

## LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 12-1/24 on December 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	COCLAV	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	500mg+125mg; (12/2x6) in blister	LABORATORIO REIG JOFRE, S.A., Calle Del Rio Jarama 111, Toledo, 45007	Spain	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	22552 16.12.2024
2	COCLAV	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	875mg+125mg; (12/2x6) in blister	LABORATORIO REIG JOFRE, S.A., Calle Del Rio Jarama 111, Toledo, 45007	Spain	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	22553 16.12.2024
3	Sanovask	acetylsalicylic acid	tablets film-coated	75mg; (30/3x10) in blister, (60/6x10) in blister	Irbitskiy himfarmzavod OJSC, 124-a, K. Marksa str., Irbit, St. Sverdlovsk, 623856	Russia	Avexima OJSC, 31A/1, Leningradsky pr., Moscow, 125284	Russia	OTC	22554 16.12.2024
4	Sanovask	acetylsalicylic acid	tablets film-coated	100mg; (30/3x10) in blister, (60/6x10) in blister	Irbitskiy himfarmzavod OJSC, 124-a, K. Marksa str., Irbit, St. Sverdlovsk, 623856	Russia	Avexima OJSC, 31A/1, Leningradsky pr., Moscow, 125284	Russia	OTC	22555 16.12.2024
5	TAVEGYL	clemastine (clemastine fumarate)	tablets	1mg; (20/1x20) in blister, (20/2x10) in blister	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb- packager, quality control, batch releaser, Hemofarm d.o.o., Novakovici bb, Banja-Luka 78000, Bosnia and Herzegovina- bulk manufacturer	Serbia	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	OTC	22556 16.12.2024
6	Femara	letrozole	tablets film-coated	2,5mg; (30/3x10) in blister	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22557 16.12.2024
7	Novex Cetirizine	cetirizine (cetirizine dihydrochloride)	tablets film-coated	10mg; (10/1x10) in blister	Herbion Pakistan Pvt. Ltd., Industrial Triangle, Kahuta Road, Humak, Islamabad	Pakistan	Herbion Pakistan Pvt. Ltd., Plot 30, Sector 28, Korangi Industrial Area, Karachi 74900	Pakistan	OTC	22558 16.12.2024

## LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision NN 12-1/24 on December 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	Rozamet	metronidazole	cream for external use	10mg/g; aluminum tube 25g	JADRAN-GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	JADRAN-GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	OTC	22566 (012145) 16.12.2024
2	Alotendin	bisoprolol (bisoprolol fumarate), amlodipine (amlodipine besilate)	tablets	5mg+5mg; (28/4x7) in blister, (30/3x10) in blister, (56/8x7) in blister, (90/9x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22567 (003658) 16.12.2024
3	Alotendin	bisoprolol (bisoprolol fumarate), amlodipine (amlodipine besilate)	tablets	5mg+10mg; (28/4x7) in blister, (30/3x10) in blister, (56/8x7) in blister, (90/9x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22568 (003658) 16.12.2024
4	Alotendin	bisoprolol (bisoprolol fumarate), amlodipine (amlodipine besilate)	tablets	10mg+5mg; (28/4x7) in blister, (30/3x10) in blister, (56/8x7) in blister, (90/9x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22569 (003658) 16.12.2024
5	Alotendin	bisoprolol (bisoprolol fumarate), amlodipine (amlodipine besilate)	tablets	10mg+10mg; (28/4x7) in blister, (30/3x10) in blister, (56/8x7) in blister, (90/9x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	22570 (003658) 16.12.2024
6	Atoris	atorvastatin (atorvastatin calcium)	tablets film-coated	40mg; (30/3x10) in blister, (60/6x10) in blister, (90/9x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	22571 (001894) 16.12.2024

7	Pronoran	piribedil	tablets prolonged-release coated	50mg; (30/2x15) in blister, (30/1x30) in blister	Les Laboratoires Servier Industrie, 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot 92284 Suresnes Cedex	France	PoM	22572 (008611) 16.12.2024
8	Pronoran	piribedil	tablets prolonged-release coated	50mg; (29/1x29) in blister, (30/1x30) in blister	«SERVIER RU»S Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes Cedex	France	PoM	22573 (008611) 16.12.2024
9	Pronoran	piribedil	tablets prolonged-release coated	50mg; (29/1x29) in blister, (30/1x30) in blister	«SERVIER RU» 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	22574 (008611) 16.12.2024
10	Emanera	esomeprazole (esomeprazole magnesium)	capsules gastro-resistant	20mg; (7/1x7) in blister, (14/2x7) in blister, (28/4x7) in blister, (56/8x7) 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	22575 (005563) 16.12.2024
11	Emanera	esomeprazole (esomeprazole magnesium)	capsules gastro-resistant	40mg; (7/1x7) in blister, (14/2x7) in blister, (28/4x7) in blister, (56/8x7) 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	22576 (005563) 16.12.2024
12	Zoloft	sertraline (sertraline hydrochloride)	tablets film-coated	50mg; (14/1x14) in blister; (28/2x14) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	22577 (006180) 16.12.2024
13	Zoloft	sertraline (sertraline hydrochloride)	tablets film-coated	100mg; (14/1x14) in blister; (28/2x14) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	22578 (006180) 16.12.2024
14	Ekvator	lisinopril (lisinopril dihydrate), amlodipine (amlodipine besilate)	tablets	10mg+5mg; (10/1x10) in blister, (30/3x10) in blister, (60/6x10) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22579 (007898) 16.12.2024

15	Ekvator	lisinopril (lisinopril dihydrate), amlodipine (amlodipine besilate)	tablets	10mg+5mg; (10/1x10) in blister, (30/3x10) in blister, (60/6x10) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoe, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, batch releaser, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoe, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoe, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoe, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22580 (007898) 16.12.2024
16	Rigevidon	levonorgestrel, ethinylestradiol	tablets coated	0,15mg+0,03mg; (21/1x21) in blister, (63/3x21) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22581 (003330) 16.12.2024
17	Flavamed effervescent tablets	ambroxol (ambroxol hydrochloride)	tablets effervescent	60mg; (10) plastic container	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- batch releaser, Hermes Pharma GmbH, Hans-Urmiler Ring 52, 82515 Wolfratshausen, Germany- bulk manufacturer, packager, quality control	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	OTC	22564 (009427) 16.12.2024
18	Motonium AVVA RUS	domperidone	film-coated tablets	10mg; (30/3x10) in blister	AVVA RUS JSC, Kirov region, Kirov city, Luganskaya Str. 53A	Russia	TOO «AVVA Kazakhstan», 050008, city Almaty, Almaty region, Abaya avenue, 109B, room 501	Republic of Kazakhstan	PoM	22565 (016088) 16.12.2024
19	Tadexim	tadalafil	tablets film-coated	5mg; (14/1x14) in blister, (28/2x14) in blister	Severnaya Zvezda CJSC, Leningradsky region, Vsevolozhsky dist., Kuzmolovskiy u. st., bld. 4, b. 1, Kuzmolovsk- batch releaser, Severnaya Zvezda CJSC, Leningradsky region, Vsevolozhsky dist., Kuzmolovskiy u. st., Kuzmolovsk, Russia- bulk manufacturer, packager, quality control	Russia	Immunofarm LLC, 0014, Yerevan, Hrachya Nersisyan St., 10-3/1 Building	Republic of Armenia	PoM	22562 (012334) 16.12.2024
20	Tadexim	tadalafil	tablets film-coated	20mg; (2/1x2) in blister, (4/1x4) in blister	Severnaya Zvezda CJSC, Leningradsky region, Vsevolozhsky dist., Kuzmolovskiy u. st., bld. 4, b. 1, Kuzmolovsk- batch releaser, Severnaya Zvezda CJSC, Leningradsky region, Vsevolozhsky dist., Kuzmolovskiy u. st., Kuzmolovsk, Russia- bulk manufacturer, packager, quality control	Russia	Immunofarm LLC, 0014, Yerevan, Hrachya Nersisyan St., 10-3/1 Building	Republic of Armenia	PoM	22563 (012334) 16.12.2024

## LIST

of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 12-1/24 on  
December 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	Capecitabine 500mg Film-Coated Tablets	capecitabine	tablets film-coated	500mg; (120/12x10) in blister	Betapharm Arzneimittel GmbH, Kobelweg 95, Augsburg, 86156- batch release, Dr. Reddy's Laboratories Ltd., Formulations Unit-VII, Plot No. P1 to P9, Phase-III, VSEZ, Duvvada, Vishakapatnam District, 530 046, Andhra Pradesh, India- bulk manufacturer, packager, quality control	Germany	Dr. Reddy's Laboratories (UK) Ltd., 410 Cambridge Science Park Milton Road, Cambridge CB4 0PE	UK	PoM	22582 16.12.2024
2	THYLO	dymethyl fumarate	capsules delayed-release	120mg; (14) plastic container	Amneal Pharmaceuticals Pvt. Ltd., Survey No. 634, 637 to 641, Near Hotel Kankavati, Sarkhej-Bavla Highway Vill. Rajota, Tal.-Bavla, Dist.-Ahmedabad, 382 220, Gujarat State	India	Amneal EU Limited, Cahir Road, Cashel, Co. Tipperary E25 XD51	Ireland	PoM	22583 16.12.2024
3	THYLO	dymethyl fumarate	capsules delayed-release	240mg; (14) plastic container	Amneal Pharmaceuticals Pvt. Ltd., Survey No. 634, 637 to 641, Near Hotel Kankavati, Sarkhej-Bavla Highway Vill. Rajota, Tal.-Bavla, Dist.-Ahmedabad, 382 220, Gujarat State	India	Amneal EU Limited, Cahir Road, Cashel, Co. Tipperary E25 XD51	Ireland	PoM	22584 16.12.2024

## LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 12-1/24 on December 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	Glycerin	glycerol	solution for external use	900mg/g; plastic 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	22585 16.12.2024
2	Akridol 3.125	carvedilol	tablets	3,125mg(30/3x10) 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	PoM	22586 16.12.2024
3	Akridol 6.25	carvedilol	tablets	6,25mg; (30/3x10) 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	PoM	22587 16.12.2024
4	Akridol 12.5	carvedilol	tablets	12,5mg; (30/3x10) 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	PoM	22588 16.12.2024
5	Linkus Plus Expectorant	solanum xanthocarpum, adhatoda vasica, glycyrrhiza glabra, ocimum basilicum, cordia latifolia, piper longum, althaea officinalis, illicium verum	syrup	30mg/10ml+70mg/10ml+15mg/10ml+30mg/10ml+10mg/10ml+10mg/10ml+15mg/10ml+50mg/10ml; glass bottle 120ml and measuring cup	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	22589 16.12.2024

6	Ubistesin	articaine (articaine hydrochloride), epinephrine (epinephrine hydrochloride)	solution for injection	40mg/ml+0,005mg/ml; (50) glass cartridges 1,7ml	3M Healthcare Germany GmbH, ESPE Platz 82229 Seefeld- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Eurofins BioPharma Product Testing Munich GmbH, Behringstrasse 6-8, 82152 Planegg Germany-quality control (microbiological)	Germany	Pierrel S.p.A., Strada Statale Appia, 7 Bis, 46/48 Capua (CE) 81043	Italy	PoM	22590 16.12.2024
7	Ubistesin forte	articaine (articaine hydrochloride), epinephrine (epinephrine hydrochloride)	solution for injection	40mg/ml+0,01mg/ml; (50) glass cartridges 1,7ml	3M Healthcare Germany GmbH, ESPE Platz 82229 Seefeld- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Eurofins BioPharma Product Testing Munich GmbH, Behringstrasse 6-8, 82152 Planegg Germany-quality control (microbiological)	Germany	Pierrel S.p.A., Strada Statale Appia, 7 Bis, 46/48 Capua (CE) 81043	Italy	PoM	22591 16.12.2024
8	ELEUTHEROCOC-CUS EXTRACT LIQUID TATPHARM	eleutherococcus senticosus rhizomes with roots	extract for oral administration (liquid)	1g/ml; glass bottle 50ml	Tatchempharmpreparaty JSC, 420091, Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091, Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	OTC	22592 16.12.2024
9	Controloc	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant film-coated	20mg; (14/1x14) in blister	Takeda GmbH, Lehnitz str. 70-98, 16515 Oranienburg	Germany	Takeda GmbH, Byk-Gulden str. 2, D-78467, Konstanz	Germany	OTC	22593 16.12.2024
10	Controloc	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant film-coated	40mg; (14/1x14) in blister, (28/2x14) in blister	Takeda GmbH, Lehnitz str. 70-98, 16515 Oranienburg	Germany	Takeda GmbH, Byk-Gulden str. 2, D-78467, Konstanz	Germany	PoM	22594 16.12.2024
11	Pirotex+B12	diminazene (diminazene diacetate), phenazone, cyanocobalamin	powder for solution for injection	444,3mg+555,3mg+0,4mg; 10ml(1,57g) glass vial, 20ml(2,36g) glass vial	Biotecsi Ltd., Jumashevi str. N8, Tbilisi	Georgia	Biotecsi Ltd., Jumashevi str. N8, Tbilisi	Georgia	PoM	22595 16.12.2024
12	Cystone	didymocarpus pedicellata, saxifraga ligulata, rubia cordifolia, cyperus scariosus, achyranthes aspera, onosma bracteatum, vernonia cinerea, mumie purified, lime silicate calx	tablets	65mg+49mg+16mg+16mg+16mg+16mg+16mg+13mg+16mg; (100) in plastic container	Himalaya Wellness Company, Makali, Bengaluru, 562 162	India	Himalaya Wellness Company, Makali, Bengaluru, 562 162	India	PoM	22596 16.12.2024
13	PHENOBARBITAL	phenobarbital	tablets	100mg; (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	22597 16.12.2024

14	Charcoal activated-Pharmstandard	charcoal activated	tablets	250mg; (10) in blister, (10/1x10/) in blister, (30/3x10) in blister, (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	22598 16.12.2024
15	METROMI- CON-NEO	metronidazole, miconazole (miconazole nitrate)	suppositories vaginal	500mg+100mg; (14/2x7)	Farnaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	Farnaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	PoM	22599 16.12.2024
16	Clotrimazole	clotrimazole	cream	10mg/g; aluminium tube 15g	Farnaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	Farnaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	OTC	22600 16.12.2024
17	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	22601 16.12.2024
18	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	22602 16.12.2024
19	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	22603 16.12.2024
20	Linkus ORVI	salix alba, adhatoda vasika, gly- cyrrhiza glabra, viola odorata, valeriana officinalis, foeniculum vulgare, eucalyptus globulus, thea sinensis	granules	750mg+300mg+550mg+100mg+100 mg+75mg+35mg+125mg; (5) sachets 5,6g, (10) sachets 5,6g	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	22604 16.12.2024
21	Linkus ORVI	salix alba, adhatoda vasika, gly- cyrrhiza glabra, viola odorata, valeriana officinalis, foeniculum vulgare, eucalyptus globulus, thea sinensis	granules with lemon flavour	750mg+300mg+550mg+100mg+100 mg+75mg+35mg+125mg; (5) sachets 5,6g, (10) sachets 5,6g	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	22605 16.12.2024



22	Linkus	adhadota vasica, glycyrrhiza glabra, piper longum, viola odorata, hyssopus officinalis, alpinia galanga, cordia latifolia, althea officinalis, zizyphus vulgaris, onosma bracteata	syrup	60mg/ml+7,5mg/ml+10mg/ml+2,5mg/ml+5mg/ml+5mg/ml+10mg/ml+10mg/ml+10mg/ml+10mg/ml; glass bottle 90ml, glass bottle 120ml, glass bottle 150ml	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	22606 16.12.2024
23	Linkus syrup sugar free	adhadota vasica, glycyrrhiza glabra, piper longum, viola odorata, hyssopus officinalis, alpinia galanga, cordia latifolia, althea officinalis, zizyphus vulgaris, onosma bracteata	syrup	60mg/ml+7,5mg/ml+10mg/ml+2,5mg/ml+5mg/ml+5mg/ml+10mg/ml+10mg/ml+10mg/ml+10mg/ml; glass bottle 90ml, glass bottle 120ml, glass bottle 150ml	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	22607 16.12.2024
24	AMITRIPTYLINE	amitriptyline (amitriptyline hydrochloride)	tablets coated	25mg; (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	22608 16.12.2024

## LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 12-1/24 on December 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	MAGNESIUM SULPHATE	magnesium sulfate	powder for oral solution	25g; (10) sachets 25g	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	22610 16.12.2024
2	MICOFLU	fluconazole	capsules	150mg; (1/1x1) in blister	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	22611 16.12.2024
3	Arixtra	fondaparinux (fondaparinux sodium)	solution for injection	5mg/ml; (10/2x5) pre-filled syringes 0,5ml in blister	Aspen Notre Dame de Bondeville, 1 rue de l' Abbaye, 76960 Notre Dame de Bondeville	France	Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24,	Ireland	PoM	22612 16.12.2024
4	Diclon	diclofenac (diclofenac sodium)	suppositories rectal	12,5mg; (10/2x5)	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	22613 16.12.2024
5	Diclon	diclofenac (diclofenac sodium)	suppositories rectal	25mg; (10/2x5)	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	22614 16.12.2024
6	Diclon	diclofenac (diclofenac sodium)	suppositories rectal	50mg; (10/2x5)	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	22615 16.12.2024
7	Diclon	diclofenac (diclofenac sodium)	suppositories rectal	100mg; (10/2x5)	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	22616 16.12.2024

## LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-1/24 on December 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	Vurdon-Neo	diclofenac (diclofenac sodium)	tablets gastro-resistant	50mg; (20/2x10) in blister	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	ARGO-PHARM LLC, 13/9 Sundukyan str., 0012 Yerevan	Republic of Armenia	PoM	19353/1/16.12.2024
2	Vurdon-Neo	diclofenac (diclofenac sodium)	tablets slow release film-coated	100mg; (10/1x10) in blister	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorphosis, Attica	Greece	PoM	19235/2/116.12.2024

3	Sinupret	gentiane radix, primulae flos, rumicis herba, sambuci flos, verbenae herba	drops oral	2mg/g+6mg/g+6mg/g+6mg/g+6mg/g; 100ml glass container-dropper	Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt in der Oberpfalz	Germany	Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	20377/1/1 16.12.2024
4	MICOFLU	fluconazole	capsules	150mg; (1) in blister	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	18940/1/1 16.12.2024
5	Vurdon-Neo	diclofenac (diclofenac sodium)	suppositories rectal	50mg; (10/2x5)	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorphosis, Attica	Greece	PoM	19230/1/1 16.12.2024

6	Vurdon-Neo	diclofenac (diclofenac sodium)	suppositories rectal	100mg; (10/2x5)	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorphosis, Attica	Greece	PoM	19231/1/1 16.12.2024
7	Emcor 2,5	bisoprolol (bisoprolol fumarate)	coated tablets	2,5mg; (30/3x10) in blister	GM Pharmaceuticals Ltd, Phnichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phnichala 65, 0165 Tbilisi	Georgia	PoM	19150/4/1 16.12.2024
8	Emcor 5	bisoprolol (bisoprolol fumarate)	coated tablets	5mg; (30/3x10) in blister	GM Pharmaceuticals Ltd, Phnichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phnichala 65, 0165 Tbilisi	Georgia	PoM	19151/3/1 16.12.2024

9	Artinibsa	articaine (articaine hydrochloride), epinephrine (epinephrine tartrate)	solution for injection	40mg/ml+0,01mg/ml; (50) cartridges 1,8ml	Laboratories Inibsa S.A., Ctra. Sabadell a Granollers, km 14.5, 08185 Llica de Vall, Barcelona	Spain	Laboratories Inibsa S.A., Ctra. Sabadell a Granollers, km 14.5, 08185 Llica de Vall, Barcelona	Spain	PoM	22174/1/1 16.12.2024
10	Protamine sulphate	protamine sulfate	solution for injection	10mg/ml; (5) glass vial 5ml	PrJSC «On the production of insulin «INDAR», 02099, Kyiv, 5 Zroshuvalna st	Ukraine	PrJSC «On the production of insulin «INDAR», 02099, Kyiv, 5 Zroshuvalna st	Ukraine	PoM	21303/1/1 16.12.2024
11	Protamine sulphate	protamine sulfate	solution for injection	10mg/ml; glass vial 10ml	PrJSC «On the production of insulin «INDAR», 02099, Kyiv, 5 Zroshuvalna st	Ukraine	PrJSC «On the production of insulin «INDAR», 02099, Kyiv, 5 Zroshuvalna st	Ukraine	PoM	21302/1/1 16.12.2024

12	CEFTRIAXONE- ASTERIA Inj. 1g	ceftriaxone (ceftriaxone sodium)	powder for solution for i/m injection	1000mg; (1) glass vial and 3,5ml solvent in ampoule	Hankook Korus Pharm Co., Ltd, 78 Daepungсандan-ro, Daeso-myeon, Eumseong-gun, Chungcheongbuk-do	Republic of Korea	Asteria LLC, 72/3 Nairi Zaryan str., 0051 Yerevan	Republic of Armenia	PoM	22438/1/1 16.12.2024
13	L-Thyroxin 25 Berlin- Chemie	levothyroxine sodium	tablets	25mcg; (28/1x28) in blister, (50/2x25) in blister, (100/4x25) in blister	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1. Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany, 2. Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin, Germany- quality control (physicochemical)	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	PoM	21167/3/1 16.12.2024
14	Amoksiklav 2x1000mg	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film- coated	875mg+125mg; (10/2x5) in blister	Sandoz GmbH, Biochemiestrass 10, A-6250, Kundl	Austria	Lek Pharmaceuticals d.d. Verovskova Str. 57, 1526 Ljub- ljana	Slovenia	PoM	20841/1/1 16.12.2024

## LIST

of the variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting  
decision N 12-1/24 on December 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	Sea Buckthorn Oil	hippopheae oil	suppositories rectal	500mg; (10/2x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, s.1- quality control and batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia- bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	002256 16.12.2024



## LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-1/24 on December 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	ELEUTHEROCOCCUS EXTRACT LIQUID TATPHARM	eleutherococcus senticosus rhizomes with roots	extract for oral administration (liquid)	1mg/ml; glass bottle 50ml	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	OTC	18656/1 16.12.2024
2	Clavoton 1g	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	875mg+125mg (14/2x7) in blister	Medochemie Ltd- Factory B, 48 Iapetou street, Agios Athanasios Industrial Area, 4101 Agios Athanasios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupoleos street, 3011 Limassol	Cyprus	PoM	19466/2 16.12.2024
3	Ketotifen Sopharma	ketotifen (ketotifen hydrofumarate)	tablets	1mg; (30/3x10) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	20735/1 16.12.2024
4	Levomycetin Tatpharm	chloramphenicol	tablets	500mg; (10/1x10) in blister	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	PoM	19079/1 16.12.2024
5	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 16.12.2024

6	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 16.12.2024
7	Controloc	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant film-coated	20mg; (14/1x14) in blister	Takeda GmbH, Lehnitz str. 70-98, 16515 Oranienburg	Germany	Takeda GmbH, Byk-Gulden str. 2, D-78467, Konstanz	Germany	OTC	18684/3/1 16.12.2024
8	Controloc	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant film-coated	40mg; (14/1x14) in blister, (28/2x14) in blister	Takeda GmbH, Lehnitz str. 70-98, 16515 Oranienburg	Germany	Takeda GmbH, Byk-Gulden str. 2, D-78467, Konstanz	Germany	PoM	18685/3/1 16.12.2024
9	MAGNESIUM SULPHATE	magnesium sulfate	powder for oral solution	25g; (10) sachets 25g	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	19008/1 16.12.2024
10	Dostinex	cabergoline	tablets	0,5mg; (8) in plastic bottle	Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno	Italy	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	20241/1 16.12.2024
11	Thioctacid 600 HR	alfa-lipoic acid	tablets film-coated	600mg; (30) in glass container, (100) in glass container	Rottapharm Ltd., Damastown Industrial Park, Mulhuddart, Dublin 15	Ireland	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg	Germany	PoM	20469/1 16.12.2024
12	Glaveral	omeprazole	capsules gastro-resistant hard	20mg; (14) in plastic container, (28) in plastic container	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorfofi, Attici	Greece	PoM	21300/1 16.12.2024
13	Akridol 3,125	carvedilol	tablets	3,125mg;(30/3x10) 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	PoM	18123/1 16.12.2024
14	Akridol 6,25	carvedilol	tablets	6,25mg; (30/3x10) 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	PoM	18124/1 16.12.2024

15	Akridol 12,5	carvedilol	tablets	12,5mg; (30/3x10) 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	PoM	18125/1 16.12.2024
16	Gliatilin	choline alfoscerate	solution for injection	250mg/ml; (3) ampoules 4ml	Italfarmaco S.p.A., Viale Fulvio Testi, 330 - 20126 Milan	Italy	Italfarmaco S.p.A., Viale Fulvio Testi, 330 - 20126 Milan	Italy	PoM	22096/1 16.12.2024
17	CoronaVac, COVID-19 Vaccine (Vero Cell), inactivated	inactivated SARS-CoV-2 Virus Antigen (CZ02 strain)	suspension for Injection	600SU/0,5ml/dose; (40) vials 0,5ml	Sinovac Life Sciences Co., Ltd., No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing	China	Sinovac Life Sciences Co., Ltd., No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing	China	PoM	21559/1 16.12.2024
18	CoronaVac, COVID-19 Vaccine (Vero Cell), inactivated	inactivated SARS-CoV-2 Virus Antigen (CZ02 strain)	suspension for Injection	600SU/0,5ml/dose; (10) syringes 0,5ml	Sinovac Life Sciences Co., Ltd., No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing	China	Sinovac Life Sciences Co., Ltd., No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing	China	PoM	21560/1 16.12.2024
19	AMITRIPTYLINE	amitriptyline (amitriptyline hydrochloride)	tablets coated	25mg; (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	18943/1 16.12.2024
20	Linkus Plus Expectorant	solanum xanthocarpum, adhatoda vasica, glycyrrhiza glabra, ocimum basilicum, cordia latifolia, piper longum, althaea officinalis, illicium verum	syrup	30mg/10ml+70mg/10ml- l+15mg/10ml+30mg/10ml- l+10mg/10ml+10mg/10ml- l+15mg/10ml+50mg/10ml; glass bottle 120ml and measuring cup	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	18985/1 16.12.2024
21	Diclone	diclofenac (diclofenac sodium)	suppositories rectal	12,5mg; (10/2x5)	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	18897/2 16.12.2024
22	Diclone	diclofenac (diclofenac sodium)	suppositories rectal	25mg; (10/2x5)	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	18898/2 16.12.2024
23	Diclone	diclofenac (diclofenac sodium)	suppositories rectal	50mg; (10/2x5)	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	18899/2 16.12.2024

24	Diclon	diclofenac (diclofenac sodium)	suppositories rectal	100mg; (10/2x5/)	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	18900/2 16.12.2024
25	PHENOBARBITAL	phenobarbital	tablets	100mg; (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	18759/1 16.12.2024
26	Cystone	didymocarpus pedicellata, saxifraga ligulata, rubia cordifolia, cyperus scariosus, achyranthes aspera, onosma bracteatum, vernonia cinerea, mumie purified, lime silicate calx	tablets	65mg+49mg+16mg+16mg+16mg+16mg+16mg+13mg+16mg; (100) in plastic container	Himalaya Wellness Company, Makali, Bengaluru, 562 162	India	Himalaya Wellness Company, Makali, Bengaluru, 562 162	India	PoM	18050/2/1 16.12.2024
27	Linkus ORVI	salix alba, adhatoda vasika, glycyrrhiza glabra, viola odorata, valeriana officinalis, foeniculum vulgare, eucalyptus globulus, thea sinensis	granules	750mg+300mg+550mg+100mg+100mg+75mg+35mg+125mg; (5) sachets, (10) sachets	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	18595/1 16.12.2024
28	Linkus ORVI	salix alba, adhatoda vasika, glycyrrhiza glabra, viola odorata, valeriana officinalis, foeniculum vulgare, eucalyptus globulus, thea sinensis	granules with lemon flavour	750mg+300mg+550mg+100mg+100mg+75mg+35mg+125mg; (5) sachets, (10) sachets	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	18594/1 16.12.2024
29	Linkus	adhadota vasica, glycyrrhiza glabra, piper longum, viola odorata, hyssopus officinalis, alpinia galanga, cordia latifolia, altaea officinalis, zizyphus vulgaris, onosma bracteata	syrup	60mg/ml+7,5mg/ml+10mg/ml+2,5mg/ml+5mg/ml+5mg/ml+10mg/ml+10mg/ml+10mg/ml+10mg/ml; glass bottle 90ml, glass bottle 120ml, glass bottle 150ml	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	18592/1 16.12.2024
30	Linkus syrup sugar free	adhadota vasica, glycyrrhiza glabra, piper longum, viola odorata, hyssopus officinalis, alpinia galanga, cordia latifolia, altaea officinalis, zizyphus vulgaris, onosma bracteata	syrup	60mg/ml+7,5mg/ml+10mg/ml+2,5mg/ml+5mg/ml+5mg/ml+10mg/ml+10mg/ml+10mg/ml+10mg/ml; glass bottle 90ml, glass bottle 120ml, glass bottle 150ml	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	18593/1 16.12.2024

31	METROMICON-NEO	metronidazole, miconazole (miconazole nitrate)	suppositories vaginal	500mg+100mg; (14/2x7/)	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	PoM	18815/1 16.12.2024
32	Levicitam	levetiracetam	tablets film- coated	250mg; (30/3x10/) in blister, (60/6x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	22104/1 16.12.2024
33	Levicitam	levetiracetam	tablets film- coated	500mg; (30/3x10/) in blister, (60/6x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	22105/1 16.12.2024

## LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting  
decision 12-1/24 on December 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	Natalsid	sodium alginate	suppositories rectal	250mg; (10/2x5)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, c.1- quality control, batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia- bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	002743 16.12.2024
2	Diabeton MR	gliclazide	tablets modified-release	60mg; (30/1x30) in blister, (60/2x30) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000531 16.12.2024
3	Diabeton MR	gliclazide	tablets modified-release	60mg; (28/2x14) in blister, (30/2x15) in blister, (60/4x15) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000531 16.12.2024
4	Diabeton MR	gliclazide	tablets modified-release	60mg; (28/2x14) in blister, (30/2x15) in blister, (30/1x30) in blister, (60/2x30) in blister, (60/4x15) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000531 16.12.2024

## LIST

of the variations requiring registration approved by the Center according to the meeting decision N 12-1/24 on December 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	Menopur	menotropin	powder lyophilized for solution for i/m or s/c injection	75IU; (5) glass vials and (5) solvent in ampoules 1ml, (10) glass vials and (10) solvent in ampoules 1ml	Ferring GmbH, Wittland 11, 24109 Kiel- powder bulk manufacturer, powder primary packager, quality control, batch releaser, Zentiva, k.s., U kabelovny 130, 102 37 Praha 10, Dolni Mecholupy, Czech Republic- solvent bulk manufacturer, primary packager, Ferring-Leciva, a.s. (areal spol. ECP, a.s.), Ke Skale 455, Vestec u Prahy, 25242, Czech Republic- secondary packager	Germany	Ferring GmbH, Wittland 11, 24109 Kiel	Germany	PoM	22617 16.12.2024