

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 10-1/24 on October 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	Ondansetron	ondansetron (ondansetron hydrochloride dihydrate)	tablets film-coated	8mg; (30/3x10) 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	22377 16.10.2024
2	Ibuprofen-Asteria	ibuprofen	tablets film-coated	600mg; (60/6x10) in blister	Medinfar Manufacturing S.A, Parque Industrial Armando Martins Tavares, Rua Outeiro Da Armada No 5, Condeixa-A-Nova, 3150-194	Portugal	Asteria LLC, 72/3 Nairi Zaryan, 0051 Yerevan	Republic of Armenia	PoM	22408 16.10.2024

LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 10-1/24 on October 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	Lidocain	lidocaine	spray for topical and external use	4,6mg/dose; 38g glass vial with measuring pump	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	22382 (005280) 16.10.2024
2	Skopryl	lisinopril (lisinopril dihydrate)	tablets	10mg; (20/2x10) in blister, (30/3x10) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	22383 (00621) 16.10.2024
3	Skopryl	lisinopril (lisinopril dihydrate)	tablets	20mg; (20/2x10) in blister, (30/3x10) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	22384 (00621) 16.10.2024
4	Vitaprost	prostate extract	suppositories rectal	10mg; (10/2x5)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	22385 (000790) 16.10.2024
5	Neobutin	trimebutin	tablets	100mg; (10/1x10) in blister	Alium AO, build. 1, No: 2, Quarter A, Obolensk settlement, Serpukhov urban district, 142279, Moscow reg.- batch releaser, Alium AO, No: 2, Quarter A, Obolensk settlement, Serpukhov urban district, 142279, Moscow region, Russia- bulk manufacturer, packager, quality control	Russia	Alium AO, No: 2, Quarter A, Obolensk settlement, Serpukhov urban district, 142279, Moscow region	Russia	PoM	22386 (007161) 16.10.2024

6	Neobutin	trimebutin	tablets	200mg; (30/3x10) in blister	Alium AO, build. 1, No: 2, Quarter A, Obolensk settlement, Serpukhov urban district, 142279, Moscow reg. - batch releaser, Alium AO, No: 2, Quarter A, Obolensk settlement, Serpukhov urban district, 142279, Moscow region, Russia-bulk manufacturer, packager, quality control	Russia	Alium AO, No: 2, Quarter A, Obolensk settlement, Serpukhov urban district, 142279, Moscow region	Russia	PoM	22387 (007161) 16.10.2024
7	Elocom	mometasone (mometasone furoate)	cream	1mg/g; 15g aluminium tube	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	22388 (000421) 16.10.2024
8	Elocom	mometasone (mometasone furoate)	ointment	1mg/g; 15g aluminum tube	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	22389 (000422) 16.10.2024
9	Bioson	dry extract of passiflora, doxylamine (doxylamine hydrogen succinate)	tablets film-coated	300mg+3,75mg; (10/1x10) in blister, (30/3x10) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev for Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev, Ukraine	Ukraine	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	OTC	22380 (007667) 16.10.2024
10	Brimoptic	timolol (timolol maleate), brimonidine (brimonidine tartrate)	drops eye	5mg/ml+2mg/ml; vial-drop-per 10ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	22381 (011917) 16.10.2024
11	ZEToptic	timolol (timolol maleate), brinzolamide	drops eye (suspension)	5mg/ml+10mg/ml; plastic vial 5ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	22379 (013499) 16.10.2024

LIST

of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 10-1/24 on October 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	Sunlenca	lenacapavir(lenacapavir sodium)	tablets film-coated	300mg; (5/1x5) in blister	Gilead Sciences Ireland UC, IDA Business and Technology Park, Carrigtohill- batch releaser, Rottendorf Pharma GmbH, Ostfelder Strasse 51-61, 59320, Germany- bulk manufacturer, Packaging Coordinators LLC, 3001 Red Lion Road, Philadelphia, Pennsylvania, 19114, USA- packager, 1.Rottendorf Pharma GmbH, Ostfelder Strasse 51-61, 59320, Germany, 2.Gilead Sciences Ireland UC, IDA Business and Technology Park, Carrigtohill, Ireland- quality control (physicochemical), SGS Institut Fresenius GmbH, Im Maisel 14, Taunusstein, 65232, Germany- quality control (microbiological)	Ireland	Gilead Sciences Ireland UC, IDA Business and Technology Park, Carrigtohill T45 DP77	Ireland	PoM	22390 16.10.2024

2	Sunlenca	lenacapavir(lenacapavir sodium)	solution for injection	464mg; (2) glass vials 1,5ml, (2) vial access devices, (2) disposable syringes and (2) injection safety needles in a tray	Gilead Sciences Ireland UC, IDA Business and Technology Park, Carrigtohill- batch releaser, Patheon Italia S.p.A., Viale Gian Battista Stucchi 110, 20900 Monza, Italy- bulk manufacturer, primary packager, quality control (microbiological), Packaging Coordinators LLC, 3001 Red Lion Road, Philadelphia, Pennsylvania, 19114, USA- secondary packager, 1.Patheon Italia S.p.A., Viale Gian Battista Stucchi 110, 20900 Monza, Italy, 2.Gilead Sciences Ireland UC, IDA Business and Technology Park, Carrigtohill, Ireland- quality control (physicochemical)	Ireland	Gilead Sciences Ireland UC, IDA Business and Technology Park, Carrigtohill T45 DP77	Ireland	PoM	22391 16.10.2024
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of the medicines recommended for the re-registration by the Center according to the meeting decision N 10-1/24 on October 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	Angiovit-AV	folic acid, pyridoxine (pyridoxine hydrochloride), cyanocobalamin	tablets film-coated	5mg+4mg+0,006mg; (50/5x10) in blister	Altayvitaminy JSC, 659325, Altay region, Biysk, st. Zavodskaya, 69	Russia	Altayvitaminy JSC, 659325, Altay region, Biysk, st. Zavodskaya, 69	Russia	OTC	22392 16.10.2024
2	Neoderm	gramicidin, neomycin (neomycin sulfate), nystatin, triamcinolone acetonide	cream	0,25mg/g+2,5mg/g+100000IU/g+1mg/g; aluminium tube 10g; aluminium tube 20g	Birzeit Pharmaceutical Company (BPC), Ramallah, Industrial Zone	Palestine	Pharmacare Int. Co/German Palestinian Joint Venture, Jerusalem, P.O. box 51621	Palestine	PoM	22393 16.10.2024
3	Biemexol	iohexol	solution for injection	350mg iodine/ml; glass vial100ml	IDOL ILAC DOLUM SAN.ve TIC.A.S. Davutpasa Cad.CebeAli Bey Sok.No:20 Zeytinburnu/ ISTANBUL/	Turkey	Biem ilac San. Ve Tic.A.S. Anittepe Mah.Turgut Reis Cad. No:21 , Tandogan/Cankaya-Ankara/	Turkey	PoM	22394 16.10.2024
4	Clopidogrel-Asteria	clopidogrel (clopidogrel bisulfate)	tablets film-coated	75mg; (28/4x7) in blister	ONE PHARMA INDUSTRIAL PHARMACEUTICAL COMPANY SOCIETE ANONYME, 60th km N.N.R. Athinon-Lamias, Sximatari Voiotias, 32009	Greece	VIAN S.A., 2, Ag. Nektariou str., 15344 Gerakas, Pallini Attiki	Greece	PoM	22395 16.10.2024
5	Azithromycin-Asteria	azithromycin (azithromycin dihydrate)	tablets film-coated	250mg; (6/1x6) in blister	ONE PHARMA INDUSTRIAL PHARMACEUTICAL COMPANY SOCIETE ANONYME, 60th km N.N.R. Athinon-Lamias, Sximatari Voiotias, 32009	Greece	VIAN S.A., 2, Ag. Nektariou str., 15344 Gerakas, Pallini Attiki	Greece	PoM	22396 16.10.2024
6	Azithromycin-Asteria	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3) in blister	ONE PHARMA INDUSTRIAL PHARMACEUTICAL COMPANY SOCIETE ANONYME, 60th km N.N.R. Athinon-Lamias, Sximatari Voiotias, 32009	Greece	VIAN S.A., 2, Ag. Nektariou str., 15344 Gerakas, Pallini Attiki	Greece	PoM	22397 16.10.2024

7	Demiflu Forte	paracetamol	tablets	1000mg; (20/2x10/) in blister, (40/4x10/) in blister, (60/6x10/) in blister	Farmalabor- Produtos Farmaceuticos, S.A. Zona Industrial de Condeixa-a-Nova, Condeixa-a-Nova, 3150-194	Portugal	Demi Pharm Griboyedovi 12,ap. 25, Sevan 1501	Republic of Armenia	PoM	22398 16.10.2024
8	Brilliant green	brilliant green	solution for external use	10mg/ml; glass bottle 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	22399 16.10.2024
9	Loperamide	loperamide (loperamide hydrochloride)	capsules	2mg; (10/1x10/) in blister	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	22400 16.10.2024
10	Januvia	sitagliptin (sitagliptin phosphate hydrate)	tablets film-coated	100mg; (28/2x14) in blister	Organon Pharma (UK) Limited, Shotton Lane, Cramlington, Northumberland NE23 3JU	UK	Merck Sharp & Dohme IDEA GmbH, Tribschenstrasse 60, 6005 Luzern	Switzerland	PoM	22401 16.10.2024

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 10-1/24 on October 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	Sulphaprim	sulfamethoxazole, trimethoprim	suspension oral	200mg/5ml+40mg/5ml; glass bottle 100ml and measuring cup	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	PoM	22402 16.10.2024
2	Oxaliplatin Ebewe concentrate for solution for infusion 5 mg/ml	oxaliplatin	concentrate for solution for infusion	5mg/ml; 10ml glass vial	Fareva Unterach GmbH, Mondseestrasse 11, A-4866 Unterach am Attersee- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological)	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	22403 16.10.2024
3	Oxaliplatin Ebewe concentrate for solution for infusion 5mg/ml	oxaliplatin	concentrate for solution for infusion	5mg/ml; 20ml glass vial	Fareva Unterach GmbH, Mondseestrasse 11, A-4866 Unterach am Attersee- batch releaser, bulk manufacturer, packager, quality control (physicochemical), Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological, sterility)	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	22404 16.10.2024
4	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	22405 16.10.2024
5	Enalapril	enalapril (enalapril maleate)	tablets	20mg; (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	22406 16.10.2024
6	Azitrom-Replek	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3) 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	22407 16.10.2024

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 10-1/24 on October 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	Oxaliplatin Ebewe concentrate for solution for infusion 5 mg/ml	oxaliplatin	concentrate for solution for infusion	5mg/ml; 10ml glass vial	Fareva Unterach GmbH, Mondseestrasse 11, A-4866 Unterach am Attersee- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LSSE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological)	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	18998/2/1 16.10.2024
2	Oxaliplatin Ebewe concentrate for solution for infusion 5mg/ml	oxaliplatin	concentrate for solution for infusion	5mg/ml; 20ml glass vial	Fareva Unterach GmbH, Mondseestrasse 11, A-4866 Unterach am Attersee- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LSSE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological)	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	18999/2/1 16.10.2024

3	Metformin	metformin (metformin hydrochloride)	tablets film-coated	500mg; (30/3x10) 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	20702/2/2 16.10.2024
4	Metformin	metformin (metformin hydrochloride)	tablets film-coated	850mg; (30/3x10) 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	20703/2/2 16.10.2024
5	Metformin	metformin (metformin hydrochloride)	tablets film-coated	1000mg; (30/3x10) 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	20704/2/2 16.10.2024
6	Dicynone	etamsylate	tablets	250mg; (100/10x10) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Novartis Pharmaceutical Manufacturing LLC, Verovskova Str. 57, 1000 Ljubljana, Slovenia- bulk manufacturer, quality control (physicochemical), Lek Pharmaceuticals d.d., Verovskova ulica 57, Ljubljana, 1526, Slovenia- quality control (microbiological)	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	20984/1/1 16.10.2024

7	Sartuzin-Neo	fluoxetine (fluoxetine hydrochloride)	capsules hard	20mg; (12/3x4) in blister, (28/4x7) in blister	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., 14452 Metamorphosis, Attica	Greece	PoM	21850/1/1 16.10.2024
8	Adaptol	temgicoluril	capsules	300mg; (20/2x10) in blister, (30/3x10) in blister, (40/4x10) in blister	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	PoM	20547/1/1 16.10.2024
9	Adaptol	temgicoluril	tablets	500mg; (20/2x10) in blister	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	PoM	20597/1/1 16.10.2024
10	Loranex	desloratadine	tablets film-coated	5mg; (10/1x10) in blister	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	19474/2/1 16.10.2024
11	Orlobin-NEO	amikacin (amikacin sulfate)	solution for injection/infusion	500mg/2ml; glass vial	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Medicus S.A., 10 Valaoritou str., GR 144 52, Metamorfofi, Attiki	Greece	PoM	21414/2/2 16.10.2024

12	Upsarin Upsa with vitamin C	acetylsalicylic acid, ascorbic acid	tablets effervescent	330mg+200mg; (20/2x10) in plastic container	UPSA SAS, 979, avenue des Pyrenees, 47520 Le Passage	France	UPSA SAS, 3, rue Joseph Monier- 92500 Rueil- Malmaison	France	OTC	19408/4/1 16.10.2024
13	Bixitor 60mg	etoricoxib	tablets film-coated	60mg; (30/3x10) in blister	Hemofarm LLC, 249035, Obninsk, Kaluga Region, 62 Kievskoye shosse- packager, quality control (physicochemical), batch releaser, AET Laboratories Private Ltd., Survey No.42, Gaddapotharam Village, Kazipally Industrial Area, Sangareddy District Telangana State, 502319, India- bulk manufacturer, Farmoborona LLC, 46a Gagarina street, Korolev, Moscow Region 141074, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	21068/1/1 16.10.2024
14	Bixitor 90mg	etoricoxib	tablets film-coated	90mg; (30/3x10) in blister	Hemofarm LLC, 249035, Obninsk, Kaluga Region, 62 Kievskoye shosse- packager, quality control (physicochemical), batch releaser, AET Laboratories Private Ltd., Survey No.42, Gaddapotharam Village, Kazipally Industrial Area, Sangareddy District Telangana State, 502319, India- bulk manufacturer, Farmoborona LLC, 46a Gagarina street, Korolev, Moscow Region 141074, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	21069/1/1 16.10.2024
15	Bixitor 120mg	etoricoxib	tablets film-coated	120mg; (10/1x10) in blister	Hemofarm LLC, 249035, Obninsk, Kaluga Region, 62 Kievskoye shosse- packager, quality control (physicochemical), batch releaser, AET Laboratories Private Ltd., Survey No.42, Gaddapotharam Village, Kazipally Industrial Area, Sangareddy District Telangana State, 502319, India- bulk manufacturer, Farmoborona LLC, 46a Gagarina street, Korolev, Moscow Region 141074, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	21070/1/1 16.10.2024

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 10-1/24 on October 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	Naratriptan	naratriptan (naratriptan hydrochloride)	tablets film-coated	2,5mg; (2/1x2) in blister, (6/1x6) in blister	Chanelle Medical Unlimited Company, Dublin Road Loughrea, Co. Galway- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Complete Laboratory Solutions, Units 3A & 8 Ida Small Business Centre Tuam Road, Galway, H91 H520, Ireland- quality control (microbiological)	Ireland	ARGO-PHARM LLC, 13/9 Sundukyan str., 0012 Yerevan	Republic of Armenia	PoM	21694/1 16.10.2024
2	Rotarix	human rotavirus vaccine live	suspension oral	not less than 10 ⁶ CCID ⁵⁰ /dose; (50) plastic tube 1.5ml (1 dose)	GlaxoSmithKline Biologicals s.a., Rue de l' Institut, 89 B-1330 Rixensart-batch releaser, GlaxoSmithKline 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	20908/3 16.10.2024
3	Clovate	clobetasol (clobetasol propionate)	ointment for external use	0,5mg/g aluminium tube 25g	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	BauschHealth LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	PoM	19604/3 16.10.2024
4	Grinterol	ursodeoxycholic acid	capsules	250mg; (50/5x10) in blister, (100/10x10) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	20575/1 16.10.2024
5	Linkus lozenges	adhadota vasica, glycyrrhiza glabra, piper longum, viola odorata, hyssopus officinalis, alpinia galanga	lozenges with honey and lemon flavour	30mg+7mg+6mg+2mg+3mg+3mg; (16/2x8) blisters	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	OTC	18598/1 16.10.2024

6	Linkus lozenges	adhadota vasica, glycyrrhiza glabra, piper longum, viola odorata, hyssopus officinalis, alpinia galanga	lozenges with mint flavour	30mg+7mg+6mg+2mg+3mg+3mg; (16/2x8) blisters	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	OTC	18597/1 16.10.2024
7	Linkus lozenges	adhadota vasica, glycyrrhiza glabra, piper longum, viola odorata, hyssopus officinalis, alpinia galanga	lozenges with orange flavour	30mg+7mg+6mg+2mg+3mg+3mg; (16/2x8) in blister	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	OTC	18596/1 16.10.2024
8	Angiovit-AV	folic acid, pyridoxine (pyridoxine hydrochloride), cyanocobalamin	tablets film-coated	5mg+4mg+0.006mg; (50/5x10) in blister	Altayvitaminy JSC, 659325, Altay region, Biysk, st. Zavodskaya, 69	Russia	Altayvitaminy JSC, 659325, Altay region, Biysk, st. Zavodskaya, 69	Russia	OTC	18787/2/1 16.10.2024
9	Drotaverine	drotaverine (drotaverine hydrochloride)	solution for i/v and i/m injection	20mg/ml; (10) ampoules 2ml, (10) ampoules 2ml label banderol, (10) ampoules 2ml dividella	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	21060/2 16.10.2024
10	Nolicin	norfloxacin	tablets film-coated	400mg; (20/2x10) 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	21033/1 16.10.2024
11	Sulphaprim	sulfamethoxazole, trimethoprim	suspension oral	200mg/5ml+40mg/5ml; glass bottle 100ml and measuring cup	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	PoM	18891/1 16.10.2024
12	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	21730/3 16.10.2024
13	Rexetin	paroxetine (paroxetine hydrochloride hemihydrate)	tablets film-coated	20mg; (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	20214/2 16.10.2024

14	Verapress MR 240 Tablets	verapamil (verapamil hydrochloride)	tablets modified-release	240mg; (28/2x14) in blister	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields Industrial Estate, Daventry, NN11 8PB- batch releaser, Dexcel Ltd., 1 Dexcel Street, Or-Akiva 3060000, Israel- bulk manufacturer, packager, quality control (physicochemical), The Institute for Food Microbiology and Consumer Goods Ltd.,9 HaShalom Road, Nesher, Israel- quality control (microbiological)	UK	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields Industrial Estate, Daventry, NN11 8PB	UK	PoM	21533/1 16.10.2024
15	Ascorbic acid with glucose	ascorbic acid, dextrose (dextrose monohydrate)	tablets	100mg+877mg; (10) in strip, (40) in plastic container	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	OTC	21239/1 16.10.2024
16	Clopidogrel-Asteria	clopidogrel (clopidogrel bisulfate)	tablets film-coated	75mg; (28/4x7) in blister	ONE PHARMA INDUSTRIAL PHARMACEUTICAL COMPANY SOCIETE ANONYME, 60th km N.N.R. Athinon-Lamias, Sximatari Voiotias, 32009	Greece	VIAN S.A., 2, Ag. Nektariou str., 15344 Gerakas, Pallini Attiki	Greece	PoM	18701/5/2 16.10.2024
17	Azithromycin-Asteria	azithromycin (azithromycin dihydrate)	tablets film-coated	250mg; (6/1x6) in blister	ONE PHARMA INDUSTRIAL PHARMACEUTICAL COMPANY SOCIETE ANONYME, 60th km N.N.R. Athinon-Lamias, Sximatari Voiotias, 32009	Greece	VIAN S.A., 2, Ag. Nektariou str., 15344 Gerakas, Pallini Attiki	Greece	PoM	18416/4/1 16.10.2024
18	Azithromycin-Asteria	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3) in blister	ONE PHARMA INDUSTRIAL PHARMACEUTICAL COMPANY SOCIETE ANONYME, 60th km N.N.R. Athinon-Lamias, Sximatari Voiotias, 32009	Greece	VIAN S.A., 2, Ag. Nektariou str., 15344 Gerakas, Pallini Attiki	Greece	PoM	18417/4/1 16.10.2024
19	Biemexol	iohexol	solution for injection	350mg iodine/ml; glass vial100ml	IDOL ILAC DOLUM SAN.ve TIC.A.S. Davutpasa Cad.CebeAli Bey Sok.No:20 Zeytinburnu/ ISTANBUL/	Turkey	Biem ilac San. Ve Tic.A.S. Anittepe Mah.Turgut Reis Cad. No:21 , Tandogan/Can-kaya-Ankara	Turkey	PoM	18262/1 16.10.2024
20	Korold-Asteria	paracetamol, pseudoephedrine (pseudoephedrine hydrochloride), chlorphenamine (chlorphenamine maleate)	tablets film-coated	500mg+30mg+2mg (20/2x10) and (100/10x10) in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-Si, Chungcheongbuk-do	Repeblic of Korea	Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan	Republic of Armenia	OTC	18757/2/1 16.10.2024

21	Bromhexin	bromhexine (bromhexine hydrochloride)	tablets	8mg; (20/1x20) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	21839/1 16.10.2024
22	Floxadex	ciprofloxacin (ciprofloxacin hydrochloride), dexamethasone	suspension eye/ear	3mg/ml+1mg/ml; plastic vial-dropper 10ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	19282/1 16.10.2024
23	Enalapril	enalapril (enalapril maleate)	tablets	20mg; (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	18932/1 16.10.2024
24	Glycerin	glycerol	solution for external use	900mg/g; glass vial 30ml, plastic vial 100ml	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	19011/1 16.10.2024
25	Azitrom-Replek	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3) 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	18691/1 16.10.2024
26	Brilliant green	brilliant green	solution for external use	10mg/ml; glass bottle 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	18945/2 16.10.2024
27	Loperamide	loperamide (loperamide hydrochloride)	capsules	2mg; (10/1x10) in blister	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	18886/2 16.10.2024
28	Tamoxifen	tamoxifen (tamoxifen citrate)	tablets film-coated	20mg; (30/3x10) in blister	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	20665/1 16.10.2024
29	Fastenal	ketoprofen lysine salt	powder for oral solution	80mg; (30) biparte sachets 2g	SPECIAL PRODUCT`S LINE S.P.A., Via Fratta Rotonda Vado Largo,1-03012 Anagni (FR)	Italy	UAB «MRA», Totoriu str. 20-9, LT-01121 Vilnius	Republic of Lithuania	PoM	20471/3 16.10.2024

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 10-1/24 on October 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	Kaporiza	rizatriptane (rizatriptane benzoate)	orodispersible tablets	10mg; (2/1x2) in blister, (6/1x6) in blister	Emcure Pharmaceuticals Ltd., Plot No. P-1 & P-2, I.T.B.T., Park Phase-II, M.I.D.C., Hinjwadi, Pune-411057	India	«Sotex»PharmFirm» CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	PoM	001129 16.10.2024
2	Alecenza	alectinib (alectinib hydrochloride)	capsules hard	150mg; (56/8x7) in blister, (224/4x56) in blister	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4058 Basel- batch releaser, Excella GmbH & Co. KG, Nummerger Strasse 12, 90537 Feucht, Germany- bulk manufacturer, Delpharm Milano S.r.l, Via Carnevale 1, 20054 Segrate, Milano, Italy- packager, quality control	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4070 Basel	Switzerland	PoM	000150 16.10.2024
3	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	006443 16.10.2024