

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 08-2/26 on August 31, 2026

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	Zanotazon GIGA	colecalfiferol	capsules	50000IU; (4/1x4) in blister	Altayvitamins JSC, 659325, Altai territory, Biysk, Zavodskaya str., d. 69	Russia	Giga Farm LLC, 3101, Gogunts st. 3/5, Gyumri	Republic of Armenia	PoM	24464 31.08.2026
2	Colchicina Lirca	colchicine	tablets	1mg; (60/2x30) in blister	Special Product's Line S.p.A, Via Fratta Rotonda Vado Largo, 1, 03012 Anagni	Italy	Acarpia Farmaceutici S.r.l, Viale L. Majno 18, 20129 Milano	Italy	PoM	24465 31.08.2026

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1	Fortrans	macrogol (macrogol 4000), sodium chloride, potassium chloride, sodium hydrogen carbonate, sodium sulfate anhydrous	powder for oral solution	64,00g+1,46g+0,75g+1,68g+5,70g; (4) sachets 73,69g	Beaufour Ipsen Industrie, Ethe Virton, 28100 Dreux	France	IPSEN CONSUMER HEALTHCARE SAS, 65 Quai Georges Gorse, 92100 Boulogne-Billancourt	France	OTC	24503 (012859) 31.08.2026
2	Valerian extract	valerian thick extract	tablets coated	20mg; (50/5x10) in blister, (50) in glass bottle	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 24, Sroiteley str., Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapayev str., Borisov 222518, Minsk region	Republic of Belarus	OTC	24504 (014935) 31.08.2026
3	Femoston 2/10	pink tablet- estradiol, yellow tablet- estradiol + dydrogesterone	tablets film-coated	2mg+2mg+10mg; (28/1x28/(14pink tablets+14yellow tablets)) in blister, (84/3x28/(14pink tablets+14yellow tablets)) in blister, (280/10x28/(14pink tablets+14yellow tablets)) in blister	Abbott Biologicals B.V., Veerweg 12, 8121 AA Olst	the Netherlands	Abbott Healthcare Products B.V., C.J. van Houtenlaan 36, 1381 CP Weesp	the Netherlands	PoM	24505 (002260) 31.08.2026
4	Pikovit	vitamin A, vitamin D3, vitamin B2, vitamin B6, vitamin B1, vitamin B12, vitamin C, vitamin B3, D-panthenol	syrup	900IU/5ml+100IU/5ml+1mg/5ml+0.6mg/5ml+1mg/5ml+1mcg/5ml+50mg/5ml+5mg/5ml+2mg/5ml; 150ml glass bottle and measuring spoon 5ml	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- quality control, batch releaser, KRKA d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia- bulk manufacturer, packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	24506 (007605) 31.08.2026
5	Tyverb	lapatinib (lapatinib diosylate monohydrate)	tablets film-coated	250mg; (70) in plastic bottle, (140) in plastic bottle	Sandoz S.R.L., str. Livezeni nr. 7A, 540472, Targu Mures, Mures County	Romania	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24507 (001794) 31.08.2026

6	KETOROLAC	ketorolac (ketorolac tromethamine)	solution for i/m injection	30mg/ml; (10) ampoules 1ml	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, No10/1, 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	24508 (001794) 31.08.2026
7	Pantocalcin	hopantenic acid (calcium hopantenate)	tablets	250mg; (50/5x10) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2- bulk manufacturer, packager, quality control (physicochemical), batch releaser, V-MIN LLC, Territoriya 6-y kilometr avtodorogi M-8 Kholmogory - Sergiyev Posad, 1, Sergiyev-Posadskiy Urban District, Moscow Region, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	PoM	24509 (023911) 31.08.2026
8	Pantocalcin	hopantenic acid (calcium hopantenate)	tablets	500mg; (50/5x10) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2- bulk manufacturer, packager, quality control (physicochemical), batch releaser, V-MIN LLC, Territoriya 6-y kilometr avtodorogi M-8 Kholmogory - Sergiyev Posad, 1, Sergiyev-Posadskiy Urban District, Moscow Region, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	PoM	24510 (023911) 31.08.2026
9	Betamaks	sulpiride	tablets	50mg; (30/3x10) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	24511 (013947) 31.08.2026
10	Betamaks	sulpiride	tablets	100mg; (30/3x10) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	24512 (013947) 31.08.2026
11	Betamaks	sulpiride	tablets	200mg; (30/3x10) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	24513 (013947) 31.08.2026
12	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	24514 (021872) 31.08.2026

13	Sinupret	gentiane radix, primulae flos, rumicis herba, sambuci flos, verbenae herba	syrup	32,08mg/g+96,23mg/g+96,23mg/g+96,23mg/g+6mg/g; 100ml glass container	Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt in der Oberpfalz	Germany	Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	24515 (003535) 31.08.2026
14	Zvezdochka noz plus	xylometazoline (xylometazoline hydrochloride), dexpanthenol	spray nasal dosed	0,1mg/dose+5mg/dose; 10ml glass vial with dispenser device, 15ml glass vial with dispenser device, 20ml glass vial with dispenser device	Danapha Pharmaceutical JSC, 253 Dung Si Thanh Khe str., Thanh Khe District, Danang city	Vietnam	"DOMINANTA-SERVIS" JSC, Komsomolskaya St. 1, building 49, room 1, apartment 223, Podolsk, Moscow region, 142100	Russia	OTC	24516 (014095) 31.08.2026
15	Zvezdochka noz plus	xylometazoline (xylometazoline hydrochloride), dexpanthenol	spray nasal dosed	0,05mg/dose+5mg/dose; 10ml glass vial with dispenser device, 15ml glass vial with dispenser device, 20ml glass vial with dispenser device,	Danapha Pharmaceutical JSC, 253 Dung Si Thanh Khe str., Thanh Khe District, Danang city	Vietnam	"DOMINANTA-SERVIS" JSC, Komsomolskaya St. 1, building 49, room 1, apartment 223, Podolsk, Moscow region, 142100	Russia	OTC	24517 (014095) 31.08.2026
16	Diaflex Chondro	diacereina, chondroitin sulfate (chondroitin sulfate sodium)	capsules	25mg+200mg; (30/3x13') in blister; (60/6x10') in blister; (90/9x10') in blister	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	PoM	24518 (010079) 31.08.2026
17	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	24466 (042683) 31.08.2026
18	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	24467 (044075) 31.08.2026
19	Zithrocyn	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3') in blister	A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan- secondary packager, quality control, batch releaser, Centurion Laboratories Pvt. Ltd., P-2 Savli Bio-Tech Park, At Manjusar, Tal-Savli, Vadodara-390016, India- bulk manufacturer, primary packager	Republic of Armenia	A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan	Republic of Armenia	PoM	24468 (044872) 31.08.2026
20	Colchicine Opocalcium	colchicine	tablets	1mg; (20/1x20') in blister	Zentiva S.A, Theodor Pallady Blvd nr. 50, sector 3, Bucharest, 032266	Romania	Laboratoires MAYOLY SPINDLER, 6 avenue de l' Europe, 78400 Chatou	France	PoM	24469 (018582) 31.08.2026

21	Ondansetron	ondansetron (ondansetron hydrochloride dihydrate)	solution for injection	2mg/ml; (5/1x5) ampoules 4ml 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	24470 (037117) 31.08.2026
22	Dinga	glimepiride, metformin (metformin hydrochloride)	tablets	2mg+500mg; (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	24471 (037118) 31.08.2026
23	Ortophen	diclofenac (diclofenac sodium)	tablets gastro-resistant	25mg; (30/3x10) in blister	PJSC "Technolog", 8, Stara prrizna street, Uman, Cherkassy region, 20300	Ukraine	PJSC "Technolog", 8, Stara prrizna street, Uman, Cherkassy region, 20300	Ukraine	PoM	24472 (037119) 31.08.2026
24	Tiamox	amoxicillin (amoxicillin trihydrate)	capsules	500mg; (10/1x10) in blister	A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan- secondary packager, quality control, batch releaser, Centurion Laboratories Pvt. Ltd., P-2 Savli Bio-Tech Park, At Manjusar, Tal-Savli, Vadodara-390016, India- bulk manufacturer, primary packager	Republic of Armenia	A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan	Republic of Armenia	PoM	24473 (044874) 31.08.2026
25	Acetylsalicylic acid	acetylsalicylic acid	tablets	500mg; (10) in blister	PJSC "Technolog", building 8, Stara prrizna street, Uman city, Cherkassy region, 20300	Ukraine	PJSC "Technolog", building 8, Stara prrizna street, Uman city, Cherkassy region, 20300	Ukraine	OTC	24474 (039608) 31.08.2026
26	Solution Protargol 2%	silver proteinate	solution for topical use	20mg/ml; 15ml plastic bottle-dropper, 15ml plastic container with pump dispenser	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	24475 (039824) 31.08.2026
27	Haloperidol	haloperidol	tablets	5mg; (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/ UC	24476 (039829) 31.08.2026
28	Distem	paracetamol, methocarbamol	tablets	300mg+380mg; (50/5x10) in blister	FAES FARMAS.A., C/Maximo Aguirre, 14, Lejona-Leioa, 48940 Vizcaya/Bizkaia	Spain	FAES FARMAS.A., C/Maximo Aguirre, 14, Lejona-Leioa, 48940 Vizcaya/Bizkaia	Spain	PoM	24477 (040821) 31.08.2026

29	Ciprofloxacin	ciprofloxacin (ciprofloxacin hydrochloride)	drops eye	3mg/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	24478 (041009) 31.08.2026
30	Be-Bo	benzyl benzoate	emulsion	200mg/g; plastic bottle 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	24479 (041620) 31.08.2026
31	ALBUCID	sulfacetamide (sulfacetamide sodium)	powder for external use	500mg; (10) sachets	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	OTC	24480 (041625) 31.08.2026
32	Synthomycin liniment	chloramphenicol	liniment	50mg/g; 25g aluminium tube	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	24481 (045803) 31.08.2026
33	Synthomycin liniment	chloramphenicol	liniment	100mg/g; 25g aluminium tube	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	24482 (045803) 31.08.2026
34	Tinctura Valerianae	valerianae rhizome with roots	tincture	200mg/ml; 30ml glass vial	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	24483 (042437) 31.08.2026
35	Gabapentin	gabapentin	capsules hard	300mg; (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	24484 (042681) 31.08.2026
36	Hypomed	lisinopril (lisinopril dihydrate), amlodipine (amlodipine besilate)	tablets	10mg;5mg; (40/1x40) 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	24485 (042905) 31.08.2026
37	Tro-Ceftriax 1g powder for solution for injection/infusion	ceftriaxone (ceftriaxone sodium)	powder for solution for injection/infusion	1000mg; (1) glass vial, (50) glass vials	Reyoung Pharmaceutical Co. Ltd., No1 Ruiyang Road, Yiyuan County, Shandong Province	China	Troge Medical GmbH, Milchstrasse 19, 20148 Hamburg	Germany	PoM	24486 (042973) 31.08.2026

38	NOVOSEPT	benzyltrimethyl ammonium chloride monohydrate	solution for topical and external use	0,1mg/ml; 50ml plastic container (pump dispenser and applicator), 150ml (dispenser), 200ml plastic container (measuring applicator)	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	IE Sergey Sergeevich Patvakanov, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	OTC	24487 (044071) 31.08.2026
39	Boric acid ointment 5%	boric acid	ointment	50mg/g; aluminium tube 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	24488 (044101) 31.08.2026
40	Vegtasone Uno	mometasone (mometasone furoate)	cream	1mg/g; 15g aluminium tube	BALKANPHARMA-RAZGRAD AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	BELINDA LABORATORIES LLP, Unit 18, 53 Norman road, Greenwich Centre Business park, SE10 9QF, London	UK	PoM	24489 (044276) 31.08.2026
41	Vametal	ondansetron (ondansetron hydrochloride dihydrate)	solution for i/v and i/m injection	2mg/ml; glass vial 2ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Medicus S.A., 10 Valaoritou str., GR 14452, Metamorphosis	Greece	PoM	24490 (044537) 31.08.2026
42	Vametal	ondansetron (ondansetron hydrochloride dihydrate)	solution for i/v and i/m injection	2mg/ml; glass vial 4ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Medicus S.A., 10 Valaoritou str., GR 14452, Metamorphosis	Greece	PoM	24491 (044537) 31.08.2026
43	Doxitus	doxofylline	syrup	100mg/5ml; 100ml glass bottle 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	24492 (044657) 31.08.2026
44	Diclofenac Ophthalmic	diclofenac (diclofenac sodium)	drops eye	1mg/ml; 10ml 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	24493 (045732) 31.08.2026
45	Otofix	phenazone, lidocaine (lidocaine hydrochloride)	drops ear (solution)	40mg/g+10mg/g; glass vial 15ml and dropper applicator	Sopharma JSC, Industrial zone Sandanski 2800	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	24495 (036672) 31.08.2026
46	HEXPANTHEN	dexpantenol, chlorhexidine (chlorhexidine bigluconate)	suppositories vaginal	100mg+16mg; (10/2x5/)	Medical Horizon Ltd, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	Medical Horizon Ltd, Ararat province, Masis city, Hrant Vardanyan 22	Republic of Armenia	OTC	24496 (044558) 31.08.2026

47	PARABRUFEN	ibuprofen	tablets film-coated	600mg (10/1x10) in blister	A LAB PHARMACEUTICALS LLC, Nor-Nork Kochinyan 13/16, Yerevan- packager, batch releaser, Zim Laboratories Ltd., B-21/22, MIDC Area, Kalmeshwar- 441 501, Dist. Nagpur (M.S.), India- bulk manufacturer	Republic of Armenia	A LAB PHARMACEUTICALS LLC, Nor-Nork Kochinyan 13/16, Yerevan	Republic of Armenia	PoM	24497 (044871) 31.08.2026
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LIST

of the medicines recommended for re-registration under the EAEU procedure by the Center according to the meeting decision N 08-2/26 on August 31, 2026

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	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	24498 (034888) 31.08.2026
2	Telmista AM	amlodipine (amlodipine besilate), telmisartan	tablets	5mg+40mg; (28/4x7) in blister, (30/3x10) in blister, (56/8x7) in blister, (60/6x10) in blister, (84/12x7) 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	24499 (046385) 31.08.2026
3	Telmista AM	amlodipine (amlodipine besilate), telmisartan	tablets	5mg+80mg; (28/4x7) in blister, (30/3x10) in blister, (56/8x7) in blister, (60/6x10) in blister, (84/12x7) 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	24500 (046385) 31.08.2026
4	Telmista AM	amlodipine (amlodipine besilate), telmisartan	tablets	10mg+40mg; (28/4x7) in blister, (30/3x10) in blister, (56/8x7) in blister, (60/6x10) in blister, (84/12x7) 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	24501 (046385) 31.08.2026
5	Telmista AM	amlodipine (amlodipine besilate), telmisartan	tablets	10mg+80mg; (28/4x7) in blister, (30/3x10) in blister, (56/8x7) in blister, (60/6x10) in blister, (84/12x7) 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	24502 (046385) 31.08.2026

LIST

of variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting decision N 08-2/26 on August 31, 2026

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1	Pergoveris	follitropin alfa, lutropin alfa	powder lyophilized for solution for s/c injection	150IU+75IU; (1) glass vial and (1) solvent in vial 1ml, (3) glass vials and (3) solvent in vials 1ml, (10) glass vials and (10) solvent in vials 1ml	Merck Serono S.A., Succursale d' Aubonne, Zone Industrielle de l' Ourietta, 1170 Aubonne	Switzerland	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	ЖП-№003837-ИТ-АМ 31.08.2026

LIST

of variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 08-2/26 on August 31, 2026

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1	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	22395/1 31.08.2026
2	ACC 200	acetylcysteine	tablets effervescent	200mg; (20) in plastic container	Salutas Pharma GmbH, Otto-von-Guericke-Allee-1, 39179 Barleben- batch releaser, Hermes Pharma Ges.m.b.H, Schwimmschulweg 1a, Wolsberg, 9400, Austria- bulk manufacturer, packager, quality control	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	22457/2 31.08.2026
3	Gardasil	human papillomavirus type 6 L1 protein, human papillomavirus type 11 L1 protein, human papillomavirus type 16 L1 protein, human papillomavirus type 18 L1 protein	suspension for i/m injection	20mcg/dose+40mcg/dose+40mcg/dose+20mcg/dose; 0,5ml/dose pre-filled syringe and (1) needle, 0,5ml/dose pre-filled syringe and (2) needles	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem- secondary packager, batch releaser, Merck Sharp & Dohme LLC, 770 Summeytown Pike, West Point, Pennsylvania (PA) 19486, USA- bulk manufacturer, primary packager, quality control	the Netherlands	Merck Sharp & Dohme IDEA GmbH, Tribschenstrasse 60, 6005 Luzern	Switzerland	PoM	20190/8/3 31.08.2026
4	Gardasil	human papillomavirus type 6 L1 protein, human papillomavirus type 11 L1 protein, human papillomavirus type 16 L1 protein, human papillomavirus type 18 L1 protein	suspension for i/m injection	20mcg/dose+40mcg/dose+40mcg/dose+20mcg/dose; 0,5ml/dose pre-filled syringe and (1) needle, 0,5ml/dose pre-filled syringe and (2) needles, 0,5ml/dose glass vial	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem- secondary packager, batch releaser, Merck Sharp & Dohme LLC, 770 Summeytown Pike, West Point, Pennsylvania (PA) 19486, USA- bulk manufacturer, primary packager, quality control	the Netherlands	Merck Sharp & Dohme IDEA GmbH, Tribschenstrasse 60, 6005 Luzern	Switzerland	PoM	23833/2 31.08.2026

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 08-2/26 on August 31, 2026

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	Torvazin Plus	atorvastatin (atorvastatin calcium trihydrate), ezetimibe	capsules	10mg+10mg; (30/3x10) in blister, (90/9x10) in blister	EGIS Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65	Hungary	EGIS Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	JITI-N°000855-ITI-AM 31.08.2026
2	Torvazin Plus	atorvastatin (atorvastatin calcium trihydrate), ezetimibe	capsules	10mg+10mg; (30/3x10) in blister, (90/9x10) 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	JITI-N°000855-ITI-AM 31.08.2026
3	Torvazin Plus	atorvastatin (atorvastatin calcium trihydrate), ezetimibe	capsules	20mg+10mg; (30/3x10) in blister, (90/9x10) in blister	EGIS Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65	Hungary	EGIS Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	JITI-N°000855-ITI-AM 31.08.2026
4	Torvazin Plus	atorvastatin (atorvastatin calcium trihydrate), ezetimibe	capsules	20mg+10mg; (30/3x10) in blister, (90/9x10) 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	JITI-N°000855-ITI-AM 31.08.2026
5	Torvazin Plus	atorvastatin (atorvastatin calcium trihydrate), ezetimibe	capsules	40mg+10mg; (30/3x10) in blister, (90/9x10) in blister	EGIS Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65	Hungary	EGIS Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	JITI-N°000855-ITI-AM 31.08.2026
6	Torvazin Plus	atorvastatin (atorvastatin calcium trihydrate), ezetimibe	capsules	40mg+10mg; (30/3x10) in blister, (90/9x10) 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	JITI-N°000855-ITI-AM 31.08.2026

7	Roxatenz-amlo	perindopril (perindopril tert-butylamine), amlodipine, rosuvastatin (rosuvastatin calcium)	tablets film-coated	4mg+5mg+10mg: (30/3x10) 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	JITI-N°000745-ITI-AM 31.08.2026
8	Roxatenz-amlo	perindopril (perindopril tert-butylamine), amlodipine, rosuvastatin (rosuvastatin calcium)	tablets film-coated	8mg+5mg+10mg: (30/3x10) 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	JITI-N°000745-ITI-AM 31.08.2026
9	Roxatenz-amlo	perindopril (perindopril tert-butylamine), amlodipine, rosuvastatin (rosuvastatin calcium)	tablets film-coated	8mg+5mg+20mg: (30/3x10) 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	JITI-N°000745-ITI-AM 31.08.2026
10	Roxatenz-amlo	perindopril (perindopril tert-butylamine), amlodipine, rosuvastatin (rosuvastatin calcium)	tablets film-coated	8mg+10mg+20mg: (30/3x10) 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	JITI-N°000745-ITI-AM 31.08.2026
11	Concor Cor	bisoprolol (bisoprolol fumarate)	tablets film-coated	2,5mg: (30/1x30) in blister, (50/2x25) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, Valovaya Street 35, Moscow 115054	Russia	PoM	JITI-N°004360-ITI-AM 31.08.2026
12	Concor	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg: (30/3x10) in blister, (30/1x30) in blister, (50/5x10) in blister, (50/2x25) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, Valovaya Street 35, Moscow 115054	Russia	PoM	JITI-N°003852-ITI-AM 31.08.2026
13	Concor	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg: (30/3x10) in blister, (30/1x30) in blister, (50/5x10) in blister, (50/2x25) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, Valovaya Street 35, Moscow 115054	Russia	PoM	JITI-N°003852-ITI-AM 31.08.2026
14	Bromocriptin-Richter	bromocriptine (bromocriptine mesilate)	tablets	2,5mg: (30) glass bottle	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°002402-ITI-AM 31.08.2026
15	Thiogamma	thioctic acid	solution for infusion	12mg/ml: (1) glass vial 50ml, (5) glass vials 50ml, (10) glass vials 50ml	Solpharm Pharmazeutische Erzeugnisse GmbH, Industriestrasse 3, 34212 Melsungen	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boblingen	Germany	PoM	JITI-N°001968-ITI-AM 31.08.2026

16	Tibsovo	ivosidenib	tablets film-coated	250mg (60) in plastic container	Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy- batch releaser, Rottendorf Pharma GmbH, Ostenfelder Strasse 51-61, Ennigerloh, 59320, Germany- bulk manufacturer, quality control (physicochemical), Almac Pharma Services Limited, Seagoe Industrial Estate, Portadaun, Creigavon, BT63 5UA, United Kingdom- packager, Eurofins BioPharma Product Testing Munich GmbH, Robert-Koch-Strasse 3a, Planegg, Bavaria, Germany- quality control (microbiological)	France	Laboratoires Servier, 50, rue Carno, 92284 Suresnes cedex	France	PoM	JITI-N°012213-ITI-AM 31.08.2026
17	Tibsovo	ivosidenib	tablets film-coated	250mg (60) in plastic container	Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy- batch releaser, Patheon Inc., 2100 Syntex Court, Mississauga, Ontario, L5N 7K9, Canada- bulk manufacturer, quality control, Almac Pharma Services Limited, Seagoe Industrial Estate, Portadaun, Creigavon, BT63 5UA, United Kingdom- packager	France	Laboratoires Servier, 50, rue Carno, 92284 Suresnes cedex	France	PoM	JITI-N°012213-ITI-AM 31.08.2026
18	Tabex	cytisine	tablets film-coated	1,5mg (100/5x20) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	JITI-N°008726-ITI-AM 31.08.2026
19	Vibrocil	dimethindene (dimethindene maleate), phenylephrine	drops nasal	0,25mg/ml+2,5mg/ml; 15ml glass vial	Haleon CH SARI, Route de l' Etraz, Nyon, 1260	Switzerland	JSC "Haleon Rus", Presnenskaya Naberezhnaya, 10, unit III, room 9, 6 floor, Moscow, 123112	Russia	OTC	JITI-N°002542-ITI-AM 31.08.2026
20	Broncholytin	glaucine (glaucine hydrobromide), ephedrine (ephedrine hydrochloride)	syrup	5,75mg/5ml+4,6mg/5ml; 125g glass or plastic bottle and measuring cup	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia- batch releaser, Sopharma JSC, Vrabovo vlg. 5660, district of Lovetch, Bulgaria- bulk manufacturer, packager, quality control	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	JITI-N°006421-ITI-AM 31.08.2026
21	Pancef	cefixime (cefixime trihydrate)	granules for oral suspension	100mg/5ml; 53g granules in 100ml glass bottle, 32g granules in 60ml glass bottle and 5ml measuring spoon	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- quality control, batch releaser, Alkaloid AD Skopje, Blvd. Partizanski odredi 98A, 1000 Skopje, Republic of North Macedonia- bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	JITI-N°000250-ITI-AM 31.08.2026

22	Faslodex	fulvestrant	solution for injection	50mg/ml; (2) pre-filled syringes and (2) needles	AstraZeneca Industries LLC, property 8,1st Vostochny passage, Dobrino village, Borovsk area, Kaluga region, 249020- secondary packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Schutzenstrasse 87 and 99-101, 88212 Ravensburg, Germany- bulk manufacturer, primary packager, quality control	Russia	AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, CB2 0AA	UK	PoM	JITI-N°000876-ITI-AM 31.08.2026
23	Faslodex	fulvestrant	solution for injection	50mg/ml; (2) pre-filled syringes and (2) needles	AstraZeneca Industries LLC, property 8,1st Vostochny passage, Dobrino village, Borovsk area, Kaluga region, 249020- secondary packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Eisenstrasse 2-4, 88085 Langenargen, Germany- bulk manufacturer, primary packager, quality control	Russia	AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, CB2 0AA	UK	PoM	JITI-N°000876-ITI-AM 31.08.2026
24	Faslodex	fulvestrant	solution for injection	50mg/ml; (2) pre-filled syringes and (2) needles	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire SK10 2NA- secondary packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Schutzenstrasse 87 and 99-101, 88212 Ravensburg, Germany- bulk manufacturer, primary packager, quality control	UK	AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, CB2 0AA	UK	PoM	JITI-N°000876-ITI-AM 31.08.2026
25	Faslodex	fulvestrant	solution for injection	50mg/ml; (2) pre-filled syringes and (2) needles	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire SK10 2NA- secondary packager, quality control, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Eisenstrasse 2-4, 88085 Langenargen, Germany- bulk manufacturer, primary packager	UK	AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, CB2 0AA	UK	PoM	JITI-N°000876-ITI-AM 31.08.2026
26	Depakine enteric 300	valproate sodium (valproic acid)	tablets gastro-resistant	300mg; (100/10x10) in blister	Sanofi-Aventis S.A., Ctra. C35 La Batlloria a Hostalric, km 63.09,17404 Riells I Viabrea (Girona)	France	Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly	France	PoM	JITI-N°001983-ITI-AM 31.08.2026
27	Nuroton Zero	ibuprofen	suspension oral	100mg/5ml; 100ml plastic bottle and measuring syringe 5ml	Pharmtechnology LLC, Korzhenevskogo str., 22, 220024, Minsk	Republic of Armenia	Giga Farm LLC, Gogunca str.3/5, Gyumri, 3101	Republic of Armenia	OTC	JITI-N°011783-PT-AM 31.08.2026
28	Detralex	diosmin, hesperidin	tablets film-coated	900mg+100mg; (18/2x9) in blister, (27/3x9) in blister, (30/3x10) in blister, (60/6x10) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	OTC	JITI-N°000880-ITI-AM 31.08.2026

29	Detralex	diosmin, hesperidin	tablets film-coated	900mg+100mg: (18/2x9) in blister, (30/3x10) in blister, (60/6x10) 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	OTC	JITI-N°000880-ITI-AM 31.08.2026
30	Detralex	diosmin, hesperidin	tablets film-coated	900mg+100mg: (18/2x9) in blister, (27/3x9) in blister, (30/3x10) in blister, (60/6x10) 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	OTC	JITI-N°000880-ITI-AM 31.08.2026
31	Detralex	diosmin, hesperidin	tablets film-coated	450mg+50mg: (28/2x14) in blister, (30/2x15) in blister, (36/3x12) in blister, (56/4x14) in blister, (60/4x15) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	OTC	JITI-N°000880-ITI-AM 31.08.2026
32	Detralex	diosmin, hesperidin	tablets film-coated	450mg+50mg: (30/2x15) in blister, (36/3x12) in blister, (60/4x15) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow- packager, quality control, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	OTC	JITI-N°000880-ITI-AM 31.08.2026
33	Detralex	diosmin, hesperidin	tablets film-coated	450mg+50mg: (28/2x14) in blister, (30/2x15) in blister, (36/3x12) in blister, (56/4x14) 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	OTC	JITI-N°000880-ITI-AM 31.08.2026
34	Tyrez	bisoprolol (bisoprolol fumarate)	tablets film-coated	2,5mg: (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	JITI-N°000117-ITI-AM 31.08.2026
35	Tyrez	bisoprolol (bisoprolol fumarate)	tablets film-coated	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	JITI-N°000117-ITI-AM 31.08.2026
36	Tyrez	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg: (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	JITI-N°000117-ITI-AM 31.08.2026

