

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 07-2/24 on July 25, 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	Ticathromb	ticagrelor	tablets film-coated	60mg; (10/1x10) in blister	IBN AL-Haytham Pharma Industries Co., Al Mansura, Aleppo	Syria	IBN AL-Haytham Pharma Industries Co., Al Mansura, Aleppo	Syria	PoM	22197 25.07.2024
2	Ticathromb	ticagrelor	tablets film-coated	90mg; (10/1x10) in blister	IBN AL-Haytham Pharma Industries Co., Al Mansura, Aleppo	Syria	IBN AL-Haytham Pharma Industries Co., Al Mansura, Aleppo	Syria	PoM	22198 25.07.2024
3	Meloxicam Avexima	meloxicam	tablets	15mg; 20(2x10) in blister	Irbitskiy himfarmzavod OJSC, 124-a, K. Marksa str., Irbit, St. Sverdlovsk, 623856	Russia	Avexima OJSC, 31A/1, Leningradsky pr., Moscow, 125284	Russia	PoM	22199 25.07.2024
4	Zometa	zoledronic acid (zoledronic acid monohydrate)	solution for infusion	0,04mg/ml; plastic vial 100ml	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- secondary packager, batch releaser, Fresenius Kabi Austria GmbH, Hafnerstrasse 36, Graz, 8055, Austria- bulk manufacturer, primary packager, Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland- quality control	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22200 25.07.2024
5	Persen Night	valeriana officinalis extract, melissa officinalis extract, mentha piperita extract	capsules	87,5mg+17,5mg+17,5mg; (20/2x10) in blister	ADIPHARMEAD, 130 Simeonovsko shose Blvd., Sofia 1700	Bulgaria	Zentiva, k.s., U kabelovny 130, 102 37 Praha 10, Dolni Mecholupy	Czech Republic	OTC	22201 25.07.2024
6	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 25.07.2024

7	Normomed	inosine pranobex	tablets	500mg; (20/2x10) in blister, (30/3x10) in blister, (50/5x10) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Centemo LTD, Moscow Region, Shchelkovo, Fabrichnaya St., 2, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	PoM	22203 25.07.2024
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2024

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1	Dexonal	dexketoprofen	tablets film-coated	25mg; (10/1x10) in blister, (30/3x10) in blister, (50/5x10) in blister	Alium AO, build. 1, No: 2, Quarter A, Obolensk working settlement, Serpukhov city, 142279, Moscow region, Russia- quality control, batch releaser, Alium AO, No: 2, Quarter A, Obolensk working settlement, Serpukhov city, 142279, Moscow region, Russia- bulk manufacturer, packager	Russia	Alium AO, No: 2, Quarter A, Obolensk working settlement, Serpukhov city, 142279, Moscow region	Russia	OTC	22204 (005074) 25.07.2024
2	Airtal	aceclofenac	cream	15mg/g; aluminium tube 60g	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	OTC	22205 (004605) 25.07.2024
3	Riqulatron	rivaroxaban	tablets film-coated	2,5mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (168/12x14) in blister, (196/14x14) in blister, (20/2x10) in blister, (30/3x10) in blister, (60/6x10) in blister, (100/10x10) in blister	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22206 (002537) 25.07.2024

4	Riquatron	rivaroxaban	tablets film-coated	10mg; (5/1x5) in blister, (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (10/1x10) in blister, (30/3x10) in blister, (100/10x10) in blister	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22207 (002537) 25.07.2024
5	Riquatron	rivaroxaban	tablets film-coated	15mg; (14/1x14) in blister, (28/2x14) in blister, (42/3x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (10/1x10) in blister, (100/10x10) in blister	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22208 (002537) 25.07.2024
6	Riquatron	rivaroxaban	tablets film-coated	20mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (10/1x10) in blister, (100/10x10) in blister	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22209 (002537) 25.07.2024
7	Groprinosin-Richter	inosine pranobex	syrup	50mg/ml; 150ml glass bottle and plastic syringe 0,5ml-5ml	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Romania S.A., Guza Voda str. 99-105, Targu-Mures, 540306, Romania- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22210 (002147) 25.07.2024
8	Groprinosin-Richter	inosine pranobex	syrup	50mg/ml; 150ml glass bottle and plastic syringe 0,5ml-5ml	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- batch releaser, Gedeon Richter Romania S.A., 99-105 Guza Voda str., Targu-Mures, Jud. Mures, 540306, Romania- bulk manufacturer, packager, quality control	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22211 (002147) 25.07.2024
9	Vermox	mebendazole	tablets	100mg; (6/1x6) in blister	Gedeon Richter Romania S.A., 99-105 Guza Voda str., Targu-Mures, Jud. Mures, 540306	Romania	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22212 (005068) 25.07.2024

10	Vermox	mebendazole	tablets	100mg; (6/1x6) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Romania S.A., 99-105 Guza Voda str., Targu-Mures, Jud. Mures, 540306, Romania- bulk manufacturer, packager, quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22213 (005068) 25.07.2024
11	Recormon	epoetin beta	solution for i/v and s/c injection	2000IU/0,3ml; (6/2x3) pre-filled syringes 0,3ml and (6) needles	Roche Diagnostics GmbH, Sandhofer Strasse 116, 68305 Mannheim- bulk manufacturer, packager, quality control, batch releaser, Bioassay-Labor Biological Analysis GmbH, Neuenheimer Feld 515-519, 69120 Heidelberg, Germany- quality control (biological)	Germany	F. Hoffmann-La Roche Ltd, Grenzacherstrasse, 124, 4070, Basel	Switzerland	PoM	22214 (009428) 25.07.2024
12	Pancef	cefixime (cefixime trihydrate)	tablets film-coated	400mg; (5/1x5) in blister, (7/1x7) in blister, (10/2x5) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- quality control, batch releaser, Alkaloid AD Skopje, Blvd. Partizanski odredi 98A, 1000 Skopje, Republic of North Macedonia- bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	22215 (006784) 25.07.2024
13	Tetracaine	tetracaine (tetracaine hydrochloride)	drops eye	10mg/ml; 10ml plastic vial-dropper	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	22216 (009430) 25.07.2024

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 07-2/24 on July 25, 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	Silkaderm	tretinoin	cream	0,5mg/g; aluminum tube 15g	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	22218 25.07.2024
2	KapsiKam	dimethyl sulfoxide, camphor racemic, turpentine oil, benzyl nicotinate, nonivamide	ointment for external use	50mg/g+30mg/g+30mg/g+20mg/g+2mg/g; 30g aluminium tube and applicator, 50g aluminium tube and applicator	Grindex JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindex JSC, Krustpils street 53, LV-1057, Riga	Latvia	OTC	22219 25.07.2024
3	Amprilan HD	ramipril, hydrochlorothiazide	tablets	5mg+25mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- packager, quality control, batch releaser, KRKA d.d., Novo mesto, Novomeskacesta 22, Sentjernej 8310, Slovenia- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22220 25.07.2024
4	Maviret	glecaprevir, pibrentasvir	tablets film-coated	100mg+40mg; (84(4x21(7x3)) in blister	AbbVie Deutschland GmbH & Co. KG, Knolstrasse, 67061 Ludwigshafen- packager, quality control, batch releaser, Fournier Laboratories Ireland Limited, Anngrove, Carrigtwohill, Co. Cork, Ireland- bulk manufacturer	Germany	AbbVie Biopharmaceuticals GmbH, Alte Steinhauserstrasse 14, 6330 Cham	Switzerland	PoM	22221 25.07.2024
5	Glycerin	glycerol	solution for local use (enema)	900mg/g; plastic container 5ml, plastic container 10ml	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	22222 25.07.2024

6	Tranexam	tranexamic acid	tablets film-coated	250mg; (10/1x10) in blister, (30/3x10) in blister	Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 3a/3- quality control (physicochemical), batch releaser, Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 107, Russia-bulk manufacturer, packager, Test center Farmoborona LTD., 46A, Gagarin st., Korolyov, Moscow Region, 141074, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	22223 25.07.2024
7	Tranexam	tranexamic acid	tablets film-coated	500mg; (10/1x10) in blister	Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 3a/3- quality control (physicochemical), batch releaser, Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 107, Russia-bulk manufacturer, packager, Test center Farmoborona LTD., 46A, Gagarin st., Korolyov, Moscow Region, 141074, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	22224 25.07.2024

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 07-2/24 on July 25, 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	Lizinopril	lisinopril (lisinopril dihydrate)	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	22225 25.07.2024
2	Lizinopril	lisinopril (lisinopril dihydrate)	tablets	20mg; (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	22226 25.07.2024
3	Metformin	metformin (metformin hydrochloride)	tablets film-coated	500mg; (30/3x10) in blister	Replek Farm Ltd. Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	Replek Farm Ltd. Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	PoM	22227 25.07.2024
4	Metformin	metformin (metformin hydrochloride)	tablets film-coated	1000mg; (30) glass bottle	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	22228 25.07.2024

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 07-2/24 on July 25, 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 (lipoid S 80), sodium glycyrrhizinate (glycyrrhizinic acid trisodium)	capsules	65mg+35mg; (50/5x10) in blister	Pharmstandard-Leksredstva OJSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva OJSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	19211/1/1 25.07.2024
2	Influcid	aconitum trit.D3, gelsemium trit.D3, ipecacuanha trit.D3, phosphorus trit.D5, bryonia trit. D2, eupatorium perfoliatum trit.D1	tablets	25mg+25mg+25mg+25mg+25mg; (40/2x20) in blister	Dr. Gustav Klein GmbH & Co. KG, Steinfeld 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, Steinfeld 3 Zell am Harmersbach, 77736	Germany	OTC	20728/1/1 25.07.2024

3	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	18937/1/1 25.07.2024
4	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	18936/1/1 25.07.2024
5	Azimac	azithromycin (azithromycin dihydrate)	capsules	250mg; (6/2x3) in blister	GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	18834/1/1 25.07.2024
6	Azimac	azithromycin (azithromycin dihydrate)	capsules	500mg; (3/1x3) in blister	GM Pharmaceuticals LTD, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	18835/1/1 25.07.2024

7	Hemastad-RN	tranexamic acid	solution for i/v injection	50mg/ml; (5) glass vials 20ml	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	PoM	19157/2/1 25.07.2024
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LIST

of variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting decision N
07-2/24 on July 25, 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	Citomed	citicoline (citicoline sodium)	solution oral	100mg/ml; glass bottle 30ml and measuring syringe, glass bottle 100ml and measuring syringe	Medical Horizon LLC, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	Medical Horizon LLC, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	PoM	004096 25.07.2024

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 07-2/24 on July 25, 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	Tafinlar	dabrafenib	capsules	75mg; (120) in plastic container	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos- packager, batch releaser, Glaxo Operations UK Ltd, Priory Street, Ware, Hertfordshire SG12 0DJ, UK- bulk manufacturer, quality control	Spain	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	18989/5/2 25.07.2024
2	Tafinlar	dabrafenib	capsules hard	75mg; (120) in plastic container	Lek Pharmaceuticals d.d. Verovskova Str. 57, 1526 Ljubljana- 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	20247/2 25.07.2024
3	Difluzol	fluconazole	capsules	150mg; (1) in blister	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	PoM	21981/1 25.07.2024
4	Cordarone	amiodarone (amiodarone hydrochloride)	tablets	200mg; (30/2x15/) in blister	Opella Healthcare Hungary Ltd., Levai u. 5., Veresegyhaz, 2112- bulk manufacturer, packager, quality control (physicochemical), batch releaser, EUROAPI Hungary Ltd., To utca 1-5, Budapest, 1045, Hungary- quality control (microbiological)	Hungary	Sanofi-Aventis Private Co. Ltd., 1045 Budapest, To u. 1-5	Hungary	PoM	20666/1/2 25.07.2024

5	Anaferon kids	affinity purified antibodies to human interferon gamma	drops oral	6mg/ml; 25ml glass vial-drop-per	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	17922/2 25.07.2024
6	Enterofuryl	nifuroxazide	capsules	100mg; (30/3x10) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	PoM	20382/3 25.07.2024
7	Enterofuryl	nifuroxazide	capsules	200mg; (16/2x8) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	PoM	20983/3 25.07.2024
8	Amprilan HD	ramipril, hydrochlorothiazide	tablets	5mg+25mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto-packager, batch releaser, KRKA d.d., Novo mesto, Novomeskacesta 22, Sentjernej 8310, Slovenia-bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	18672/2 25.07.2024
9	Esomeprazol SANDOZ 20mg	esomeprazole (esomeprazole magnesium dihydrate)	tablets gastro-resistant	20mg; (14/2x7) in blister, (28/4x7) in blister	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	19961/3 25.07.2024
10	Esomeprazol SANDOZ 40mg	esomeprazole (esomeprazole magnesium dihydrate)	tablets gastro-resistant	40mg; (14/2x7) in blister, (28/4x7) in blister	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	19962/3 25.07.2024
11	Clariscan	gadoteric acid	solution for injection	0,5mmol/ml; (10) glass vials 10ml	GE Healthcare AS-Oslo Plant, Nycov-eien 1, NO-0485 Oslo	Norway	GE Healthcare AS, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	PoM	20610/3 25.07.2024
12	Clariscan	gadoteric acid	solution for injection	0,5mmol/ml; (10) glass vials 15ml	GE Healthcare AS-Oslo Plant, Nycov-eien 1, NO-0485 Oslo	Norway	GE Healthcare AS, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	PoM	20611/3 25.07.2024

13	Clariscan	gadoteric acid	solution for injection	0,5mmol/ml; (10) glass vials 20ml	GE Healthcare AS-Oslo Plant, Nycov- eien 1, NO-0485 Oslo	Norway	GE Healthcare AS, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	PoM	20612/3 25.07.2024
14	Clariscan	gadoteric acid	solution for injection	0,5mmol/ml; (10) plastic bottles 50ml	GE Healthcare AS-Oslo Plant, Nycov- eien 1, NO-0485 Oslo	Norway	GE Healthcare AS, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	PoM	20613/3 25.07.2024
15	Clariscan	gadoteric acid	solution for injection	0,5mmol/ml, (10) plastic bottles 100ml	GE Healthcare AS-Oslo Plant, Nycov- eien 1, NO-0485 Oslo	Norway	GE Healthcare AS, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	PoM	20615/3 25.07.2024
16	Furazolidon	furazolidone	tablets	50mg; (10) in strip	Irbitskiy himfarmzavod OJSC, 124-a, K. Marksa str., Irbit, St. Sverdlovsk, 623856	Russia	Irbitskiy himfarm- zavod OJSC, 172, Kirova str., Irbit, St. Sverdlovsk, 623856	Russia	PoM	18489/1 25.07.2024
17	Tantum Verde	benzydamine (benzydamine hydrochloride)	lozenges	3mg; (20/2x10), in pack	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A., Via Vecchia del Pinocchio, 22, 60100 Ancona- quality control, batch releaser, Disch AG, Bahnhofstrasse 21, 5504 Othmarsingen, Switzerland- bulk manufacturer, packager	Italy	Angelini Pharma S.p.A. Viale Amelia, 70-00181 Rome	Italy	OTC	19983/4/1 25.07.2024
18	Ketonal	ketoprofen	cream for external use	50mg/g; aluminium tube 30g	Salutas Pharma GmbH, Lange Goehren 3, 39171 Osterweddingen	Germany	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19812/3 25.07.2024
19	Glycerin	glycerol	suppositories rectal	1000mg; (10/2x5/)	Medical Horizon Ltd, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	Medical Horizon Ltd, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	OTC	18853/1 25.07.2024
20	Glycerin	glycerol	suppositories rectal	2110mg; (10/2x5/)	Medical Horizon Ltd, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	Medical Horizon Ltd, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	OTC	18854/1 25.07.2024

21	Lizinopril	lisinopril (lisinopril dihydrate)	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	18571/1 25.07.2024
22	Lizinopril	lisinopril (lisinopril dihydrate)	tablets	20mg; (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	18572/1 25.07.2024
23	Tranexam	tranexamic acid	tablets film-coated	250mg; (10/1x10/) in blister, (30/3x10/) in blister	Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 107- bulk manufacturer, packager, Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 3a/3, Russia- quality control (physico-chemical), batch releaser, Test center Â«FARMOBORONAÂ» LTD., 46A, Gagarin st., Korolyov, Moscow Region, 141074, Russia - quality control (microbiological)	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	18484/4/1 25.07.2024
24	Tranexam	tranexamic acid	tablets film-coated	500mg; (10/1x10/) in blister	Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 107- bulk manufacturer, packager, Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 3a/3, Russia- quality control (physicochemical), batch releaser, Test center Â«FARMOBORONAÂ» LTD., 46A, Gagarin st., Korolyov, Moscow Region, 141074, Russia - quality control (microbiological)	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	18485/4/1 25.07.2024
25	Metformin	metformin (metformin hydrochloride)	tablets film-coated	500mg; (30/3x10/) in blister	REPLEK FARM Ltd. Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	REPLEK FARM Ltd. Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	PoM	18926/1 25.07.2024
26	Metformin	metformin (metformin hydrochloride)	tablets film-coated	1000mg; (30) glass bottle	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	18927/1 25.07.2024

27	Hexaxim	diphtheria toxoid, tetanus toxoid, pertussis toxoid/filamentous haemagglutinin, poliovirus types 1/2/3, hepatitis B surface antigen, haemophilus influenzae type b polysaccharide, haemophilus influenzae type b polysaccharide conjugated to tetanus protein	suspension for injection	20IU/0,5ml+40IU/0,5ml+25/25mcg/0,5ml+40/8/32 DU/0,5ml+10mcg/0,5ml+12mcg/0,5ml+22-36mcg/0,5ml; (10) glass vials 0,5ml	Sanofi Pasteur, Parc Industriel d' Incarville, 27100 Val de Reuil	France	Sanofi Pasteur, 14 Espace Henry Vallee, 69007 Lyon	France	PoM	20298/8 25.07.2024
28	Hexaxim	diphtheria toxoid, tetanus toxoid, pertussis toxoid/filamentous haemagglutinin, poliovirus types 1/2/3, hepatitis B surface antigen, haemophilus influenzae type b polysaccharide, haemophilus influenzae type b polysaccharide conjugated to tetanus protein	suspension for injection	20IU/0,5ml+40IU/0,5ml+25/25mcg/0,5ml+40/8/32 DU/0,5ml+10mcg/0,5ml+12mcg/0,5ml+22-36mcg/0,5ml; pre-filled syringe 0,5ml and (2) needles	Sanofi Pasteur, Parc Industriel d' Incarville, 27100 Val de Reuil	France	Sanofi Pasteur, 14 Espace Henry Vallee, 69007 Lyon	France	PoM	20299/8 25.07.2024

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 07-2/24 on July 25, 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	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 25.07.2024
2	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 25.07.2024
3	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 25.07.2024
4	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 25.07.2024

5	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 25.07.2024
6	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 25.07.2024
7	Salbutamol	salbutamol (salbutamol sulfate)	tablets	2mg; (30/2x15) in blister	Pharmaceutical Works Polpharma S.A. Production Department in Nowa Deba, 2 Metalowca St, 39-460 Nowa Deba	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	PoM	005171 25.07.2024
8	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 25.07.2024