str. 99-105, Targu-Mures, 540306	Romania	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	000724 16.09.2024
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