

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 01-1/26 on January 29, 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	CinnoRA	adalimumab	solution for injection	40mg/0,8ml; (2) glass pre-filled syringes 0,8ml	CinnaGen Co., Plot No. 72, 74, 87, 88, 3rd Sq., Simin Dasht Non-Governmental Industrial Area, Fardis County, Alborz Province	Iran	CinnaGen Co., Plot No. 72, 74, 87, 88, 3rd Sq., Simin Dasht Non-Governmental Industrial Area, Fardis County, Alborz Province	Iran	PoM	23806 29.01.2026
2	Kermoven	rivaroxaban	tablets film-coated	15mg; (30/2x15) in blister	Saneca Pharmaceuticals a.s., Nitrianska 100, 920 27 Hlohovec	Slovak Republic	Aversi-Rational Ltd, 33 David Kobakhidze Str., 0198, Tbilisi	Georgia	PoM	23807 29.01.2026
3	Kermoven	rivaroxaban	tablets film-coated	20mg; (30/2x15) in blister	Saneca Pharmaceuticals a.s., Nitrianska 100, 920 27 Hlohovec	Slovak Republic	Aversi-Rational Ltd, 33 David Kobakhidze Str., 0198, Tbilisi	Georgia	PoM	23808 29.01.2026
4	Allerway	levocetirizine (levocetirizine dihydrochloride)	tablets film-coated	5mg; (7/1x7) in blister, (10/1x10) in blister, (14/2x7) in blister, (20/2x10) in blister, (21/3x7) in blister, (30/3x10) in blister	Dr. Reddy's Laboratories Ltd., FTO Unit 3, Survey No. 41, 42 part, 45 part & 46 part, Bachupally (Village), Bachupally (Mandal), Medchal-Malkajgiri (Dist.), Telangana	India	Dr. Reddy's Laboratories Ltd., 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana-500034	India	OTC	23809 29.01.2026
5	Allerway	levocetirizine (levocetirizine dihydrochloride)	tablets film-coated	5mg; (7/1x7) in blister, (10/1x10) in blister, (14/2x7) in blister, (20/2x10) in blister, (21/3x7) in blister, (30/3x10) in blister	Dr. Reddy's Laboratories Limited, Formulations Unit 6, Vill, Khol, Nalagarh Raod, Baddi, Distt Solan, H, P, 173205	India	Dr. Reddy's Laboratories Ltd., 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana-500034	India	OTC	23810 29.01.2026
6	ORALSEPT	benzylamine	spray oromucosal	1,5mg/ml; 30ml plastic container with pump dispenser	Replek Farm Ltd. Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	Replek Farm Ltd. Skopje, 188 str. Kozle, 1000 Skopje	Republic of North Macedonia	OTC	23811 29.01.2026

LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 01-1/26 on January 29, 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	Ultrix Quadri Tetravalent inactivated split influenza vaccine	Influenza vaccine	solution for i/m injection	15mcg/dose+15mcg/dose+15mcg/ dose+15mcg/dose; (1) pre-filled syringe 0,5ml (dose), (10) pre-filled syringes 0,5ml (dose)	FORT LLC, Ryazan region, Ryazanskiy m. district, s/p Okskoe, Yaltunovo vill., Pharmaceutical complex area, b. 1j, 390540	Russia	FORT LLC, Ryazan region, Ryazanskiy m. district, s/p Okskoe, Yaltunovo vill., Pharmaceutical complex area, b. 1a, 390540	Russia	PoM	23814 (016076) 29.01.2026
2	Ultrix Quadri Tetravalent inactivated split influenza vaccine	Influenza vaccine	solution for i/m injection	15mcg/dose+15mcg/dose+15mcg/ dose+15mcg/dose; (10) ampoules 0,5ml (dose) label banderol, (10/2x5) ampoules 0,5ml (dose) in blister	Microgen, Republic of Bashkortostan, Ufa, 105 Novorossiyskaya Street, 450014	Russia	FORT LLC, Ryazan region, Ryazanskiy m. district, s/p Okskoe, Yaltunovo vill., Pharmaceutical complex area, b. rural settlement, Yaltunovo, pharm complex, bld. 1a, 390540	Russia	PoM	23815 (016076) 29.01.2026
3	Hemomycin	azithromycin (azithromycin dihydrate)	powder lyophilized for solution for infusion	500mg; glass vial	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	PoM	23816 (011219) 29.01.2026
4	Loratadine	loratadine	tablets	10mg; (10/1x10) in blister, (30/3x10) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64A, Chapayev str., Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapayev str., Borisov 222518, Minsk region	Republic of Belarus	OTC	23817 (016156) 29.01.2026

5	Fervex	paracetamol, ascorbic acid, pheniramine (pheniramine maleate)	powder for oral solution with lemon flavor, sugar free	500mg+200mg+25mg; (8) sachets 4,95g	UPSA SAS, 979, Avenue des Pyrenees, 47520 Le Passage	France	UPSA SAS, 3, rue Joseph Monier-92500 Rueil-Malmaison	France	OTC	23818 (009961) 29.01.2026
6	Carsil	silymarin	tablets film-coated	22,5mg; (80/8x10) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	23819 (011543) 29.01.2026
7	Canephron N	centauri herba, levistici radix, rosmarini folia	tablets coated	18mg+18mg+18mg; (60/3x20) in blister, (120/6x20) in blister	Bionorica SE, Kerschensteiner str. 11-15, 92318 Neumarkt in der Oberpfalz- packager, quality control, batch releaser, Rottendorf Pharma GmbH, Ostenfelder Strasse 51-61, 59320 Ennigerloh, Germany- bulk manufacturer	Germany	Bionorica SE, Kerschensteiner str. 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	23820 (020451) 29.01.2026
8	Canephron N	centauri herba, levistici radix, rosmarini folia	tablets coated	18mg+18mg+18mg; (60/3x20) in blister, (120/6x20) in blister	Bionorica SE, Kerschensteiner str. 11-15, 92318 Neumarkt in der Oberpfalz- packager, quality control, batch releaser, Wivelhofe GmbH, Dernebrink 19, 49479 Ibbenburen, Germany- bulk manufacturer	Germany	Bionorica SE, Kerschensteiner str. 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	23821 (020451) 29.01.2026
9	Canephron N	centauri herba, levistici radix, rosmarini folia	tablets coated	18mg+18mg+18mg; (60/3x20) in blister, (120/6x20) in blister	Bionorica Pharmaceuticals LLC, 396333, Voronezh Region, Novousmanskoy Municipal District, Nikolskoye Rural Settlement, Maslovsky Industrial Park territory, 1st Parkovaya Street, Building 2- packager, quality control (physicochemical), batch releaser, Rottendorf Pharma GmbH, Ostenfelder Strasse 51-61, 59320 Ennigerloh, Germany- bulk manufacturer, "ICLS Biotechnology", 142700, h.10A, 8th Liniya Street, Vidnoye, Leninsky Urban District, Moscow Region, Russia- quality control (microbiological)	Russia	Bionorica SE, Kerschensteiner str. 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	23822 (020451) 29.01.2026

10	Canephron N	centauri herba, levistici radix, rosmarini folia	tablets coated	18mg+18mg+18mg; (60/3x20) in blister, (120/6x20) in blister	Bionorica Pharmaceuticals LLC, 396333, Voronezh Region, Novousmansky Municipal District, Nikolskoye Rural Settlement, Maslovsky Industrial Park territory, 1st Parkovaya Street, Building 2- packager, quality control (physicochemical), batch releaser, Wivelhofe GmbH, Dernebrink 19, 49479 Ibbenburen, Germany- bulk manufacturer, "ICLS Biotechnology", 142700, h.10A, 8th Liniya Street, Vidnoye, Leninsky Urban District, Moscow Region, Russia- quality control (microbiological)	Russia	Bionorica SE, Kerschensteiner str. 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	23823 (020451) 29.01.2026
11	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	23824 (003276) 29.01.2026
12	Captopril	captopril	tablets	50mg; (30/3x10) in blister, (60/6x10) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64A, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	PoM	23825 (003276) 29.01.2026
13	Artrozan- Pharmstandard	meloxicam	solution for i/m injection	6mg/ml; (3/1x3) ampoules 2,5ml in blister, (5/1x5) ampoules 2,5ml in blister, (10/2x5) ampoules 2,5ml in blister, (5/1x5) "blow-fill-seal" ampoules 2,5ml, (10/2x5) "blow-fill-seal" ampoules 2,5ml, (5/1x5) "blow-fill-seal" ampoules 2,5ml in foil pack, (10/2x5) "blow-fill-seal" ampoules 2,5ml in foil pack	Pharmstandard-Ufa VITA OJSC, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	Pharmstandard-Ufa VITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	PoM	23826 (001596) 29.01.2026

14	EVICOLON	macrogol (macrogol 4000)	powder for oral solution	64g; (4) sachets 73,69g	Pharmakor Production LLC, Int. Ter. Knyazyevo municipal district, Leninsky p., building 140, lit. Zh, premises 1N/2N/5N, Saint Petersburg- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Expert Bio LLC, Institutsky Prospect, building 21, lit. M, Saint Petersburg, Russia- quality control (microbiological)	Russia	Giga Farm LLC, Gogunca str.3/5, Gyumri, 3101	Republic of Armenia	OTC	23813 (028090) 29.01.2026
----	----------	--------------------------	-----------------------------	-------------------------	---	--------	---	------------------------	-----	------------------------------

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 01-1/26 on January 29, 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	Cosopt PF	timolol (timolol maleate), dorzolamide (dorzolamide hydrochloride)	drops eye (solution)	5mg/ml+20mg/ml; plastic vial 10ml	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, Tubilux Pharma S.p.A., Via Costarica, 20/22, 00071 Pomezia/Rome, Italy- bulk manufacturer, packager, quality control	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	PoM	23805 29.01.2026

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 01-1/26 on January 29, 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	Intellan	ginkgo biloba, centella asiatica, herpestis monniera, coriandrum sativum, amomum subulatum, emblica officinalis	syrup	50mg/10ml+500mg/10ml+50mg/10ml+150mg/10ml+150mg/10ml+200mg/10ml; 90ml glass bottle, 120ml glass bottle, 150ml glass bottle	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	23827 29.01.2026
2	On.setron-Denk 8mg ODT	ondansetron	tablets orodispersible	8mg; (6/1x6) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning-bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LSSE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	23828 29.01.2026
3	Trimecor MR	trimetazidine (trimetazidine dihydrochloride)	tablets film-coated modified-release	35mg; (30/3x10) in blister, (60/6x10) in blister	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	23829 29.01.2026
4	Ricozib-60	etoricoxib	tablets film-coated	60mg; (30/3x10) in blister	Zim Laboratories Ltd., B-21/22, MIDC Area, Kalmeshwar-441 501, Dist. Nagpur (M.S.)	India	Zim Laboratories Ltd., Ground Floor, Sadoday Gyan, Nelson Square, Chhindwara Road, Nagpur-440 013	India	PoM	23830 29.01.2026

5	Ricozib-90	etoricoxib	tablets film-coated	90mg; (30/3x10') in blister	Zim Laboratories Ltd., B-21/22, MIDC Area, Kalmeshwar-441 501, Dist. Nagpur (M.S.)	India	Zim Laboratories Ltd., Ground Floor, Sadoday Gyan, Nelson Square, Chhindwara Road, Nagpur-440 013	India	PoM	23831 29.01.2026
6	Ricozib-120	etoricoxib	tablets film-coated	120mg; (30/3x10') in blister	Zim Laboratories Ltd., B-21/22, MIDC Area, Kalmeshwar-441 501, Dist. Nagpur (M.S.)	India	Zim Laboratories Ltd., Ground Floor, Sadoday Gyan, Nelson Square, Chhindwara Road, Nagpur-440 013	India	PoM	23832 29.01.2026
7	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 29.01.2026
8	Duphalac	lactulose	syrup	667mg/ml; plastic bottle 200ml, plastic bottle 500ml, plastic bottle 1000ml, (10) sachets 15ml	ABBOTT Biologicals B.V., Veerweg 12, 8121 AA Olst	the Netherlands	ABBOTT Healthcare Products B.V., C.J. van Houtenlaan 36, NL-1381 CP Weesp	the Netherlands	OTC	23834 29.01.2026
9	Duspatalin	mebeverine (mebeverine hydrochloride)	capsules hard prolonged-release	200mg; (30/2x15') in blister	Mylan Laboratories SAS, Route de Belleville, Lieu-dit Maillard, 01400 Chatillon sur Chalaronne	France	Abbott Healthcare Products B.V., C.J. van Houtenlaan 36, 1381 CP Weesp	the Netherlands	PoM	23835 29.01.2026
10	Heptral	ademetionine	powder lyophilized for solution for injection	400mg; (5) glass vials and (5) solvent in ampoules 5ml	BIOLOGICI ITALIA LABORATORIES S.R.L., VIA FILIPPO SERPERO, 2- 20060 MASATE (MI)- bulk manufacturer, packager, quality control, batch releaser of powder, BIOLOGICI ITALIA LABORATORIES S.R.L., VIA FILIPPO SERPERO, 2- 20060 MASATE (MI), Italy- solvent manufacturer and primary packager	Italy	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	PoM	23836 29.01.2026

LIST

of the variations requiring registration approved by the Center according to the meeting decision N 01-1/26 on January 29, 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	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	7,5mg/0,15ml; pre-filled syringe 0,15ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel- secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany- bulk manufacturer, primary packager, quality control	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	23798 29.01.2026
2	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	10mg/0,2ml; pre-filled syringe 0,2ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel- secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany- bulk manufacturer, primary packager, quality control	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	23799 29.01.2026
3	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	12,5mg/0,25ml; pre-filled syringe 0,25ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel- secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany- bulk manufacturer, primary packager, quality control	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	23800 29.01.2026
4	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	15mg/0,3ml; pre-filled syringe 0,3ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel- secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany- bulk manufacturer, primary packager, quality control	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	23801 29.01.2026

5	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	17,5mg/0,35ml; pre-filled syringe 0,35ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel- secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany- bulk manufacturer, primary packager, quality control	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	23802 29.01.2026
6	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	20mg/0,4ml; pre-filled syringe 0,4ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel- secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany- bulk manufacturer, primary packager, quality control	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	23803 29.01.2026
7	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	25mg/0,5ml; pre-filled syringe 0,5ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel- secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany- bulk manufacturer, primary packager, quality control	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	23804 29.01.2026

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 01-1/26 on January 29, 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	Aqvipaxel	paclitaxel	concentrate for solution for infusion	6mg/ml; glass vial 5ml	AqVida GmbH, Kaiser-Wilhelm-Str. 89, Hamburg, 20355- batch releaser, AqVida GmbH, Werkstrasse 21, Dassow, Mecklenburg-Vorpommern 23942, Germany- bulk manufacturer, packager, quality control	Germany	Aversi-Rational Ltd, 33 David Kobakhidze Str., 0198, Tbilisi	Georgia	PoM	20649/1/1 29.01.2026
2	Aqvipaxel	paclitaxel	concentrate for solution for infusion	6mg/ml; glass vial 16,7ml	AqVida GmbH, Kaiser-Wilhelm-Str. 89, Hamburg, 20355- batch releaser, AqVida GmbH, Werkstrasse 21, Dassow, Mecklenburg-Vorpommern 23942, Germany- bulk manufacturer, packager, quality control	Germany	Aversi-Rational Ltd, 33 David Kobakhidze Str., 0198, Tbilisi	Georgia	PoM	20650/1/1 29.01.2026
3	Aqvipaxel	paclitaxel	concentrate for solution for infusion	6mg/ml; glass vial 25ml	AqVida GmbH, Kaiser-Wilhelm-Str. 89, Hamburg, 20355- batch releaser, AqVida GmbH, Werkstrasse 21, Dassow, Mecklenburg-Vorpommern 23942, Germany- bulk manufacturer, packager, quality control	Germany	Aversi-Rational Ltd, 33 David Kobakhidze Str., 0198, Tbilisi	Georgia	PoM	20651/1/1 29.01.2026
4	Omeprazole Pharmproekt	omeprazole	capsules gastro-resistant	20mg; (100/10x10) in strip	Health Care Formulations Pvt. Ltd, C/8, Sardar Estate, Ajwa Road, Vadodara (Gujarat), 390019	India	Pharmproekt LLC, G. Maharu St., 133, 0020, Yerevan	Republic of Armenia	PoM	23382/1/1 29.01.2026

5	Ubistesin	articaine (articaine hydrochloride), epinephrine (epinephrine hydrochloride)	solution for injection	40mg/ml+0,005mg/ml; (50) glass cartridges 1,7ml	Pierrel S.p.A., Strada Statale Appia, 7 Bis, 46/48 Capua (CE) 81043	Italy	Pierrel S.p.A., Strada Statale Appia, 7 Bis, 46/48 Capua (CE) 81043	Italy	PoM	22590/1/1 29.01.2026
6	Ubistesin forte	articaine (articaine hydrochloride), epinephrine (epinephrine hydrochloride)	solution for injection	40mg/ml+0,01mg/ml; (50) glass cartridges 1,7ml	Pierrel S.p.A., Strada Statale Appia, 7 Bis, 46/48 Capua (CE) 81043	Italy	Pierrel S.p.A., Strada Statale Appia, 7 Bis, 46/48 Capua (CE) 81043	Italy	PoM	22591/1/1 29.01.2026
7	Tenikam	tenoxicam	powder lyophilized for solution for injection	20mg; (1) glass vial and solvent in ampoule 2ml	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi- secondary packager, quality control (physicochemical), batch releaser, Anfarm Hellas S.A., 61st Km National Road Athens Lamia, Schimatari Viotias, 32009, Greece- bulk manufacturer, primary packager, quality control (microbiological)	Georgia	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	23307/1/1 29.01.2026
8	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	7,5mg/0,15ml; pre-filled syringe 0,15ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel- batch releaser, Medac Gesellschaft fuer klinische Spezialpraeparate mbH, Wilfried-Mohr-Strasse 1-5, Tomesch, Schleswig-Holstein, 25436, Germany- secondary packager, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany- bulk manufacturer, primary packager, quality control	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	22267/1/1 29.01.2026

9	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	10mg/0,2ml; pre-filled syringe 0,2ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel- batch releaser, Medac Gesellschaft fuer klinische Spezialpraeparate mbH, Wilfried- Mohr-Strasse 1-5, Tormesch, Schleswig-Holstein, 25436, Germany- secondary packager, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany- bulk manufacturer, primary packager, quality control	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	22268/1/1 29.01.2026
10	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	12,5mg/0,25ml; pre-filled syringe 0,25ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel- batch releaser, Medac Gesellschaft fuer klinische Spezialpraeparate mbH, Wilfried- Mohr-Strasse 1-5, Tormesch, Schleswig-Holstein, 25436, Germany- secondary packager, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany- bulk manufacturer, primary packager, quality control	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	22269/1/1 29.01.2026
11	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	15mg/0,3ml; pre-filled syringe 0,3ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel- batch releaser, Medac Gesellschaft fuer klinische Spezialpraeparate mbH, Wilfried- Mohr-Strasse 1-5, Tormesch, Schleswig-Holstein, 25436, Germany- secondary packager, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany- bulk manufacturer, primary packager, quality control	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	22270/1/1 29.01.2026

12	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	17,5mg/0,35ml; pre-filled syringe 0,35ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel- batch releaser, Medac Gesellschaft fuer klinische Spezialpraeparate mbH, Wilfried- Mohr-Strasse 1-5, Tormesch, Schleswig-Holstein, 25436, Germany- secondary packager, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany- bulk manufacturer, primary packager, quality control	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	22271/1/1 29.01.2026
13	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	20mg/0,4ml; pre-filled syringe 0,4ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel- batch releaser, Medac Gesellschaft fuer klinische Spezialpraeparate mbH, Wilfried- Mohr-Strasse 1-5, Tormesch, Schleswig-Holstein, 25436, Germany- secondary packager, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany- bulk manufacturer, primary packager, quality control	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	22272/1/1 29.01.2026
14	Metobject	methotrexate (methotrexate disodium)	solution for s/c injection	25mg/0,5ml; pre-filled syringe 0,5ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel- batch releaser, Medac Gesellschaft fuer klinische Spezialpraeparate mbH, Wilfried- Mohr-Strasse 1-5, Tormesch, Schleswig-Holstein, 25436, Germany- secondary packager, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany- bulk manufacturer, primary packager, quality control	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	22273/1/1 29.01.2026

15	Furazolidone	furazolidone	tablets	50mg; (10) in strip, (50/5x10) in strip, (20/2x10) in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel- batch releaser, Medac Gesellschaft fuer klinische Spezialpraeparate mbH, Wilfried- Mohr-Strasse 1-5, Tornesch, Schleswig-Holstein, 25436, Germany- secondary packager, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany- bulk manufacturer, primary packager, quality control	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	19942/1/1 29.01.2026
16	Linex forte	lyophilized viable lactic acid bacterias (Lactobacillus acidophilus, Bifidobacterium animalis subsp. Lactis)	capsules	2x10 ⁹ CFU; (14/2x7) in blister, (28/4x7) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- quality control, batch releaser, Lek Pharmaceuticals d.d., Kolodvorska cesta 27, Menges, 1234, Slovenia- bulk manufacturer, packager	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	21534/3/1 29.01.2026

LIST

of variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting decision N 01-1/26 on January 29, 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	Co-Sentor	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+12,5mg; (30/3x10) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Poland Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager, Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N*004779-ITI-AM 29.01.2026
2	Co-Sentor	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+25mg; (30/3x10) in blister	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Poland Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N*004780-ITI-AM 29.01.2026
3	Co-Sentor	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	50mg+12,5mg; (30/3x10) in blister	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Poland Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N*004780-ITI-AM 29.01.2026

LIST

of variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 01-1/26 on January 29, 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	Vitaprost Plus	prostate extract (water-soluble peptide), lomefloxacin (lomefloxacin hydrochloride)	suppositories rectal	20mg+400mg; (10/2x5)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, s.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	PoM	22998/1 29.01.2026
2	Caffetin COLD	paracetamol, pseudoephedrine (pseudoephedrine hydrochloride), dextromethorphan (dextromethorphan hydrobromide), ascorbic acid	tablets film-coated	500mg+30mg+15mg+60mg; (10/1x10) 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	OTC	21046/2 29.01.2026
3	Contractubex	extract cepae, heparin (heparin sodium), allantoin	gel for external use	100mg/g+50IU/g+10mg/g; 20g aluminium tube	Merz Pharma GmbH & Co. KGaA, Ludwigstrasse 22, Reinheim, Hessen, 64354	Germany	Merz Pharmaceuticals GmbH, Eckenheimer Landstrasse 100, 60318 Frankfurt/Main	Germany	OTC	21081/4/1 29.01.2026
4	Azimac	azithromycin (azithromycin dihydrate)	powder for oral suspension	200mg/5ml; glass bottle 37,5ml and measuring syringe	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	GM Pharmaceuticals Ltd, Rustavi Highway 52, Tbilisi	Georgia	PoM	22451/1 29.01.2026
5	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	5mg; (56/4x14) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22013/1 29.01.2026
6	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	15mg; (56/4x14) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	22014/1 29.01.2026

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 01-1/26 on January 29, 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	Blemaren	citric acid, potassium hydrogencarbonate, sodium citrate	tablets effervescent	1197mg+967,5mg+835,5mg; (80/4x20) plastic tube	C/Solana, 26, Torrejon de Ardoz, 28850 Madrid	Spain	Aristo Pharma GmbH, Wallenroder strasse 8-10, 13435, Berlin	Germany	OTC	ЈИП-№000446-ITI-AM 29.01.2026
2	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	ЈИП-№000250-ITI-AM 29.01.2026
3	ESCITAM ACINO	escitalopram (escitalopram oxalate)	tablets film-coated	10mg; (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	ЈИП-№009009-ITI-AM 29.01.2026
4	ESCITAM ACINO	escitalopram (escitalopram oxalate)	tablets film-coated	20mg; (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	ЈИП-№009009-ITI-AM 29.01.2026
5	Belara	chlormadinone (chlormadinone acetate), ethinylestradiol	tablets film-coated	2mg+0,03mg; (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	ЈИП-№000127-PF-AM 29.01.2026
6	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	ЈИП-№001081-PF-AM 29.01.2026

7	Diclofenac	diclofenac (diclofenac sodium)	solution for i/m injection	25mg/ml; (5) ampoules 3ml in blister	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	PoM	JITI-N°000992-ITI-AM 29.01.2026
8	Grandaxin	tofisopam	tablets	50mg; (20/2x10/) in blister, (60/6x10/) 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	JITI-N°000172-ITI-AM 29.01.2026
9	Grandaxin	tofisopam	tablets	50mg; (20/2x10/) in blister, (60/6x10/) in blister, (90/9x10/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly u. 65- packager, batch releaser, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	JITI-N°000172-ITI-AM 29.01.2026
10	Caffetin SC	paracetamol, propyphenazone, caffeine	tablets	250mg+210mg+50mg; (6/1x6/) in strip, (10/1x10/) in strip, (12/2x6/) in strip	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	OTC	JITI-N°001987-ITI-AM 29.01.2026
11	GENFERON LIGHT	interferon alfa-2b, taurine	suppositories vaginal and rectal	125000IU+5mg; (10/2x5/)	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalneye, Krasnogorsk Urban District, Moscow Region, 143422	Russia	BIOCAD JSC, d. 38, str.1, pomesch. 89, Intracity Municipality the Settlement of Strelna, ul. Svyazi, Saint Petersburg, 198515	Russia	PoM	JITI-N°007484-ITI-AM 29.01.2026
12	GENFERON LIGHT	interferon alfa-2b, taurine	suppositories vaginal and rectal	125000IU+5mg; (10/2x5/)	PK-137 LLC, bld. 2, 5557th proyezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460	Russia	BIOCAD JSC, d. 38, str.1, pomesch. 89, Intracity Municipality the Settlement of Strelna, ul. Svyazi, Saint Petersburg, 198515	Russia	PoM	JITI-N°007484-ITI-AM 29.01.2026
13	GENFERON LIGHT	interferon alfa-2b, taurine	suppositories vaginal and rectal	250000IU+5mg; (10/2x5/)	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalneye, Krasnogorsk Urban District, Moscow Region, 143422	Russia	BIOCAD JSC, d. 38, str.1, pomesch. 89, Intracity Municipality the Settlement of Strelna, ul. Svyazi, Saint Petersburg, 198515	Russia	PoM	JITI-N°007484-ITI-AM 29.01.2026
14	GENFERON LIGHT	interferon alfa-2b, taurine	suppositories vaginal and rectal	250000IU+5mg; (10/2x5/)	PK-137 LLC, bld. 2, 5557th proyezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460	Russia	BIOCAD JSC, d. 38, str.1, pomesch. 89, Intracity Municipality the Settlement of Strelna, ul. Svyazi, Saint Petersburg, 198515	Russia	PoM	JITI-N°007484-ITI-AM 29.01.2026

15	Arifam	amlodipine (amlodipine besilate), indapamide	tablets film-coated modified-release	5mg+1,5mg; (30/2x15/) in blister, (90/6x15/) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЖПІ-№001627-ІТІ-AM 29.01.2026
16	Trichopol Polpharma	metronidazole	tablets	250mg; (20/2x10/) in blister	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	PoM	ЖПІ-№001260-ІТІ-AM 29.01.2026
17	Terbisil	terbinafine (terbinafine hydrochloride)	cream for external use	10mg/g; aluminium tube 15g	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	OTC	ЖПІ-№002081-РТ-AM 29.01.2026

LIST

of registered variations under the EAEU procedure requiring registration and reformulation of registration certificate approved by the Center according to the meeting decision N 01-1/26 on January 29, 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	Telmista	telmisartan	tablets	40mg; (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°000860-ITI-AM 29.01.2026
2	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, National Laboratory of Health, Environment and Food (NLZOH), Dalmatinova ulica 3, Novo mesto, 8000, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026
3	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, Nacional Laboratory of Health, Environment and Food (NLZOH), Dalmatinova ulica 3, Novo mesto, 8000, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026

4	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control, batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026
5	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- quality control, batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026
6	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, packager, Nacional Laboratoriy of Health, Environment and Food (NLZOH), Dalmatinova ulica 3, Novo mesto, 8000, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026
7	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Chemilab d.o.o., Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026

8	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, Chemilab d.o.o., Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026
9	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, packager, Chemilab d.o.o., Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026
10	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Labena d.o.o., Teslova Ulica 30, 1000 Ljubljana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026

11	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, Labena d.o.o., Teslova Ulica 30, 1000 Ljubljana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026
12	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, packager, Labena d.o.o., Teslova Ulica 30, 1000 Ljubljana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026
13	Telmista	telmisartan	tablets	80mg; (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°000860-ITI-AM 29.01.2026
14	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, National Laboratory of Health, Environment and Food (NLZOH), Dalmatinova ulica 3, Novo mesto, 8000, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026

15	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, Nacional Laboratoriy of Health, Environment and Food (NLZOH), Dalmatinova ulica 3, Novo mesto, 8000, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026
16	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control, batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026
17	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- quality control, batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026

18	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, packager, Nacional Laboratory of Health, Environment and Food (NLZOH), Dalmatinova ulica 3, Novo mesto, 8000, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026
19	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Chemilab d.o.o., Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026
20	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, Chemilab d.o.o., Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026

21	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, packager, Chemilab d.o.o., Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026
22	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Labena d.o.o., Teslova Ulica 30, 1000 Ljubljana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026
23	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, Labena d.o.o., Teslova Ulica 30, 1000 Ljubljana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-ITI-AM 29.01.2026

24	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, packager, Labena d.o.o., Teslova Ulica 30, 1000 Ljubljana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	ЛП-№000860-ІТІ-AM 29.01.2026
----	----------	-------------	---------	----------------------------	--	----------	---	----------	-----	------------------------------