

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 01-1/23 on January 31, 2023

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	Minoxil	minoxidil	solution for topical use	50mg/ml; 60ml plastic bottle with nozzle spray	Tonus-Les LLC, N1 Laboratory complex, 6th str., v. Nor Gyugh, com. Akunk, Kotayk marz-secondary packager, batch releaser, Medical Horizon LLC, Ararat province, Masis city, Hrant Vardanyan 22, Republic of Armenia- bulk manufacturer, primary packager, quality control	Republic of Armenia	Tonus-Les LLC, Yerevan, 1 Yervand Kochar str., 0070	Republic of Armenia	OTC	21114 02.02.2023
2	Levoquix eye drops	levofloxacin (levofloxacin hemihydrate)	drops eye	5mg/ml; plastic vial-droper 5ml	Diamond Pharma, Damascus Countryside, Alghezlanieh, Aldilbeh, Estate No.183/1983	Syria	Bion Group, Sheram str. App.19	Republic of Armenia	PoM	21115 02.02.2023

3	Shelsy	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	500mg+125mg; (14(2x7/1x7/)) blister in sachet	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi- secondary packager, quality control, batch releaser, Reyoung Pharmaceutical Co. Ltd., No1 Ruiyang Road, Yiyuan County, Shandong Province, China- bulk manufacturer, primary packager	Georgia	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi	Georgia	PoM	21116 02.02.2023
4	Shelsy	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	875mg+125mg; (14(2x7/1x7/)) blister in sachet	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi- secondary packager, quality control, batch releaser, Reyoung Pharmaceutical Co. Ltd., No1 Ruiyang Road, Yiyuan County, Shandong Province, China- bulk manufacturer, primary packager	Georgia	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi	Georgia	PoM	21117 02.02.2023

5	Rivarox	rivaroxaban	tablets film-coated	2,5mg; (56/4x14/) in blister	Combino Pharm (Malta) Ltd., HF60, Hal Far Industrial Estate Hal Far BBG3000, Warehouse No.1 and No.2, Hal Farrug Road, Luqa LQA9040- bulk manufacturer, packager, quality control (physicochemical), batch releaser, BioDNA Laboratory Services Ltd., LS2.1.1 and LS2.1.2, Malta Life Sciences Park, San Gwann Industrial Estate, San Gwann, SGN3000, Malta- quality control (microbiological)	Malta	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	21118 02.02.2023
6	Rivarox	rivaroxaban	tablets film-coated	10mg; (10/1x10/) in blister	Combino Pharm (Malta) Ltd., HF60, Hal Far Industrial Estate Hal Far BBG3000, Warehouse No.1 and No.2, Hal Farrug Road, Luqa LQA9040- bulk manufacturer, packager, quality control (physicochemical), batch releaser, BioDNA Laboratory Services Ltd., LS2.1.1 and LS2.1.2, Malta Life Sciences Park, San Gwann Industrial Estate, San Gwann, SGN3000, Malta- quality control (microbiological)	Malta	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	21119 02.02.2023

7	Rivarox	rivaroxaban	tablets film-coated	15mg; (28/2x14/) in blister	Combino Pharm (Malta) Ltd., HF60, Hal Far Industrial Estate Hal Far BBG3000, Warehouse No.1 and No.2, Hal Farrug Road, Luqa LQA9040- bulk manufacturer, packager, quality control (physicochemical), batch releaser, BioDNA Laboratory Services Ltd., LS2.1.1 and LS2.1.2, Malta Life Sciences Park, San Gwann Industrial Estate, San Gwann, SGN3000, Malta- quality control (microbiological)	Malta	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	21120 02.02.2023
8	Rivarox	rivaroxaban	tablets film-coated	20mg; (28/2x14/) in blister	Combino Pharm (Malta) Ltd., HF60, Hal Far Industrial Estate Hal Far BBG3000, Warehouse No.1 and No.2, Hal Farrug Road, Luqa LQA9040- bulk manufacturer, packager, quality control (physicochemical), batch releaser, BioDNA Laboratory Services Ltd., LS2.1.1 and LS2.1.2, Malta Life Sciences Park, San Gwann Industrial Estate, San Gwann, SGN3000, Malta- quality control (microbiological)	Malta	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	21121 02.02.2023

LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 01-1/23 on January 31, 2023

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	Predictal OD	trimetazidine (trimetazidine dihydrochloride)	capsules prolonged-release	80mg; (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	PoM	21157 (000238) 02.02.2023
2	Predictal OD	trimetazidine (trimetazidine dihydrochloride)	capsules prolonged-release	80mg; (30/3x10/) in blister, (60/6x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, quality control, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65, Hungary- bulk manufacturer	Hungary	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21158 (000238) 02.02.2023
3	Predictal MR	trimetazidine (trimetazidine dihydrochloride)	tablets film-coated modified-release	35mg; (60/2x30/) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21159 (000263) 02.02.2023

4	Preductal MR	trimetazidine (trimetazidine dihydrochloride)	tablets film-coated modified-release	35mg; (60/2x30/) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21160 (000263) 02.02.2023
5	Coraxan 5mg	ivabradine	tablets film-coated	5mg; (28/2x14/) in blister, (56/4x14/) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21161 (000789) 02.02.2023
6	Coraxan 5mg	ivabradine	tablets film-coated	5mg; (14/1x14/) in blister, (28/2x14/) in blister, (52/2x26/) in blister, (56/4x14/) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21162 (000789) 02.02.2023
7	Coraxan 5mg	ivabradine	tablets film-coated	5mg; (14/1x14/) in blister, (28/2x14/) in blister, (52/2x26/) in blister, (56/4x14/) 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	PoM	21163 (000789) 02.02.2023

8	Coraxan 7,5mg	ivabradine	tablets film-coated	7,5mg; (14/1x14/) in blister, (28/2x14/) in blister, (52/2x26/) in blister, (56/4x14/) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21164 (000789) 02.02.2023
9	Coraxan 7,5mg	ivabradine	tablets film-coated	7,5mg; (28/2x14/) in blister, (56/4x14/) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	21165 (000789) 02.02.2023
10	Coraxan 7,5mg	ivabradine	tablets film-coated	7,5mg; (14/1x14/) in blister, (28/2x14/) in blister, (52/2x26/) in blister, (56/4x14/) 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	PoM	21166 (000789) 02.02.2023

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 01-1/23 on January 31, 2023

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	Broncholytin	glaucine (glaucine hydrobromide), ephedrine (ephedrine hydrochloride)	syrup	5,75mg/5ml+4,6mg/5ml; 125ml 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	21122 02.02.2023
2	GripptoFlu cold and flu	paracetamol, phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid	powder for oral solution with cranberry flavour	325mg+10mg+20mg+50mg; (10) sachets 13g	Marbiopharm JSC, 424006, the Republic of Mari El, Yoshkar-Ola, st. Karl Marx 121	Russia	Marbiopharm JSC, 424006, the Republic of Mari El, Yoshkar-Ola, st. Karl Marx 121	Russia	OTC	21123 02.02.2023
3	Dimedrol-Darnitsa	diphenhydramine (diphenhydramine hydrochloride)	tablets	50mg; (10) in blister, (10/1x10/) in blister	PrJSC "Pharmaceutical firm "Darnitsa", 02093, Kyiv, Boryspilska Str.,13	Ukraine	PrJSC "Pharmaceutical firm "Darnitsa", 02093, Kyiv, Boryspilska Str.,13	Ukraine	PoM	21124 02.02.2023

4	Solution sodium chloride 10%	sodium chloride	solution for infusion	100mg/ml; plastic pack 50ml	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	21125 02.02.2023
5	Glycine	glycine	tablets sublingual	100mg; (50/1x50/) in blister	Limited Liability Company Medical Scientific and Production Complex" BIOTIKI", 6-ya Radialnaya str. 24, b. 14, 115404, Moscow	Russia	Limited Liability Company Medical Scientific and Production Complex" BIOTIKI", 6-ya Radialnaya str. 24, b. 14, 115404, Moscow	Russia	OTC	21126 02.02.2023
6	Olanzapine	olanzapine	tablets coated	5mg; (24/1x24/) in blister	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	PoM	21127 02.02.2023
7	Metrogyl denta	metronidazole (metronidazole benzoate), chlorhexidine digluconate (chlorhexidine digluconate 20% solution)	gel dental	10mg/g+0,5mg/g; 5g plastic tube, 10g plastic tube, 20g plastic tube	Unique Pharmaceutical Laboratories (a division of J. B. Chemicals & Pharmaceuticals Ltd.), Plot No. 304-308, G.I.D.C. Industrial Area, Panoli: 394 116, Gujarat State	India	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	OTC	21128 02.02.2023

8	Mucosat-Belmed	chondroitin sulfate (chondroitin sulfate sodium)	solution for i/m injection	100mg/ml; (5/1x5/) ampoules 2ml in blister, (10/2x5/) ampoules 2ml in blister	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30- quality control, batch releaser, Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30, No2, Republic of Belarus- bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	21129 02.02.2023
9	Izoconazol-M	isoconazole (isoconazole nitrate)	suppositories vaginal	600mg; (1)	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	PoM	21130 02.02.2023
10	Femoston 1/5 conti	estradiol (estradiol hemihydrate), dydrogesterone	tablets film- coated	1mg+5mg; (28/1x28/) in blister	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	PoM	21131 02.02.2023
11	Venosmil	hidrosmin	capsules	200mg; (60/6x10/) in blister	FAES FARMA S.A., C/Maximo Aguirre, 14, 48940 Lejona/Leioa (Vizcaya/Bizkaia)	Spain	FAES FARMA S.A., C/Maximo Aguirre, 14, 48940 Lejona/Leioa (Vizcaya/Bizkaia)	Spain	PoM	21132 02.02.2023

12	Diphereline 0,1mg	triptorelin (triptorelin acetate)	lyophilizate for solution for s/c injection	0,1mg; (7) glass vials 0,1mg and (7) solvent in ampoules 1ml	Ipsen Pharma Biotech, Parc d'Activites du Plateau de Signes, Chemin departemental No 402, SIGNES, 83870, CENEXI, 52 rue Marcel et Jacques Gaucher, FONTENAY SOUS BOIS, 94120, France-solvent bulk manufacturer, primary packager	France	Ipsen Pharma, 65 quai Georges Gorse,92100 Boulogne Billancourt	France	PoM	21133 02.02.2023
13	Diphereline 3,75mg	triptorelin (triptorelin acetate)	lyophilizate for prolonged-release suspension for i/m injection	3,75mg; 3,75mg glass vial, solvent in ampoule 2ml, syringe 3ml and (2) needles	Ipsen Pharma Biotech, Parc d'Activites du Plateau de Signes, Chemin departemental No 402, SIGNES, 83870, CENEXI, 52 rue Marcel et Jacques Gaucher, FONTENAY SOUS BOIS, 94120, France-solvent bulk manufacturer, primary packager	France	Ipsen Pharma, 65 quai Georges Gorse,92100 Boulogne Billancourt	France	PoM	21134 02.02.2023
14	Almagel NEO	aluminium hydroxide, magnesium hydroxide, simeticone	suspension oral	340mg/5ml+395mg/5ml +36mg/5ml; 170ml plastic bottle and measuring spoon, (10) sachets 10ml, (20) sachets 10ml	Balkanpharma-Troyan AD, Krayrechna Str. N1, 5600, Troyan	Bulgaria	Balkanpharma-Troyan AD, (ACTAVIS GROUP) Krayrechna Str. N1, 5600, Troyan	Bulgaria	OTC	21135 02.02.2023

15	Mezym forte	pancreatin (lipase, amylase, protease)	tablets film-coated	3500U+4200U+250U; (20/2x10/) in blister, (20/1x20/) in blister, (40/4x10/) in blister, (40/2x20/) in blister, (80/8x10/) in blister, (80/4x20/) in blister, (100/10x10/) in blister, (100/5x20/) in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- batch releaser, Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden, Germany- bulk manufacturer, packager, quality control	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	OTC	21136 02.02.2023
16	Mildronat	meldonium (meldonium dihydrate)	capsules	500mg; (20/2x10/) in blister, (60/6x10/) in blister, (90/9x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	21137 02.02.2023
17	Lorista	losartan (losartan potassium)	tablets film-coated	100mg; (28/2x14/) 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	21138 02.02.2023
18	Turbo micron G	diosmin, hesperidin	tablets film-coated	450mg+50mg; (60/6x10/) in blister	KERN PHARMA, S.L., Poligon Industrial Colon II. C/ Venus, 72 08228 TERRASSA (Barcelona)	Spain	GM Pharmaceuticals Ltd, Phonichala 65, Tbilisi	Georgia	OTC	21139 02.02.2023
19	Levomecol	chloramphenicol, methyluracil	ointment for external use	7,5mg/g+40mg/g; 40g aluminium tube	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	21140 02.02.2023

20	Mexidol	ethylmethylhydroxypyridine succinate	solution for i/v and i/m injection	50mg/ml; (10/2x5/) ampoules 2ml in blister	OOO "Ellara", 601122, Vladimir reg., Petushinsky district, Pokrov, str. Franza Shtolverka, b. 20/2	Russia	LLC "RPC "PHARMASOFT", 115407, Moscow, Sudostroitel'naya str., bld. 41, floor 1, premises 12	Russia	PoM	21141 02.02.2023
21	Mexidol	ethylmethylhydroxypyridine succinate	solution for i/v and i/m injection	50mg/ml; (5/1x5/) ampoules 5ml, in blister	OOO "Ellara", 601122, Vladimir reg., Petushinsky district, Pokrov, str. Franza Shtolverka, b. 20/2	Russia	LLC "RPC "PHARMASOFT", 115407, Moscow, Sudostroitel'naya str., bld. 41, floor 1, premises 12	Russia	PoM	21142 02.02.2023
22	Triderm	betamethasone (betamethasone dipropionate), clotrimazole, gentamicin (gentamicin sulfate)	ointment	0,5mg/g+10mg/g+1mg/g; aluminium tube 15g	Schering-Plough Labo N.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	21143 02.02.2023
23	Urolesan	abies oil, mentha piperita oil, daucus carota fluid extract, humulus lupulus fluid extract, organum fluid extract	drops oral	67,6mg/ml+16,9mg/ml+194,35mg/ml+278,8mg/ml+192,95mg/ml; bottle-dropper 25ml	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	OTC	21144 02.02.2023

24	Zolaxa ODT	olanzapine	tablets orodispersible	5mg; (28/2x14/) in blister, (30/3x10/) in blister, (56/4x14/) in blister	Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 10 Wladyslawa Lokietka St. 98-200 Sieradz -batch releaser, Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 57 Polskiej Organizacji Wojskowej st. 98-200 Sieradz, Poland- bulk manufacturer, packager, quality control	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	PoM	21145 02.02.2023
25	Azopt	brinzolamide	drops eye (suspension)	10mg/ml; 5ml plastic vial	S.A. Alcon-Couvreur N.V., Rijksweg 14, Puurs (Puurs- Sint- Amands), 2870	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	21146 02.02.2023
26	Exforge H	amlodipine (amlodipine besilate), valsartan, hydrochlorothiazide	tablets film- coated	5mg+160mg+12,5mg; (14/1x14/) in blister, (28/2x14/) in blister	Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	21147 02.02.2023
27	Exforge H	amlodipine (amlodipine besilate), valsartan, hydrochlorothiazide	tablets film- coated	10mg+160mg+12,5mg; (14/1x14/) in blister, (28/2x14/) in blister	Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	21148 02.02.2023

28	Liprimar ST	atorvastatin (atorvastatin calcium)	tablets film-coated	10mg; (30/3x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstätte Freiburg, Mosswaldalee 1, 79090 Freiburg- packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	Upjohn US 1 LLC, 235, East 42nd Street, New York, New York, 10017	USA	PoM	21149 02.02.2023
29	Liprimar ST	atorvastatin (atorvastatin calcium)	tablets film-coated	20mg; (30/3x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstätte Freiburg, Mosswaldalee 1, 79090 Freiburg- packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	Upjohn US 1 LLC, 235, East 42nd Street, New York, New York, 10017	USA	PoM	21150 02.02.2023
30	Liprimar ST	atorvastatin (atorvastatin calcium)	tablets film-coated	40mg; (30/3x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstätte Freiburg, Mosswaldalee 1, 79090 Freiburg- packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	Upjohn US 1 LLC, 235, East 42nd Street, New York, New York, 10017	USA	PoM	21151 02.02.2023

31	Lipimar ST	atorvastatin (atorvastatin calcium)	tablets film-coated	80mg; (30/3x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstätte Freiburg, Mosswaldalee 1, 79090 Freiburg- packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	Upjohn US 1 LLC, 235, East 42nd Street, New York, New York, 10017	USA	PoM	21152 02.02.2023
32	Glucose 5% and Sodium chloride 0,45% solution for injection	glucose (glucose monohydrate), sodium chloride	solution for infusion	50mg/ml+4,5mg/ml; 500ml plastic pack	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	21153 02.02.2023
33	Cardiomagnyl	acetylsalicylic acid, magnesium hydroxide	tablets film-coated	75mg+15,2mg; (30) in glass container, (100) in glass container	Takeda GmbH, Lehnitzstrasse 70-98, Oranienburg 16515	Germany	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	21154 02.02.2023
34	Cardiomagnyl	acetylsalicylic acid, magnesium hydroxide	tablets film-coated	150mg+30,39mg; (30) in glass container, (100) in glass container	Takeda GmbH, Lehnitzstrasse 70-98, Oranienburg 16515	Germany	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	21155 02.02.2023

35	Tricor	fenofibrate	tablets film-coated	145mg; (30/3x10/) in blister	Recipharm Fontaine, Rue des Pres Potets, 21121 Fontaine les Dijon- packager, quality control, batch releaser, Fournier Laboratories Ireland Limited, Anngrove, Carrigtwohill, Co. Cork, Ireland- bulk manufacturer	France	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	PoM	21156 02.02.2023
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of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 01-1/23 on January 31, 2023

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	Calcium chloride-Darnitsa	calcium chloride (calcium chloride dihydrate)	solution for injection	50,7mg/ml; (10/2x5/) ampoules 5ml in blister	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	PoM	17722/1/1 02.02.2023
2	Prograf	tacrolimus	capsules hard	0,5mg; (50/5x10/) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry, V93 FC86	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	PoM	20195/1/1 02.02.2023
3	Prograf	tacrolimus	capsules hard	1mg; (50/5x10/) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry, V93 FC86	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	PoM	20196/1/1 02.02.2023
4	Prograf	tacrolimus	capsules hard	5mg; (50/5x10/) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry, V93 FC86	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	PoM	20197/1/1 02.02.2023

5	Advagraf	tacrolimus	capsules prolonged-release	0,5mg; (50/5x10/) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry, V93 FC86	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	PoM	19027/3/1 02.02.2023
6	Advagraf	tacrolimus	capsules prolonged-release	1mg; (50/5x10/) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry, V93 FC86	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	PoM	19028/3/1 02.02.2023
7	Advagraf	tacrolimus	capsules prolonged-release	5mg; (50/5x10/) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry, V93 FC86	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	PoM	19029/3/1 02.02.2023
8	Olestezin-AV	concentrate of sea buckthorn oil, sulfaetidol, benzocaine	suppositories rectal	330mg+50mg+100mg; (10/2x5/)	Altayvitaminy JSC, 659325, Altay region, Biysk, st. Zavodskaya, 69	Russia	Altayvitaminy JSC, 659325, Altay region, Biysk, st. Zavodskaya, 69	Russia	OTC	18731/1/1 02.02.2023
9	Gastritol	anserinae herba, matricariae flos, liquiritiae radix, angelicae radix, cnici benedicti herba, absinthii herba	drops oral	0,35ml/ml+0,2ml/ml+ 0,15ml/ml+0,05ml/ml+ 0,05ml/ml+0,05ml/ml glass vial-dropper 20ml, glass vial-dropper 50ml, glass vial-dropper 100ml	Dr. Gustav Klein GmbH & Co. KG, Steinenfeld 3, 77736 Zell am Harmersbach	Germany	Alpen Pharma GmbH, Steinenfeld 3, 77736 Zell am Harmersbach	Germany	OTC	18559/1/1 02.02.2023

10	Prostamed	ground pumpkin seed (deoiled), purified dry extract from deoiled ground pumpkin seed, dry extract from trembling poplar leaves, dry extract from golden rod	tablets chewable	200mg+100mg+6,3mg+2,6mg; (60), (120) and (200) in plastic container	Dr. Gustav Klein GmbH & Co. KG, Steinenfeld 3, 77736 Zell am Harmersbach	Germany	Alpen Pharma GmbH, Steinenfeld 3, 77736 Zell am Harmersbach	Germany	OTC	18031/1/1 02.02.2023
11	Metformin	metformin (metformin hydrochloride)	tablets film-coated	500mg; (30/3x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64A, No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	20702/1/1 02.02.2023
12	Metformin	metformin (metformin hydrochloride)	tablets film-coated	850mg; (30/3x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64A, No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	20703/1/1 02.02.2023
13	Metformin	metformin (metformin hydrochloride)	tablets film-coated	1000mg; (30/3x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64A, No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	20704/1/1 02.02.2023

14	Solidagoren	liquid extract of mixture of goldenrod herb, silverweed herb and horsetail herb	drops oral	0,79ml/ml; 20ml, 50ml and 100ml glass bottle	Dr. Gustav Klein GmbH & Co. KG, Steinenfeld 3, 77736 Zell am Harmersbach	Germany	Alpen Pharma GmbH, Steinenfeld 3, 77736 Zell am Harmersbach	Germany	OTC	18030/1/1 02.02.2023
15	Linezolid injection	linezolid	solution for infusion	2mg/ml; plastic pack 300ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	19868/1/1 02.02.2023
16	Mikoderil	naftifine hydrochloride	solution for external use	10mg/g; 10ml in dropper bottle, 20ml in dropper bottle	Pharmstandard-Leksredstva JSC, 305022, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, flr. 12, apartment II, room. 29, Moscow 123112	Russia	OTC	20472/2/2 02.02.2023
17	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)	Spain	Sanofi-Aventis Group, 54, rue La Boetie 75008 Paris	France	PoM	20628/2/2 02.02.2023
18	Articaine with adrenaline forte	articaine (articaine hydrochloride), epinephrine (epinephrine hydrotartrate)	solution for injection	40mg/ml+0.01mg/ml; (50/5x10/) glass cartridges 1.7ml, in blister	FKP "Armavirskaya biofabrika", 352212, Krasnodar reg., Novokubanskiy district, Progress settlement, str. Mechnikova, b. 11	Russia	Binergy JSC, 143910, Moscow region, Balashikha, Krupeshina str., b. 1	Russia	PoM	18778/1/1 02.02.2023

19	Dorsob T	dorzolamide (dorzolamide hydrochloride), timolol (timolol maleate)	drops eye	20mg/ml+5mg/ml; plastic vial 5ml	Famar A.V.E. Alimos Plant 63, Agiou Dimitriou str. 63, Alimos Attiki, 17456	Greece	Belinda Laboratories LLP,Unit 18, Norman Road 53, Greenwich Centre Business Park, SE10 9QF, London	UK	PoM	20248/1/1 02.02.2023
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LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 01-1/23 on January 31, 2023

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	GripptoFlu cold and flu	paracetamol, phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid	powder for oral solution with cranberry flavour	325mg+10mg+20mg+50mg; (10) sachet 13g	Marbiopharm JSC, 424006, the Republic of Mari El, Yoshkar-Ola, st. Karl Marx 121	Russia	Marbiopharm JSC, 424006, the Republic of Mari El, Yoshkar-Ola, st. Karl Marx 121	Russia	OTC	17123/2 02.02.2023
2	Zindolin	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	500mg (10/1x10/) in blister	Remedica Ltd, Aharnon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	Remedica Ltd, Aharnon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	PoM	18476/4 02.02.2023

3	Traumeel	achillea millefolium MT, aconitum napellus D1, arnica montana D3, atropa bella- donna D1, bellis perennis MT, calendula officinalis MT, echinacea MT, echinacea purpurea MT, hamamelis virginiana MT, hepar sulfuris D6, hypericum perforatum D6, matricaria recutita MT, mercurius solubilis Hahnemanni D6, symphytum officinale D4	ointment	0,9mg/g+0,5mg/g+ 15mg/g+0,5mg/g+ 1mg/g+4,5mg/g+ 1,5mg/g+1,5mg/g+ 4,5mg/g+0,25mg/g+ 0,9mg/g+1,5mg/g+ 0,4mg/g+1mg/g; 50g aluminium tube	Biologische Heilmittel Heel GmbH, Dr.-Reckeweg- Strasse 2-4, 76532 Baden- Baden	Germany	Biologische Heilmittel Heel GmbH, Dr.- Reckeweg-Strasse 2-4, 76532 Baden- Baden	Germany	OTC	19610/3/1 02.02.2023
4	Turbo micron G	diosmin, hesperidin	tablets film-coated	450mg+50mg; (60/6x10/) in blister	KERN PHARMA, S.L., Poligon Industrial Colon II. C/ Venus, 72 08228 TERRASSA (Barcelona)	Spain	GM Pharmaceuticals Ltd, Phonichala 65, Tbilisi	Georgia	OTC	17401/3 02.02.2023
5	Piracetam	piracetam	solution for i/m and i/v injection	200mg/ml; (10) ampoules 5ml C.A.M.A., (10) ampoules 5ml label banderol, (10) ampoules 5ml dividella	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	PoM	20422/1 02.02.2023

6	Almagel NEO	aluminium hydroxide, magnesium hydroxide, simeticone	suspension oral	340mg/5ml+395mg/5 ml+36mg/5ml; 170ml plastic bottle and measuring spoon, (10) sachets 10ml, (20) sachets 10ml	Balkanpharma-Troyan AD, Krayrechna Str. N1, 5600, Troyan	Bulgaria	Balkanpharma- Troyan AD, (ACTAVIS GROUP) Krayrechna Str. N1, 5600, Troyan	Bulgaria	OTC	16691/2 02.02.2023
7	Glycine	glycine	tablets sublingual	100mg; (50/1x50/) in blister	Limited Liability Company Medical Scientific and Production Complex" BIOTIKI", 6-ya Radialnaya str. 24, b. 14, 115404, Moscow	Russia	Limited Liability Company Medical Scientific and Production Complex" BIOTIKI", 6-ya Radialnaya str. 24, b. 14, 115404, Moscow	Russia	OTC	17013/2/1 02.02.2023
8	Cardiomagnyl	acetylsalicylic acid, magnesium hydroxide	tablets film- coated	75mg+15.2mg; (30) in glass container, (100) in glass container	Takeda GmbH, Lehnitzstrasse 70-98, Oranienburg 16515	Germany	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	17292/4/2 02.02.2023
9	Cardiomagnyl	acetylsalicylic acid, magnesium hydroxide	tablets film- coated	150mg+30,39mg; (30) in glass container, (100) in glass container	Takeda GmbH, Lehnitzstrasse 70-98, Oranienburg 16515	Germany	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	17291/4/2 02.02.2023

10	Amlo-Denk 10	amlodipine (amlodipine mesilate monohydrate)	tablets	10mg; (50/5x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, packager, batch releaser, GBA Pharma GmbH, Ernst-Abbe-Str. 40, Ulm, Baden-Wuerttemberg, 89079, Germany- quality control	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20536/1 02.02.2023
11	Klimaktoplan A	cimicifuga Trit. D2, sepia Trit. D2, ignatia Trit. D3, sanguinaria Trit. D6	tablets	25mg+25mg+25mg+25mg; (60/3x20/) in blister	Dr. Gustav Klein GmbH & Co. KG, Steinenfeld 3, 77736 Zell am Harmersbach- bulk manufacturer, packager, quality control (physicochemical), batch releaser, GBA Pharma GmbH, Ernst-Abbe-Str. 40, Ulm, Baden-Wuerttemberg, 89079, Germany- quality control (microbiological)	Germany	Alpen Pharma GmbH, Steinenfeld 3 Zell am Harmersbach, 77736	Germany	OTC	19628/1 02.02.2023
12	Lidocain	lidocaine	aerosol for external use	4,6mg/dose; 38g glass vial with measuring pump	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	20122/1 02.02.2023
13	KOXIKEA	etoricoxib	tablets film-coated	60mg; (28/4x7/) in blister	Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa	Greece	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	20346/2 02.02.2023

14	KOXIKEA	etoricoxib	tablets film-coated	90mg; (28/4x7/) in blister	Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa	Greece	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	20347/2 02.02.2023
15	KOXIKEA	etoricoxib	tablets film-coated	120mg; (7/1x7/) in blister	Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa	Greece	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	20348/2 02.02.2023
16	Arifam 1.5mg/5mg	indapamide, amlodipine (amlodipine besilate)	tablets modified-release	1,5mg+5mg; (30/2x15/) in blister	Les Laboratoires Servier Industrie, 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot 92284 Suresnes cedex	France	PoM	18548/4 02.02.2023
17	Arifam 1.5mg/10mg	indapamide, amlodipine (amlodipine besilate)	tablets modified-release	1,5mg+10mg; (30/2x15/) in blister	Les Laboratoires Servier Industrie, 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot 92284 Suresnes cedex	France	PoM	18549/4 02.02.2023
18	Triplixam	perindopril (perindopril arginine), indapamide, amlodipine (amlodipine besilate)	tablets film-coated	5mg+1,25mg+5mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	18423/5 02.02.2023
19	Triplixam	perindopril (perindopril arginine), indapamide, amlodipine (amlodipine besilate)	tablets film-coated	5mg+1,25mg+10mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	18424/5 02.02.2023

20	Triplixam	perindopril (perindopril arginine), indapamide, amlodipine (amlodipine besilate)	tablets film-coated	10mg+2,5mg+5mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	18425/4 02.02.2023
21	Triplixam	perindopril (perindopril arginine), indapamide, amlodipine (amlodipine besilate)	tablets film-coated	10mg+2,5mg+10mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	18426/5 02.02.2023
22	Biseptol Medana	sulfamethoxazole, trimethoprim	suspension oral	200mg/5ml+ 40mg/5ml; 80ml glass bottle and measuring cup	Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 10 Wladyslawa Lokietka St. 98-200 Sieradz- batch releaser, Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 57 Polskiej Organizacji Wojskowej St. 98-200 Sieradz, Poland- bulk manufacturer, packager, quality control	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplinska St., 83-200 Starogard Gdanski	Poland	PoM	17990/3/1 02.02.2023
23	Lorista H 100	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+12,5mg; (28/2x14/) 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	17964/3 02.02.2023

24	Diphereline 0,1mg	triptorelin (triptorelin acetate)	powder lyophilized for solution for s/c injection	0,1mg; (7) glass vial 0,1mg and (7) solvent in ampoules 1ml	Ipsen Pharma Biotech, Parc d'Activites du Plateau de Signes, Chemin departemental No 402, SIGNES, 83870	France	Ipsen Pharma, 65 quai Georges Gorse,92100 Boulogne-Billancourt	France	PoM	16724/1 02.02.2023
25	Diphereline 3,75mg	triptorelin (triptorelin acetate)	powder lyophilized for prolonged-release suspension for i/m injection	3,75mg; 3,75mg glass vial, solvent in ampoule 2ml, syringe 3ml and (2) needles	Ipsen Pharma Biotech, Parc d'Activites du Plateau de Signes, Chemin departemental No 402, SIGNES, 83870	France	Ipsen Pharma, 65 quai Georges Gorse,92100 Boulogne-Billancourt	France	PoM	16725/1 02.02.2023
26	Proserin-Darnitsa	neostigmine (neostigmine methylsulfate)	solution for injection	0,5mg/ml; (10/2x5/) ampoules 1ml, in blister	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	PoM	17720/1 02.02.2023
27	Sorbifer Durules	ferrous sulphate, ascorbic acid	tablets film-coated	320mg+60mg; (30) in glass bottle, (50) in glass bottle	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	20194/1 02.02.2023
28	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	18819/3 02.02.2023

29	Lorista	losartan (losartan potassium)	tablets film-coated	50mg; (28/2x14/) blisters, (28/4x7/) blisters	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	18820/2 02.02.2023
30	Lorista	losartan (losartan potassium)	tablets film-coated	100mg; (28/2x14/) 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	16942/4 02.02.2023
31	Tricor	fenofibrate	tablets film-coated	145mg; (30/3x10/) in blister	Recipharm Fontaine, Rue des Pres Potets, 21121 Fontaine les Dijon- batch releaser, packager, Fournier Laboratories Ireland Limited, Anngrove, Carrigtwohill, Co. Cork, Ireland- bulk manufacturer	France	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	PoM	17395/3/1 02.02.2023
32	Acyclovir Denk 200	aciclovir	tablets	200mg; (25/5x5/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	17984/4 02.02.2023
33	Laticort	hydrocortisone (hydrocortisone 17-n-butyrate)	solution for external use	1mg/ml; 20ml plastic vial	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	Bausch Health LLC., Shabolovka st. 31, building 5, 115162, Moscow	Russia	OTC	20544/1 02.02.2023

34	Laticort	hydrocortisone (hydrocortisone 17-n- butyrate)	ointment for external use	1mg/g; 15g aluminium tube	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	Bausch Health LLC., Shabolovka st. 31, building 5, 115162, Moscow	Russia	OTC	20533/1 02.02.2023
35	Zyvox	linezolid	solution for infusion	2mg/ml; (10) plastic packs 300ml	Fresenius Kabi Norge AS, Svinesundsveien 80 HALDEN, NO-1788	Norway	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	PoM	17651/5 02.02.2023
36	Lucentis	ranibizumab	solution for injection	10mg/ml; glass vial 0.23ml and fitler needle	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20779/1 02.02.2023
37	Zolaxa ODT	olanzapine	tablets orodispersible	5mg; (28/2x14/), (30/3x10/) and (56/4x14/) 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	16958/1 02.02.2023

38	Forxiga	dapagliflozin	tablets film-coated	10mg; (28/2x14/) in blister	AstraZeneca UK Ltd., Silk Road Business Park, Macclesfield, Cheshire, SK102NA- packager, batch releaser, AstraZeneca Pharmaceuticals LP, 4601 Highway 62 East, Mount Vernon, Indiana, 47620, USA- bulk manufacturer, AstraZeneca AB Gartunavagen, Sodertalje, SE-15185, Sweden- quality control	UK	AstraZeneca AB Gartunavagen, Sodertalje, SE-15185	Sweden	PoM	19132/1 02.02.2023
39	Persen Day	valeriana officinalis extract, melissa officinalis extract, mentha piperita extract	tablets coated	35mg+17,5mg+17,5mg; (40/4x10/) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana, Slovenia- bulk manufacturer, quality control	Slovenia	Zentiva, k.s., U kabelovny 130, 102 37 Praha 10, Dolni Mecholupy	Czech Republic	OTC	20979/1 02.02.2023
40	Metrogyl denta	metronidazole (metronidazole benzoate), chlorhexidine digluconate (chlorhexidine digluconate 20% solution)	gel dental	10mg/g+0,5mg/g; 5g, 10g and 20g plastic tube	Unique Pharmaceutical Laboratories (a division of J. B. Chemicals & Pharmaceuticals Ltd.), Plot No. 304-308, G.I.D.C. Industrial Area, Panoli: 394 116, Gujarat State	India	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	OTC	16932/1 02.02.2023

41	Neoton	phosphocreatine (phosphocreatine sodium)	powder for solution for infusion	1000mg; glass vial, solvent in glass vial 50ml, infusion system	Alfasigma S.p.A., Via Enrico Fermi, 1-65020, Alanno (Pescara)	Italy	Alfasigma S.p.A., Via Ragazzi del, 99, 5-40133 Bologna (BO)	Italy	PoM	19216/2 02.02.2023
42	Dopegyt	methyldopa (methyldopa sesquihydrate)	tablets	250mg (50) in glass container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30- 38	Hungary	PoM	19590/1 02.02.2023
43	Amikaton 500mg/2ml	amikacin (amikacin sulfate)	solution for injection/ infusion	500mg/2ml; (10) ampoules 2ml	Medochemie Ltd., 48 Iapetou street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupole os street, 3011 Limassol	Cyprus	PoM	19884/2 02.02.2023
44	Carvedi-Denk 6,25	carvedilol	tablets	6,25mg; (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	17815/2 02.02.2023
45	Carvedi-Denk 25	carvedilol	tablets	25mg; (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	17816/2 02.02.2023

46	Venosmil	hidrosmin	capsules	200mg; (60/6x10/) blisters	FAES FARMA, S.A., C/ Maximo Aguirre 14, 48940, Leioa	Spain	FAES FARMA, S.A., C/ Maximo Aguirre 14, 48940, Leioa	Spain	PoM	16871/1 02.02.2023
47	Recormon	epoetin beta	solution for i/v and s/c injection	2000IU/0,3ml; (6) pre-filled syringes 0,3ml and (6) needles	Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim	Germany	F. Hoffmann-La Roche Ltd., Grenzachstrasse, 124, CH-4070, Basel	Switzerland	PoM	18566/4 02.02.2023
48	TaiCold with raspberry flavour	paracetamol, chlorpheniramine (chlorpheniramine maleate), ascorbic acid	powder for oral solution with raspberry flavour	500mg+2mg+30mg; (10) sachet	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	OTC	17689/2 02.02.2023
49	TaiCold with lemon flavour	paracetamol, chlorpheniramine (chlorpheniramine maleate), ascorbic acid	powder for oral solution with lemon flavour	500mg+2mg+30mg; (10) sachet	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	OTC	17688/2 02.02.2023
50	Mildronat	meldonium (meldonium dihydrate)	capsules	500mg; (20/2x10/) in blister, (60/6x10/) in blister, (90/9x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	17185/2/1 02.02.2023
51	Xarelto	rivaroxaban	tablets film-coated	10mg; (30/3x10/) in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368, Leverkusen	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	17616/4/1 02.02.2023

52	Xarelto	rivaroxaban	tablets film-coated	15mg; (28/2x14/), in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	17615/4/1 02.02.2023
53	Xarelto	rivaroxaban	tablets film-coated	20mg; (28/2x14/), in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	17614/4/1 02.02.2023
54	Sandostatin	octreotide (octreotide acetate)	solution for injection	0,05mg/ml; (5) ampoules 1ml	Delpharm Dijon, 6, Boulevard de l'Europe, Quetigny, 21800	France	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20837/2 02.02.2023
55	Sandostatin	octreotide (octreotide acetate)	solution for injection	0,05mg/ml; (5) ampoules 1ml	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20504/1 02.02.2023
56	Sandostatin	octreotide (octreotide acetate)	solution for injection	0,1mg/ml; (5) ampoules 1ml	Delpharm Dijon, 6, Boulevard de l'Europe, Quetigny, 21800	France	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20838/2 02.02.2023
57	Sandostatin	octreotide (octreotide acetate)	solution for injection	0,1mg/ml; (5) ampoules 1ml	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20505/1 02.02.2023

58	DONA	glucosamine (glucosamine sulfate)	solution for i/m injection	200mg/ml; (6) ampoule A 2ml, (6) ampoule B 1ml (with solvent)	Biologici Italia Laboratories S.r.l., via Filippo Serpero, 2 - 20060 Masate (MI)	Italy	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg	Germany	PoM	19697/1 02.02.2023
59	Amorolfine Moosmann Medicated Nail Laquer 5%	amorolfine (amorolfine hydrochloride)	medicated nail laquer	50mg/ml; 3ml glass vial, (10) spatulas, (30) nail files, (30) alcohol swabs	Poul W. Beyvers GmbH, Schaffhausener Strasse 26-34 12099 Berlin	Germany	Moosmann Pharmaceuticals LLC, Vanahovit 8, Proshyan v., Ashtarak Ave., Kotayk Marz 2413	Republic of Armenia	OTC	17943/4/1 02.02.2023
60	Afinitor	everolimus	tablets	5mg; (30/3x10/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	19599/5/1 02.02.2023
61	Afinitor	everolimus	tablets	10mg; (30/3x10/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	19600/5/1 02.02.2023
62	Rexetin	paroxetine (paroxetine hydrochloride hemihydrate)	tablets film-coated	20mg; (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	20214/1 02.02.2023

63	Levomecol	chloramphenicol, methyluracil	ointment for external use	7,5mg/g+40mg/g; 40g aluminium tube	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	17196/2 02.02.2023
64	Sevoflurane	sevoflurane	liquid for inhalation	100%; 250ml glass bottle	Piramal Pharma Limited, Sy.No.7-70, 70/1 & 70/2, Digwal Village, Kohir Mandal, Sangareddy District- 502 321, Telangana	India	Piramal Pharma Limited, Piramal Ananta, Agastya Corporate Park, Opposite Fire Brigade, Kamani Junction, LBS Marg, Kurla (West), Mumbai- 400070, Maharashtra	India	PoM	16824/3/1 02.02.2023
65	Diclaren	diclofenac (diclofenac sodium)	gel	10mg/g; 100g aluminium tube	Laboratorios Basi-Industria Farmaceutica, S.A., Parque Industrial Manuel Lourenco Ferreira, lote 8,15,16, 3450-232 Mortagua	Portugal	GM Pharmaceuticals Ltd, 65,Phonichala str., Tbilisi	Georgia	OTC	20577/1 02.02.2023
66	Trittico	trazodone	tablets prolonged- release	150mg; (20/2x10) in blister	Aziende Chimiche Riunite Angelini Francesco ACRAF S.p.A., Via Vecchia del Pinocchio, 22-60100 Ancona	Italy	Aziende Chimiche Riunite Angelini Francesco ACRAF S.p.A., Viale Amelia, 70, 00181, Rome	Italy	PoM	18798/2/1 02.02.2023
67	Azopt	brinzolamide	drops eye (suspension)	10mg/ml; 5ml plastic vial	S.A. Alcon-Couvreur N.V., Rijksweg 14, Puurs (Puurs- Sint- Amands), 2870	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	17390/5 02.02.2023

68	Exforge H	amlodipine (amlodipine besilate), valsartan, hydrochlorothiazide	tablets film-coated	5mg+160mg+ 12,5mg; (14/1x14/) and (28/2x14/) in blister	Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	17440/7/1 02.02.2023
69	Exforge H	amlodipine (amlodipine besilate), valsartan, hydrochlorothiazide	tablets film-coated	10mg+160mg+ 12,5mg; (14/1x14/) and (28/2x14/) in blister	Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	17441/7/1 02.02.2023