

## LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 11-1/24 on November 15, 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	Afinitor	everolimus	tablets	5mg; (30/3x10) in blister	Sandoz S.R.L., str. Livezeni nr. 7A, 540472, Targu Mures	Romania	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22458 15.11.2024
2	Afinitor	everolimus	tablets	10mg; (30/3x10) in blister	Sandoz S.R.L., str. Livezeni nr. 7A, 540472, Targu Mures	Romania	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22459 15.11.2024
3	Simulect	basiliximab	powder lyophilized for solution for injection or infusion	20mg; glass vial	Novartis Pharmaceutica, S.A., Gran Via de les Corts Catalanes 764, 08013 Barcelona- batch releaser, Patheon Italia S.p.A., Viale Gian Battista Stucchi 110, 20900 Monza, Italy- bulk manufacturer, primary packager, quality control (microbiological), Delpharm Dijon, 6 Boulevard de l' Europe, Quetigny, 21800, France- secondary packager, 1.Patheon Italia S.p.A., Viale Gian Battista Stucchi 110, 20900 Monza, Italy, 2.Eurofins Biolab Srl, Viale Bruno Buozzi 2, 20055 Viomodrone, Italy- quality control (physicochemical)	Spain	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	22460 15.11.2024
4	Simulect	basiliximab	powder lyophilized for solution for injection or infusion	20mg; glass vial	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein AG, 4332	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	22461 15.11.2024

5	Amoxicillin EXPRESS- Pharmstandard	amoxicillin (amoxicillin trihydrate)	tablets dispersible	125mg; (20/2x10) in blister	Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279- quality control, batch releaser, Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager	Russia	Pharmaceutical Firm «LEKKO» CJSC, 601125, Vladimir region, Volginsky settlement, Zavodskaya s. 278	Russia	PoM	22462 15.11.2024
6	Amoxicillin EXPRESS- Pharmstandard	amoxicillin (amoxicillin trihydrate)	tablets dispersible	250mg; (20/2x10) in blister	Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279- quality control, batch releaser, Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager	Russia	Pharmaceutical Firm «LEKKO» CJSC, 601125, Vladimir region, Volginsky settlement, Zavodskaya s. 278	Russia	PoM	22463 15.11.2024
7	Amoxicillin EXPRESS- Pharmstandard	amoxicillin (amoxicillin trihydrate)	tablets dispersible	500mg; (20/2x10) in blister	Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279- quality control, batch releaser, Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager	Russia	Pharmaceutical Firm «LEKKO» CJSC, 601125, Vladimir region, Volginsky settlement, Zavodskaya s. 278	Russia	PoM	22464 15.11.2024
8	Amoxicillin EXPRESS- Pharmstandard	amoxicillin (amoxicillin trihydrate)	tablets dispersible	1000mg; (20/2x10) in blister	Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279- quality control, batch releaser, Pharmaceutical Firm «LEKKO» CJSC, Vladimir region, Petushinskiy district, Volginsky settlement, Zavodskaya s., 279, Russia- bulk manufacturer, packager	Russia	Pharmaceutical Firm «LEKKO» CJSC, 601125, Vladimir region, Volginsky settlement, Zavodskaya s. 278	Russia	PoM	22465 15.11.2024
9	Doxycycline EXPRESS- Pharmstandart	doxycycline (doxycycline monohidrate)	tablets dispersible	100mg; (10/1x10) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	PoM	22466 15.11.2024
10	SYBRAVA	inclisiran	solution for subcutaneous injection	189mg/ml; pre-filled syringe 1,5ml	Novartis Pharmaceutical Manufacturing GmbH, Biochemiestrasse 10, Langkampfen, 6336	Austria	Novartis Overseas Investments AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22467 15.11.2024

## LIST

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1	Skopryl plus	lisinopril (lisinopril dihydrate), hydrochlorothiazide	tablets	20mg+12,5mg; (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	22469 (004087) 15.11.2024
2	Skopryl plus	lisinopril (lisinopril dihydrate), hydrochlorothiazide	tablets	20mg+25mg; (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	22470 (004087) 15.11.2024
3	Airtal	aceclofenac	powder for oral suspension	100mg; (20) sachets 3g	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Industrias Farmaceuticas Almirall S.A., Ctra. De Martorel 41-61, 08740 Sant Andreu de la Barca, Barcelona, Spain- bulk manufacturer, packager, quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22471 (002382) 15.11.2024
4	Trittico	trazodone (trazodone hydrochloride)	tablets prolonged-release	150mg; (20/2x10) in blister, (60/6x10) in blister, (90/6x15) in blister	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. Via Vecchia Del Pinocchio, 22, 60131 Ancona	Italy	Angelini Pharma S.p.A., Viale, Amelia 70, 00181, Rome	Italy	PoM	22472 (002817) 15.11.2024
5	Arduan	pipecuronium bromide	powder lyophilized and solvent for solution for injection	4mg; (50/5x10(5 glass vials 10ml+5 ampoules 2ml with solvent)) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22473 (009088) 15.11.2024

6	Arduan	pipecuronium bromide	powder lyophilized and solvent for solution for injection	4mg; (50/5x10(5 glass vials 10ml+5 ampoules 2ml with solvent)) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- powder manufacturer, secondary packager, quality control, batch releaser, Hemofarm A.D., 26300, Vrsac, Beogradski put b.b., Serbia- solvent bulk manufacturer, primary packager	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	22474 (009088) 15.11.2024
7	Moxiral	moxifloxacin (moxifloxacin hydrochloride)	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	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	22475 (000533) 15.11.2024
8	Lindynette 20	ethinylestradiol, gestodene	tablets coated	0,02mg+0,075mg; (21/1x21) in blister, (63/3x21) in blister	Gedeon Richter PLC, Gyomroi st. 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi st. 19-21, 1103 Budapest	Hungary	PoM	22476 (000492) 15.11.2024
9	Belara	chlormadinone (chlormadinone acetate), ethinylestradiol	tablets film-coated	2mg+0,03mg; (21/1x21) in blister, (63/3x21) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi st. 19-21, 1103 Budapest	Hungary	PoM	22477 (000359) 15.11.2024
10	Bilobil forte	ginkgo biloba leaf dry extract	capsules	80mg; (20/2x10) in blister, (60/6x10) 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	OTC	22478 (000475) 15.11.2024
11	Bilobil intense 120	ginkgo biloba folies dry extract	capsules	120mg; (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	22479 (000483) 15.11.2024
12	Soligamma	coleciferol	tablets film-coated	10000IU; (10/1x10) in blister, (20/2x10) in blister, (30/3x10) in blister, (40/4x10) in blister	Saneca Pharmaceuticals. a.s., Nitrianska 100, 92027 Hlohovec	Slovak Republic	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen	Germany	PoM	22480 (005564) 15.11.2024
13	CITOLEPT	citicoline (citicoline sodium)	solution for i/v and i/m injection	125mg/ml; (3/1x3) ampoules 4ml in blister, (5/1x5) ampoules 4ml in blister, (10/2x5) ampoules 4ml in blister	PharmFirma Sotex» CJSC, Bld. 11, village Belikovo, Sergiev-Posad, Moscow Region-quality control, batch releaser, «PharmFirma «Sotex» CJSC, Bld. 10, village Belikovo, Sergiev-Posad, Moscow Region, Russia-bulk manufacturer, packager	Russia	«PharmFirma «Sotex» CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	PoM	22481 (004411) 15.11.2024

14	CITOLEPT	citicoline (citicoline sodium)	solution for i/v and i/m injection	250mg/ml; (3/1x3/) ampoules 4ml in blister, (5/1x5/) ampoules 4ml in blister, (10/2x5) ampoules 4ml in blister	PharmFirma Sotex» CJSC, Bld. 11, village Belikovo, Sergiev-Posad, Moscow Region- quality control, batch releaser, «PharmFirma «Sotex» CJSC, Bld. 10, village Belikovo, Sergiev-Posad, Moscow Region, Russia- bulk manufacturer, packager	Russia	«PharmFirma «Sotex» CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	PoM	22482 (004411) 15.11.2024
15	Sevorane	sevoflurane	liquid for inhalation	100%; (1) plastic container 250ml with Quikfil closure system, (6) plastic containers 250ml with Quikfil closure system	AbbVie S.r.l., S.R. 148 Pontina KM 52, SNC 04011 Campoverde di Aprilia (LT)	Italy	AbbVie LLC, 125196, Lesnaya str, 7, floor 4, room 1, Moscow	Russia	PoM	22483 (004411) 15.11.2024
16	Sevorane	sevoflurane	liquid for inhalation	100%; (1) plastic container 250ml with Quikfil closure system, (6) plastic containers 250ml with Quikfil closure system	ORTAT JSC, Kostromskaya distr., Susa- ninsky region, vil. Severnoe, microdistr. Kharitonovo, 157092- secondary packager, quality control, batch releaser, AbbVie S.r.l., S.R. 148 Pontina KM 52, SNC 04011 Campoverde di Aprilia (LT), Italy- bulk manufacturer, primary packager	Russia	AbbVie LLC, 125196, Lesnaya str, 7, floor 4, room 1, Moscow	Russia	PoM	22484 (004411) 15.11.2024
17	Sevorane	sevoflurane	liquid for inhalation	100%; (1) plastic container 250ml with Quikfil closure system, (6) plastic containers 250ml with Quikfil closure system	R-Pharma JSC, Gromova str., 15, 150061, Yaroslavl- bulk manufacturer, packager, batch releaser, AbbVie S.r.l., S.R. 148 Pontina KM 52, SNC 04011 Campoverde di Aprilia (LT), Italy- quality control	Russia	AbbVie LLC, 125196, Lesnaya str, 7, floor 4, room 1, Moscow	Russia	PoM	22485 (004411) 15.11.2024

## LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 11-1/24 on November 15, 2024

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1	Bonjigar	eclipta alba, picrorrhiza kurrooa, solanum nigrum, cichorium intybus, glycyrrhiza glabra, tamarix gallica, raphanus sativus, berberis aristata, silybum marianum, spherantus indica, boerhavia diffusa	capsules	250mg+100mg+50mg+175mg+200mg+100mg+50mg+150mg+200mg+50mg+100mg; (20) and (60) in plastic container	Herbion Pakistan Pvt. Ltd., Plot No. 30, Sector 28, Korangi Industrial Area, Karachi	Pakistan	Herbion Pakistan Pvt. Ltd., Plot No. 30, Sector 28, Korangi Industrial Area, Karachi	Pakistan	PoM	22486 15.11.2024
2	BENZONAL	benzobarbital	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	22487 15.11.2024
3	DicloFLEX 5% gel	diclofenac (diclofenac sodium)	gel	50mg/g; aluminium tube 50g	Vetprom AD, Otets Paisiy str. 26, Radomir 2400	Bulgaria	Danhson-BG, Otets Paisiy str. 26, Radomir 2400	Bulgaria	OTC	22488 15.11.2024
4	Isoniazid	isoniazid	tablets	100mg; (100/10x10) in blister	Macleods Pharmaceuticals Ltd., Plot No 25-27, Sr. No 366, Premier Ind. Estate, Kachigam, Daman-396210 (UT)	India	Macleods Pharmaceuticals Ltd., 304, Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai-400 059	India	PoM	22489 15.11.2024
5	Isoniazid	isoniazid	tablets	300mg; (672/24x28) in blister	Macleods Pharmaceuticals Ltd., Phase-II, Plot No 25-27, Sr. No 366, Premier Ind. Estate, Kachigam, Daman-396210	India	Macleods Pharmaceuticals Ltd., 304, Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai-400 059	India	PoM	22490 15.11.2024
6	Distem	paracetamol, methocarbamol	tablets	300mg+380mg; (50/5x10) in blister	FAES FARMA S.A., C/Maximo Aguirre, 14, Lejona-Leioa, 48940 Vizcaya/Bizkaia	Spain	FAES FARMA S.A., C/Maximo Aguirre, 14, Lejona-Leioa, 48940 Vizcaya/Bizkaia	Spain	PoM	22491 15.11.2024

7	Ibufene	ibuprofen	suspension oral	20mg/ml; 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	OTC	22492 15.11.2024
8	Liv.52	capparis spinosa, cichorium intybus, ferric oxide, solanum nigrum, terminalia arjuna, cassia occidentalis, achillea millefolium, tamarix gallica	tablets	65mg+65mg+33mg+32mg+32mg+16mg+16mg+16mg; (100) plastic container	Himalaya Wellness Company, Makali, Bengaluru, 562 162	India	Himalaya Wellness Company, Makali, Bengaluru, 562 162	India	PoM	22493 15.11.2024
9	Biozan 900	oxyclozanide, oxfenazole	tablets	600mg+300mg; (50) plastic container, (300) plastic container	Biotecsi Ltd., Jumashevi str. N8, Tbilisi	Georgia	Biotecsi Ltd., Jumashevi str. N8, Tbilisi	Georgia	PoM	22494 15.11.2024
10	Neiralgin B	thiamine (thiamine hydrochloride), pyridoxine (pyridoxine hydrochloride), cyanocobalamin, lidocaine (lidocaine hydrochloride)	solution for i/m injection	100mg/2ml+100mg/2ml+1mg/2ml+20mg/2ml; (5/1x5) ampoules 2ml in blister, (10/2x5) ampoules 2ml in blister, (25/5x5) ampoules 2ml in blister	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, Grindeks JSC, Krustpils street 53, LV-1057, Riga, Latvia- quality control (physicochemical), HBM pharma s.r.o., Sklabinska 39, 03680 martin, Slovakia- quality control (microbiological)	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	22495 15.11.2024
11	CARBOCISTEINE 2% syrup for children	carbocisteine	syrup	100mg/5ml; glass bottle 120ml	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	22496 15.11.2024
12	CARBOCISTEINE 5% syrup for adults	carbocisteine	syrup	250mg/5ml; glass bottle 120ml	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	22497 15.11.2024
13	Levomycetin	chloramphenicol	tablets	500mg; (10) in blister, (10) in strip	Irbitskiy himfarmzavod OJSC, 124a, K. Marksa str., Irbit, St. Sverdlovsk, 623856	Russia	Irbitskiy himfarmzavod OJSC, 172, Kirova str., Irbit, St. Sverdlovsk, 623856	Russia	PoM	22498 15.11.2024
14	Heparin-Belmed	heparin (heparin sodium)	solution for i/v and s/c injection	5000IU/ml; (1) glass vial 5ml, (5) glass vials 5ml	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30, No2	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	22499 15.11.2024
15	Hemastad-RN	tranexamic acid	solution for i/v injection	50mg/ml; (5) glass vials 20ml	Rubicon LLC, 62B, M. Gorky street, Vitebsk	Republic of Belarus	Rubicon LLC, 62B, M. Gorky street, Vitebsk	Republic of Belarus	PoM	22500 15.11.2024

16	Lorista	losartan (losartan potassium)	tablets film-coated	25mg; (28/2x14) in blister, (28/4x7) 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	22501 15.11.2024
17	Lorista	losartan (losartan potassium)	tablets film-coated	50mg; (28/2x14) in blister, (28/4x7) 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	22502 15.11.2024



## LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 11-1/24 on November 15, 2024

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1	Laxalac	lactulose	solution oral	670mg/ml; glass bottle 100ml and measuring cup, plastic bottle 200ml and measuring cup, plastic bottle 250ml and measuring cup, plastic bottle 500ml 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	OTC	22503 15.11.2024
2	Eskomecol	chloramphenicol, dioxomethyltetrahydropyrimidine	ointment for external use	7,5mg/g+40mg/g; aluminium tube 25g	Esco-Pharm LLC, Nor-Norq, Mikoyan 13, Yerevan	Republic of Armenia	Esco-Pharm LLC, Nor-Norq, Mikoyan 13, Yerevan	Republic of Armenia	OTC	22504 15.11.2024

## LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 11-1/24 on November 15,  
2024

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1	Carditon	levocarnitine	solution oral	100mg/ml; (10) glass vials 10ml	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi- secondary packager, quality control, batch releaser, Anfarm Hellas S.A., 61st Km National Road Athens Lamia, Schimatari Viotias, 32009, Greece- bulk manufacturer, primary packager	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	19234/2/1 15.11.2024
2	Lasolvan syrup 15mg/5ml	ambroxol (ambroxol hydrochloride)	syrup	15mg/5ml; 100ml glass bottle and measuring cup	Opella Healthcare Italy S.R.L., Viale Europa, 11, 21040 Origgio (VA)	Italy	A. Nattermann & Cie. GmbH, Bruningstrasse 50, 65929 Frankfurt am Main	Germany	OTC	20899/1/1 15.11.2024

3	Ingavirin	pentanedioic acid (pentanedioic acid imidazolyl ethanamide)	syrup	30mg/5ml; polyethylene bottle 50ml and measuring syringe, polyethylene bottle 90ml and measuring syringe	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2- secondary packager, quality control (physicochemical), batch releaser, ABC Farmaceutici S.p.A, Via Cantone Moretti, 29, 10015, Ivrea, Italy- bulk manufacturer, primary packager, Testing laboratory Centemo Ltd, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 1, housing 1, office 315, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	20758/3/2 15.11.2024
4	Grammidin neo	gramicidin S (gramicidin S dihydrochloride), cetylpyridinium chloride (cetylpyridinium chloride monohydrate)	tablets to be sucked	3mg+1mg; (18/2x9) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	20067/3/1 15.11.2024

## LIST

of the variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting  
decision N 11-1/24 on November 15, 2024

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1	Tamsol	tamsulosin (tamsulosin hydrochloride)	capsules modified-release	0,4mg; (10/1x10) in blister, (30/3x10) in blister	Gedeon Richter-RUS JSC, Lesnaya st. 40, Bld. 2, Shuvoye, Moscow region, Yegoriyevsky district, 140342- quality control, batch releaser, Gedeon Richter-RUS JSC, Lesnaya st. 40, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia-bulk manufacturer, Gedeon Richter-RUS JSC, Lesnaya st. 40, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager	Russia	Gedeon Richter Plc., Gyomroi ut 19-21, Budapest, 1103	Hungary	PoM	000753 15.11.2024

## LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 11-1/24 on November 15,  
2024

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1	Kanamycin	kanamycin (kanamycin sulfate)	powder for solution for i/m injection	1000mg; (40) glass vials	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	PoM	21949/1 15.11.2024
2	Abrobion	ambroxol (ambroxol hydrochloride)	syrup	6mg/ml; 125ml glass bottle	Help S.A. Pedini, Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 144 52, Metamorphosis, Attika	Greece	OTC	19933/2 15.11.2024
3	Farmorubicin Rapid Dissolution	epirubicin (epirubicin hydrochloride)	powder lyophilized for solution for infusion	10mg; glass vial	Corden Pharma Latina S.p.A, Via Muriolo 7, Sermoneta, 04013	Italy	Pfizer Inc., Corporation, 235, East 42nd Street, New York 10017	USA	PoM	21267/1 15.11.2024
4	Farmorubicin Rapid Dissolution	epirubicin (epirubicin hydrochloride)	powder lyophilized for solution for infusion	50mg; glass vial	Corden Pharma Latina S.p.A, Via Muriolo 7, Sermoneta, 04013	Italy	Pfizer Inc., Corporation, 235, East 42nd Street, New York 10017	USA	PoM	21268/1 15.11.2024
5	Rosulip Plus	rosuvastatin (rosuvastatin zinc), ezetimibe	capsules	5mg+10mg; (30/3x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19700/4 15.11.2024

6	Rosulip Plus	rosuvastatin (rosuvastatin zinc), ezetimibe	capsules	10mg+10mg; (30/3x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19673/4 15.11.2024
7	Rosulip Plus	rosuvastatin (rosuvastatin zinc), ezetimibe	capsules	20mg+10mg; (30/3x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19674/4 15.11.2024
8	Rosulip Plus	rosuvastatin (rosuvastatin zinc), ezetimibe	capsules	40mg+10mg; (30/3x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19675/4 15.11.2024
9	Laxalac	lactulose	solution oral	670mg/ml; glass bottle 100ml and measuring cup, plastic bottle 200ml and measuring cup, plastic bottle 250ml and measuring cup, plastic bottle 500ml 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	OTC	18863/2/1 15.11.2024
10	Puregon	follitropin beta (recombinant)	solution for s/c injection	300IU/0,36ml; cartridge 0,42ml, (6/2x3) needles	N.V. Organon, Molenstraat 110, 5342 CC OSS- secondary packager, quality control, batch releaser (legal address- N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands), Vetter Pharma-Fertigung GmbH & Co. KG, Mooswiesen 2, Ravensburg, Baden-Wuerttemberg, 88214, Germany- bulk manufacturer, primary packager	the Netherlands	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	19260/6/1 15.11.2024

11	Puregon	folitropin beta (recombinant)	solution for s/c injection	600IU/0,72ml; cartridge 0,78ml, (6/2x3) needles	N.V. Organon, Molenstraat 110, 5342 CC OSS- secondary packager, quality control, batch releaser (legal address- N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands), Vetter Pharma-Fertigung GmbH & Co. KG, Mooswiesen 2, Ravensburg, Baden-Wuerttemberg, 88214, Germany- bulk manufacturer, primary packager	the Netherlands	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	19261/6/1 15.11.2024
12	Mesalazol	mesalazine	suppositories rectal	500mg; (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	21281/1 15.11.2024
13	BENZONAL	benzobarbital	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	18904/1 15.11.2024
14	Tot` Hema	iron (iron gluconate), manganese (manganese gluconate), copper (copper gluconate)	solution oral	50mg/10ml+1,33mg/10ml+0,7mg/10ml; (20/2x10) ampoules 10ml in blister	Innothera Chouzy, Rue Rene Chantereau, Chouzy-sur-Cisse, Valloire-sur-Cisse, 41150	France	Laboratoire Innotech International, 22, Avenue Aristide Briand, 94110 Arcueil	France	PoM	19991/2 15.11.2024
15	Metoclopramide	metoclopramide (metoclopramide hydrochloride)	solution for i/v and i/m injection	5mg/ml; (10) ampoules 2ml label banderol, (10) ampoules 2ml dividella, (10) ampoules 2ml CAMA	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64 ul. Chapaveva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64 ul. Chapaveva, Borisov, Minsk region	Republic of Belarus	PoM	20953/2/1 15.11.2024
16	DicloFLEX 5% gel	diclofenac (diclofenac sodium)	gel	50mg/g; aluminium tube 50g	Vetprom AD, Otez Paissij str. 26, Radomir 2400	Bulgaria	Dahnsen-BG Co Ltd., Otez Paissij str. 26, Radomir 2400	Bulgaria	OTC	19048/1 15.11.2024
17	Isoniazid	isoniazid	tablets	100mg; (100/10x10) in blister	Macleods Pharmaceuticals Ltd., Phase-II, Plot No 25-27, Sr. No 366, Premier Ind. Estate, Kachigam, Daman-396210	India	Macleods Pharmaceuticals Ltd., 304, Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai-400 059	India	PoM	16015/1 15.11.2024
18	Isoniazid	isoniazid	tablets	300mg; (672/24x28) in blister	Macleods Pharmaceuticals Ltd., Phase-II, Plot No 25-27, Sr. No 366, Premier Ind. Estate, Kachigam, Daman-396210	India	Macleods Pharmaceuticals Ltd., 304, Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai-400 059	India	PoM	16016/1 15.11.2024

19	Ibufene	ibuprofen	suspension oral	20mg/ml; 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	OTC	19078/1 15.11.2024
20	Liv.52	capparis spinosa, cichorium intybus, ferric oxide, solanum nigrum, terminalia arjuna, cassia occidentalis, achillea millefolium, tamarix gallica	tablets	65mg+65mg+33mg+32mg+32mg+16mg+16mg+16mg; (100) plastic container	Himalaya Wellness Company, Makali, Bengaluru, 562 162	India	Himalaya Wellness Company, Makali, Bengaluru, 562 162	India	PoM	18049/2/1 15.11.2024
21	CARBOCISTEINE 2% syrup for children	carbocisteine	syrup	100mg/5ml; glass bottle 120ml	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	18727/1 15.11.2024
22	CARBOCISTEINE 5% syrup for adults	carbocisteine	syrup	250mg/5ml; glass bottle 120ml	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	18683/1 15.11.2024
23	Grammidin for kids	gramicidin S (gramicidin S dihydrochloride), cetylpyridinium chloride (cetylpyridinium chloride monohydrate)	tablets to be sucked	1,5mg+1mg; (18/2x9) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	19855/4/1 15.11.2024
24	Grammidin with anesthetic neo	gramicidin S (gramicidin S dihydrochloride), oxybuprocaine hydrochloride, cetylpyridinium chloride (cetylpyridinium chloride monohydrate)	tablets to be sucked	3mg+0,2mg+1mg; (18/2x9) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Centemo LTD, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	21237/1 15.11.2024



25	ACRIPTEGA	dolutegravir (dolutegravir sodium), lamivudine, tenofovir (tenofovir disoproxil fumarate)	tablets film-coated	50mg+300mg+300mg; (30) in plastic container, (90) in plastic container, (180) in plastic container	Mylan Laboraories Limited, Plot No.11, 12 & 13, Indore SEZ, Pharma Zone, Phase-II, Sector-III, Pithampur-454775, Dist. Dhar, Madhya Pradesh	India	Mylan Laboratories Limited, Plot No. 564/A/22, Road No.92, Jubilee Hills, Hyderabad, Telangana, 500096	India	PoM	21072/1 15.11.2024
26	HepBest	tenofovir alafenamide fumarate	tablets film-coated	25mg; (30) in plastic bottle	Mylan Laboraories Limited, Plot No.11, 12 & 13, Indore SEZ, Pharma Zone, Phase-II, Sector-III, Pithampur-454775, Dist. Dhar, Madhya Pradesh	India	Mylan Laboratories Limited, Plot No. 564/A/22, Road No.92, Jubilee Hills, Hyderabad, Telangana, 500096	India	PoM	20869/1 15.11.2024
27	Avonza	tenofovir disoproxil fumarate, lamivudine, efavirenz	tablets film-coated	300mg+300mg+400mg; (30) in plastic container, (90) in plastic container	Mylan Laboraories Limited, Plot No.11, 12 & 13, Indore SEZ, Pharma Zone, Phase-II, Sector-III, Pithampur-454775, Dist. Dhar, Madhya Pradesh	India	Mylan Laboratories Limited, Plot No. 564/A/22, Road No.92, Jubilee Hills, Hyderabad, Telangana, 500096	India	PoM	21224/1 15.11.2024
28	Clopi-Denk 75	clopidogrel (clopidogrel besylate)	tablets film-coated	75mg; (30/3x10) in blister	Artesan Pharma GmbH & Co. KG, Wendlandstrasse 1, 29439 Luechow	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	19149/2 15.11.2024

## LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting  
decision N 11-1/24 on November 15, 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	Lixiana	edoxaban (edoxaban tosylate monohydrate)	tablets film-coated	15mg; (14/1x14) in blister, (1000-300000) (in-bulk) in bag	Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen	Germany	Servier JSC, 125196, Lesnaya str., 7, floor 7/8/9, Moscow	Russia	PoM	000022 15.11.2024
2	Lixiana	edoxaban (edoxaban tosylate monohydrate)	tablets film-coated	15mg; (14/1x14) in blister	LLC SERVIER RUS, 108828, Krasnopakhorskoe district, quarter 158, estate 2, bld. 1, Moscow- packager, quality control, batch releaser, Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen, Germany- bulk manufacturer	Russia	Servier JSC, 125196, Lesnaya str., 7, floor 7/8/9, Moscow	Russia	PoM	000022 15.11.2024
3	Lixiana	edoxaban (edoxaban tosylate monohydrate)	tablets film-coated	30mg; (14/1x14) in blister, (28/2x14) in blister, (98/7x14) in blister, (1000-300000) (in-bulk) in bag	Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen	Germany	Servier JSC, 125196, Lesnaya str., 7, floor 7/8/9, Moscow	Russia	PoM	000022 15.11.2024
4	Lixiana	edoxaban (edoxaban tosylate monohydrate)	tablets film-coated	30mg; (14/1x14) in blister, (28/2x14) in blister, (98/7x14) in blister	LLC SERVIER RUS, 108828, Krasnopakhorskoe district, quarter 158, estate 2, bld. 1, Moscow- packager, quality control, batch releaser, Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen, Germany- bulk manufacturer	Russia	Servier JSC, 125196, Lesnaya str., 7, floor 7/8/9, Moscow	Russia	PoM	000022 15.11.2024
5	Lixiana	edoxaban (edoxaban tosylate monohydrate)	tablets film-coated	60mg; (14/1x14) in blister, (28/2x14) in blister, (98/7x14) in blister, (1000-300000) (in-bulk) in bag	Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen	Germany	Servier JSC, 125196, Lesnaya str., 7, floor 7/8/9, Moscow	Russia	PoM	000022 15.11.2024

6	Lixiana	edoxaban (edoxaban tosylate monohydrate)	tablets film-coated	60mg; (14/1x14) in blister, (28/2x14) in blister, (98/7x14) in blister	LLC SERVIER RUS, 108828, Krasnopakhorskoe district, quarter 158, estate 2, bld. 1, Moscow- packager, quality control, batch releaser, Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen, Germany- bulk manufacturer	Russia	Servier JSC, 125196, Lesnaya str., 7, floor 7/8/9, Moscow	Russia	PoM	000022 15.11.2024
7	Tamsol	tamsulosin (tamsulosin hydrochloride)	capsules modified-release	0,4mg; (10/1x10) in blister, (30/3x10) in blister	Gedeon Richter Romania S.A., Guza Voda str. 99-105, Targu-Mures, 540306	Romania	Gedeon Richter Plc., Gyomroi ut 19-21, Budapest, 1103	Hungary	PoM	000753 15.11.2024