

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 02-1/23 on February 28, 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	Linestar	linezolid	solution for infusion	200mg/ml; plastic bottle 300ml	Aculife Healthcare Private Limited, Unit-5, IDP, Village-Sachana, Tal.-Virangam, Dist.-Ahmedabad, Gujarat, 382150	India	Aculife Healthcare Private Limited, Commerce House-V, Besides Vodafone House, Prahladnagar Corporate Road, Ahmedabad, Gujarat, 380051	India	PoM	21171 28.02.2023
2	Roxatenz-inda	perindopril (perindopril tert-butylamine), indapamide, rosuvastatin (rosuvastatin calcium)	tablets film-coated	4mg+1,25mg+10mg; (30/3x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	21172 28.02.2023
3	Roxatenz-inda	perindopril (perindopril tert-butylamine), indapamide, rosuvastatin (rosuvastatin calcium)	tablets film-coated	4mg+1,25mg+20mg; (30/3x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	21173 28.02.2023

4	Roxatenz-inda	perindopril (perindopril tert-butylamine), indapamide, rosuvastatin (rosuvastatin calcium)	tablets film-coated	8mg+2,5mg+10mg; (30/3x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	21174 28.02.2023
5	Roxatenz-inda	perindopril (perindopril tert-butylamine), indapamide, rosuvastatin (rosuvastatin calcium)	tablets film-coated	8mg+2,5mg+20mg; (30/3x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	21175 28.02.2023
6	Haedensa	monochlorcarvacrol, menthol, ichtammolum	suppositories rectal	1mg+5mg+4mg; (5/1x5/)	Merz Pharma GmbH & Co. KGaA, Ludwigstrasse 22, 64354 Reinheim, Hessen- quality control, batch releaser, AMCAPHARM Pharmaceutical GmbH, Industriestrasse 10-14, 61191 Rosbach v.d. Hoehe, Hessen, Germany- bulk manufacturer, packager	Germany	Alpen Pharma AG, Finkenhübelweg 16, 3012 Bern	Switzerland	OTC	21176 28.02.2023
7	Hemorol	matricariae extractum spissum (3:1), belladonnae radices extractum spissum normatum, extractum compositum spissum (4:1) ex: cytisi scoparii herba, hippocastani cortice, tormetillae rhizoma, millefolii herba, benzocaine	suppositories rectal	50mg/2g+20mg/2g+80mg/2g+100mg/2g; (12/2x6/)	Wroclaw Herbal Products Works "Herbapol" SA , SW. Mikolaja Street 65/68, Wroclaw , 50-951- batch releaser, Wroclaw Herbal Products Works "Herbapol" SA, Hetmanska street 1, Legnica, 59-220, Poland- bulk manufacturer, packager, quality control	Poland	Wroclaw Herbal Products Works "Herbapol" SA , SW. Mikolaja Street 65/68, Wroclaw, 50-951	Poland	OTC	21177 28.02.2023

8	Trexan	methotrexate	tablets	2,5mg; (30) in plastic container, (100) in plastic container, (24/2x12/) in blister, (100/10x10/) in blister	Orion Corporation / Orion Pharma, Tengstrominkatu 8, FI-20360 Turku- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Orion Corporation / Orion Pharma, Orionintie 1, 02200 Espoo, Finland- quality control (microbiological)	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	PoM	21178 28.02.2023
9	Trexan	methotrexate	tablets	2,5mg; (30) in plastic container, (100) in plastic container, (24/2x12/) in blister, (100/10x10/) in blister	Orion Corporation / Orion Pharma, Orionintie 1, 02200 Espoo- quality control, batch releaser, Orion Corporation, Tengstrominkatu 8, 20360 Turku, Finland- bulk manufacturer, packager	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	PoM	21179 28.02.2023
10	Trexan	methotrexate	tablets	10mg; (15) in plastic container, (25) in plastic container, (50) in plastic container, (16/4x4/) in blister, (30/3x10/) in blister	Orion Corporation / Orion Pharma, Tengstrominkatu 8, FI-20360 Turku- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Orion Corporation / Orion Pharma, Orionintie 1, 02200 Espoo, Finland- quality control (microbiological)	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	PoM	21180 28.02.2023

11	Trexan	methotrexate	tablets	10mg; (15) in plastic container, (25) in plastic container, (50) in plastic container, (16/4x4/) in blister, (30/3x10/) in blister	Orion Corporation / Orion Pharma, Orionintie 1, 02200 Espoo- quality control, batch releaser, Orion Corporation, Tengstrominkatu 8, 20360 Turku, Finland- bulk manufacturer, packager	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	PoM	21181 28.02.2023
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LIST

of the medicines recommended for the registration (new packaging) by the Center according to the meeting decision N 02-1/23 on February 28, 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	Validol-Pharmstandard	levomenthol solution in menthyl isovalerate	tablets sublingual	60mg; (10) in blister, (10/1x10/) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	20901/1 28.02.2023
2	Amoxicillin 500mg	amoxicillin (amoxicillin trihydrate)	capsules	500mg; (10/1x10/) in blister, (100/10x10/) in blister	Medopharm Private Limited, No. 50 Kayarambedu Village, Guduvanchery, Chennai-603202	India	Troge Scientific Research I.PVT.LTD., Unit no.412, 4 th floor, Plot no.D-6 Wave Silver Tower, sector-18 Noida-201301, Gautam Buddha nagar,Uttar Pradesh	India	POM	21032/1 28.02.2023

LIST

of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 02-1/23 on February 28, 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	L-Thyroxin 25 Berlin-Chemie	levothyroxine sodium	tablets	25mcg; (100/4x25/) in blister	Berlin-Chemie A.G.,Glienicker Weg 125, 12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1. Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany, 2. Berlin-Chemie A.G.,Glienicker Weg 125, 12489 Berlin, Germany- quality control (physicochemical)	Germany	Berlin-Chemie A.G.,Glienicker Weg 125, 12489 Berlin	Germany	PoM	21167 28.02.2023

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 02-1/23 on February 28, 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	Bilobil	ginkgo biloba folies dry extract	capsules	40mg; (20/2x10/) in blister, (60/6x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	21182 28.02.2023
2	Tablets for cough Tatpharm	thermopsis herb, sodium hydrocarbonate	tablets	6,7mg+250mg; (10) in strip	Tatchempharmpreparaty JSC, 420091, Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091, Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	OTC	21183 28.02.2023
3	Ambroxol	ambroxol (ambroxol hydrochloride)	tablets	30mg; (20/2x10/) in blister	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	OTC	21184 28.02.2023
4	Pelethrocin Plus	diosmin, hesperidin	tablets film-coated	450mg+50mg; (30/2x15/) in blister, (60/4x15/) in blister	Help S.A. Pedini, Ioanninon, Ioannina, 45500	Greece	Help S.A ,10 Valaoritou str., GR 144 52, Metamorphosis, Attika	Greece	OTC	21185 28.02.2023

5	Bilobil intense	ginkgo biloba folies dry extract	capsules	120mg; (20/2x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	21186 28.02.2023
6	Clexane	enoxaparin (enoxaparin sodium)	solution for injection	20mg/0,2ml; (2) pre-filled syringes 0,2ml	SANOFI WINTHROP INDUSTRIE, MAISONS-ALFORT, 180 rue Jean Jaures, 94700	France	Sanofi-Aventis France, 82 avenue Raspail, 94250 Gentilly	France	PoM	21187 28.02.2023
7	Clexane	enoxaparin (enoxaparin sodium)	solution for injection	40mg/0,4ml; (10/5x2/) pre-filled syringes 0,4ml	SANOFI WINTHROP INDUSTRIE, MAISONS-ALFORT, 180 rue Jean Jaures, 94700	France	Sanofi-Aventis France, 82 avenue Raspail, 94250 Gentilly	France	PoM	21188 28.02.2023
8	Ziglip tablets 145mg	fenofibrate	tablets	145mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- packager, quality control, batch releaser, Ethypharm-Le Grand Quevilly, chemin de la Poudriere, Le Grand Quevilly, 76120, France- I-bulk granules, Ethypharm-Chateauneuf En Thymerais, Zone Industrielle de Saint-Arnoult, Chateauneuf En Thymerais, 28170, France-II-tableting	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	21189 28.02.2023

9	Essentiale N	phospholipids (essential)-EPL	solution for i/v injection	50mg/ml; (5) ampoules 5ml	Famar Health Care Services Madrid, S.A.U., Avenida de Leganes, 62, 28923 Alcorcon (Madrid)	Spain	Opella Healthcare LLC, Tverskaya str. 22, Moscow	Russia	PoM	21190 28.02.2023
10	Cilapenem	imipenem (imipenem monohydrate), cilastatin (cilastatin sodium)	powder for solution for infusion	500mg+500mg; (1) glass vial, (12) glass vials	Belmedpreparaty RUE, Grodninsky region, 231286, Lida, str. Kachana, 19/8- quality control, batch releaser, Belmedpreparaty RUE, Grodninsky region, 231286, Lida, str. Kachana, 19/8, N18, Republic of Belarus- bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	21191 28.02.2023
11	Sindranol	ropinirol (ropinirol hydrochloride)	tablets prolonged-release film-coated	2mg; (28/2x14/) in blister, (56/4x14/) in blister, (84/6x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Pharmathen International S.A., Industrial Park Sapes, Rodopi Prefecture, Block No5, Rodopi 69300, Greece- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	21192 28.02.2023

12	Sindranol	ropinirol (ropinirol hydrochloride)	tablets prolonged-release film-coated	3mg; (28/2x14/) in blister, (56/4x14/) in blister, (84/6x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120-batch releaser, Pharmathen International S.A., Industrial Park Sapes, Rodopi Prefecture, Block No5, Rodopi 69300, Greece-bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	21193 28.02.2023
13	Sindranol	ropinirol (ropinirol hydrochloride)	tablets prolonged-release film-coated	4mg; (28/2x14/) in blister, (56/4x14/) in blister, (84/6x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120-batch releaser, Pharmathen International S.A., Industrial Park Sapes, Rodopi Prefecture, Block No5, Rodopi 69300, Greece-bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	21194 28.02.2023
14	Sindranol	ropinirol (ropinirol hydrochloride)	tablets prolonged-release film-coated	8mg; (28/2x14/) in blister, (56/4x14/) in blister, (84/6x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120-batch releaser, Pharmathen International S.A., Industrial Park Sapes, Rodopi Prefecture, Block No5, Rodopi 69300, Greece-bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	21195 28.02.2023

15	Dimedrol-Belmed	diphenhydramine (diphenhydramine hydrochloride)	tablets	50mg; (10/1x10/) in blister, (20/2x10/) in blister, (30/3x10/) in blister	Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo St., 1- quality control, batch releaser, Belmedpreparaty RUE, 220006, Minsk, Mayakovskogo st. 1/5, No6, Republic of Belarus- bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	PoM	21196 28.02.2023
16	Akistan	latanoprost	drops eye (solution)	50mcg/ml; 2,5ml plastic vial	Pharmaselect International Beteiligungs GmbH, Ernst-Melchior-Gasse 20, 1020 Vienna- batch releaser, Bruschetti S.r.l., Via Isonzo, 6, 16147 Genova, Italy- bulk manufacturer, packager, quality control	Austria	Pharmaselect International Beteiligungs GmbH, Ernst-Melchior-Gasse 20, 1020 Vienna	Austria	PoM	21197 28.02.2023
17	Ondansetron	ondansetron (ondansetron hydrochloride dihydrate)	solution for injection	2mg/ml; (5) ampoules 2ml, (5/1x5/) ampoules 2ml in blister	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	PoM	21198 28.02.2023
18	Ondansetron	ondansetron (ondansetron hydrochloride dihydrate)	solution for injection	2mg/ml; (5) ampoules 4ml, (5/1x5/) ampoules 4ml in blister	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	PoM	21199 28.02.2023

19	Laennec	human placenta hydrolisate	solution for injection	112mg/2ml; (10) ampoules 2ml, (50) ampoules 2ml	Japan Bio Products Co., Ltd., Aza Edamitsu, Fujimitsu-machi, Kurumeshi, Fukuoka-ken	Japan	LLC Medical Corporation "RHANA", Zoologicheskaya st. 22, Moscow 123242	Russia	PoM	21200 28.02.2023
20	Somazina	citicoline (citicoline sodium)	solution oral	100mg/ml; glass bottle 30ml and measuring syringe	Ferrer Internacional, S.A., Joan Buscalla,1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer Internacional, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	PoM	21201 28.02.2023
21	Somazina	citicoline (citicoline sodium)	solution for injection	500mg/4ml; (5) ampoules 4ml	Ferrer Internacional, S.A., Joan Buscalla,1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer Internacional, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	PoM	21202 28.02.2023
22	Citramon P	acetylsalicylic acid, paracetamol, caffeine (caffeine monohydrate)	tablets	240mg+180mg+30mg; (10) in blister, (10/1x10/) in blister, (20/2x10/) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	21203 28.02.2023
23	Spasmalgon	metamizole (metamizole sodium), pitofenone (pitofenone hydrochloride), fempiverinium bromide	tablets	500mg+5mg+0,1mg; (10/1x10/) in blister, (20/2x10/) in blister, (50/5x10/) in blister	Balkanpharma-Dupnitsa AD, str."Samokovsko Shosse" N3, Dupnitsa 2600	Bulgaria	Balkanpharma-Dupnitsa AD, str."Samokovsko Shosse" N3, Dupnitsa 2600	Bulgaria	OTC	21204 28.02.2023

24	Thioctacid 600 T	thioctic acid (alfa-lipoic acid)	solution for injection	25mg/ml; (5) ampoules 24ml	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg- batch releaser, Siegfried Hameln GmbH, Langes Feld 13, Hameln, Niedersachsen, 31789, Germany- bulk manufacturer, packager, quality control	Germany	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg	Germany	PoM	21205 28.02.2023
25	Pyrazinamide	pyrazinamide	tablets	400mg; (672/24x28/) in blister	Macleods Pharmaceuticals Ltd., Plot No 25-27, Sr. No 366, Premier Ind. Estate, Kachigam, Daman-396210 (UT)	India	Macleods Pharmaceuticals Ltd., 304, Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai-400 059	India	PoM	21206 28.02.2023
26	Lamal	lamotrigine	tablets	25mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	21207 28.02.2023
27	Lamal	lamotrigine	tablets	50mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	21208 28.02.2023

28	Lamal	lamotrigine	tablets	100mg; (30/2x15/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	21209 28.02.2023
29	Lamal	lamotrigine	tablets	200mg; (30/2x15/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	21210 28.02.2023
30	Aevit	retinol palmitate (vitamin A), alpha-tocopherol acetate (vitamin E)	capsules	55mg (100000IU)+100mg; (20/2x10/) in blister	Pharmaceutical company MELIGEN" CJSC, 188676, Leningrad region, Vsevolozhsk district, p.Shcheglovo, 53a	Russia	Pharmaceutical company MELIGEN" CJSC, 188676, Leningrad region, Vsevolozhsk district, p.Shcheglovo, 53a	Russia	OTC	21211 28.02.2023
31	Oxivin-DF	oxymetazoline (oxymetazoline hydrochloride)	spray nasal	0,5mg/ml; 10ml plastic vial with pump dispenser	Dosfarm LLP, 050034, Almaty city, Chaplygin str.3	Kazakhstan	Dosfarm LLP, 050034, Almaty city, Chaplygin str.3	Kazakhstan	OTC	21212 28.02.2023
32	Valused	valerian root dry extract, hop strobiles dry extract, passion flower dry extract	capsules soft	60mg+40mg+40mg; (30/2x15/) in blister	P.P.F. "Hasco-Lek" S.A., ul. Zmigrodzka 242 E, 51-131 Wroclaw	Poland	P.P.F. "Hasco-Lek" S.A., ul. Zmigrodzka 242 E, 51-131 Wroclaw	Poland	OTC	21213 28.02.2023

33	A-cnotren	isotretinoin	capsules soft	20mg; (30/3x10/) in blister	Pharmathen International S.A., Industrial Park Sapes, Rodopi Prefecture, Block No 5, Rodopi 69300- packager, quality control, batch releaser, G.A. Pharmaceuticals S.A., (GAP S.A), 46, Agisilaou str., Agios Dimitrios Attiki, 17341, Greece- bulk manufacturer	Cyprus	Pharmathen Investments Group Limited, 32, Kritis str., Papachristoforou Bulding, 4th floor, 3087, Limassol	Cyprus	PoM	21214 28.02.2023
34	ACC ACTIVE 600mg oral powder	acetylcysteine	powder oral	600mg; (10) sachets 3g, (20) sachets 3g	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben- batch releaser, Hermes Pharma Ges.m.b.H, Schwimmschulweg 1a, Wolfsberg, 9400, Austria- bulk manufacturer, packager, quality control	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	21215 28.02.2023
35	Spirolon	spironolactone	tablets film-coated	25mg; (50/5x10/) in blister	Remedica Ltd., Limassol Industrial Estate, Aharnon street, 3056 Limassol	Cyprus	Remedica Ltd., Limassol Industrial Estate, Aharnon street, 3056 Limassol	Cyprus	PoM	21216 28.02.2023

36	Nervomix	valerianae radix, melissae folium, lupuli strobilus, hyperici herba	capsules hard	210mg+52,5mg+52,5mg+35mg; (30/3x10/)in blister, (60/3x20/) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	OTC	21217 28.02.2023
37	Hexicon	chlorhexidine (chlorhexidine bigluconate)	suppositories vaginal	16mg; (10/2x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	21218 28.02.2023
38	BC Benzogel	benzocaine	gel	200mg/g; syringe 6g	Bio-Chem LLC Yerevan, Manandyan, 33, 1/1	Republic of Armenia	Bio-Chem LLC Yerevan, Manandyan, 33, 1/1	Republic of Armenia	OTC	21219 28.02.2023
39	Avodart	dutasteride	capsules soft	0,5mg; (30/3x10/) in blister	GlaxoSmithKline Pharmaceuticals S.A.,189 Grunwaldzka street, 60-322 Poznan	Poland	GlaxoSmithKline Export Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	PoM	21220 28.02.2023
40	Axetine 750mg	cefuroxime (cefuroxime sodium)	powder for solution for injection or infusion	750mg; (10) glass vials	Medochemie Ltd (Factory C), 2 Michael Erakleous street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupolos street, 3011 Limassol	Cyprus	PoM	21221 28.02.2023

41	Axetine 1,5g	cefuroxime (cefuroxime sodium)	powder for solution for injection or infusion	1500mg; (10) glass vials	Medochemie Ltd (Factory C), 2 Michael Erakleous street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupolos street, 3011 Limassol	Cyprus	PoM	21222 28.02.2023
42	Bactox 250mg/5ml	amoxicillin (amoxicillin trihydrate)	powder for oral suspension	250mg/5ml; glass bottle 60ml and measuring spoon	Innothera Chouzy Rue Rene Chantereau, Chouzy-sur-Cisse Valloire-sur-Cisse, 41150- batch releaser, Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl, Tirol, Austria- bulk manufacturer, packager, quality control	France	Laboratoire Innotech International, 22 Avenue Aristide Brand 94110 Arcueil	France	PoM	21223 28.02.2023

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 02-1/23 on February 28, 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	Spironolactone	spironolactone	tablets	25mg; (30/3x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64A, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Republic of Belarus	PoM	20061/1/1 28.02.2023
2	Orabloc	articaine (articaine hydrochloride), adrenaline (adrenaline tartrate)	solution for injection	40mg/ml+10mcg/ml; (100/10x10/) cartridges 1,8ml in blister	Pierrel S.p.A., S.S. Appia, Capua (CE) 81043	Italy	Pierrel S.p.A, Strada statale Appia, 7 Bis, 46/48 Capua (CE) 81043	Italy	PoM	18536/1/1 28.02.2023
3	Alecensa	alectinib (alectinib hydrochloride)	capsules hard	150mg; (56/8x7/) in blister	F. Hoffmann-La Roche AG, Viadukstrasse 33, 4051 Basel-batch releaser, Excella GmbH & Co.KG, Nuernberger st. 12, Feucht, Bayern 90537, Germany-bulk manufacturer, Delpharm Milano S.R.L., Via Carnevale, 1-20090 Segrate (MI), Italy-packager	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	18205/2/2 28.02.2023

4	Nifuroxazide	nifuroxazide	tablets film-coated	100mg; (30/3x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 24, Stroiteley str., Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	PoM	20022/1/1 28.02.2023
5	Dilatrend	carvedilol	tablets	6,25mg; (30/3x10/) in blister	Cheplapharm Arzneimittel GmbH, Ziegelhof 23-24, 17489 Greifswald- batch releaser, Delpharm Milano S.r.l, Via Carnevale, 1, 20054 Segrate (MI), Italy- bulk manufacturer, packager, quality control	Germany	Cheplapharm Arzneimittel GmbH, Ziegelhof 24, 17489 Greifswald	Germany	PoM	18234/3/2 28.02.2023
6	Dilatrend	carvedilol	tablets	12,5mg; (30/3x10/) in blister	Cheplapharm Arzneimittel GmbH, Ziegelhof 23-24, 17489 Greifswald- batch releaser, Delpharm Milano S.r.l, Via Carnevale, 1, 20054 Segrate (MI), Italy- bulk manufacturer, packager, quality control	Germany	Cheplapharm Arzneimittel GmbH, Ziegelhof 24, 17489 Greifswald	Germany	PoM	18235/3/2 28.02.2023
7	Dilatrend	carvedilol	tablets	25mg; (30/3x10/) in blister	Cheplapharm Arzneimittel GmbH, Ziegelhof 23-24, 17489 Greifswald- batch releaser, Delpharm Milano S.r.l, Via Carnevale, 1, 20054 Segrate (MI), Italy- bulk manufacturer, packager, quality control	Germany	Cheplapharm Arzneimittel GmbH, Ziegelhof 24, 17489 Greifswald	Germany	PoM	18236/3/2 28.02.2023

8	Proposol-AV	propolis	spray for topical use	3g/50g; 50g aluminium container	Altayvitaminy JSC, Altay region, Biysk, st. Zavodskaya, 69	Russia	Altayvitaminy JSC, Altay region, Biysk, st. Zavodskaya, 69	Russia	OTC	18918/1/1 28.02.2023
9	Metronidazole 0,5%	metronidazole	solution for infusion	5mg/ml; 100ml plastic (PVC) pack in light-proof bag	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	17734/1/1 28.02.2023
10	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	18505/8/1 28.02.2023
11	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	18506/8/1 28.02.2023
12	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	20mg; (56/4x14/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18507/8/1 28.02.2023
13	Zavicefta	ceftazidime (ceftazidime pentahydrate), avibactam (avibactam sodium)	powder for solution for infusion	2g+0,5g; (10) glass vials 20ml	ACS DOBFAR SpA, Via Alesandro Fleming, 2, Verona, 37135	Italy	Pfizer Limited Ramsgate Road, Sandwich, Kent, CT13 9NJ	UK	PoM	18293/2/3 28.02.2023

14	GONAL-f	follitropin alfa	powder lyophilized for solution for injection	5,5mcg (75IU); (1) glass vial 3ml, (1) solvent in pre-filled syringe 1ml, (2) needles	Merck Serono S.A., Succursale d Aubonne, Zone Industrielle de l Ouriettazz, 1170 Aubonne, Merck Serono S.p.A., Via delle Magnolie 15, I-70026-Modugno (BA) Italy- solvent manufacturer	Switzerland	Merck LLC, Valovaya Street 35, 115054 Moscow	Russia	PoM	18080/1/1 28.02.2023
15	GONAL-f	follitropin alfa	powder lyophilized for solution for injection	5,5mcg (75IU); glass vial 3ml, solvent in pre-filled syringe 1ml, (2) sterile needles	Merck Serono S.A., Succursale d Aubonne, Zone Industrielle de l Ouriettazz, 1170 Aubonne, Merck Serono S.A., Succursale d Aubonne, Zone Industrielle de l Ouriettazz, 1170 Aubonne, Switzerland- solvent manufacturer	Switzerland	Merck LLC, Valovaya Street 35, 115054 Moscow	Russia	PoM	18081/1/1 28.02.2023
16	Nurofen Express	ibuprofen	capsules soft	200mg; (8/1x8/) in blister, (16/2x8/) in blister, (24/3x8/) in blister	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB- packager, batch releaser, Patheon Softgels B.V., De Posthoornstraat 7, 5048 AS Tilburg, the Netherlands- bulk manufacturer, quality control	UK	Reckitt Benckiser HealthCare (UK) Limited, Dansom Lane, Hull, East Yorkshire, HU8 7DS	UK	OTC	20100/2/1 28.02.2023

17	Avamys	fluticasone (fluticasone furoate)	spray nasal (suspension)	27,5mcg/dose; glass bottle with metering pump (120 dose)	Glaxo Wellcome S.A., Avenida de Extremadura, 3, 09400 Aranda de Duero, Burgos	Spain	GlaxoSmithKline Consumer Healthcare (UK) Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	PoM	20107/1/1 28.02.2023
18	Jodbalance	potassium iodide	tablets	100mcg; (100/4x25/) in blister	Merck Healthcare KgaA, Frankfurter Strasse 250, A31, A32, D11, D12, D15, D39,F128, PH5, PH16, PH23, PH24, PH 26,PH28, PH31, PH33, PH50, PH51, PH52, PH80, PH85, PH95, 64293 Darmstadt	Germany	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	OTC	18718/2/1 28.02.2023
19	Jodbalance	potassium iodide	tablets	200mcg; (100/4x25/) in blister	Merck Healthcare KgaA, Frankfurter Strasse 250, A31, A32, D11, D12, D15, D39,F128, PH5, PH16, PH23, PH24, PH 26,PH28, PH31, PH33, PH50, PH51, PH52, PH80, PH85, PH95, 64293 Darmstadt	Germany	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	18719/2/1 28.02.2023
20	Hexicon	chlorhexidine (chlorhexidine bigluconate)	suppositories vaginal	16mg; (10/2x5/) in blister	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	17592/3/1 28.02.2023

21	Espumisan	simeticone	capsules soft	40mg; (25/1x25/) in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, quality control, batch releaser, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany- bulk manufacturer	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	OTC	19106/1/1 28.02.2023
22	Cytosar	cytarabine	powder lyophilized for solution for injection	500mg; glass vial	Corden Pharma Latina S.p.A, Via Murillo7, Sermoneta, 04013	Italy	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	20395/1/1 28.02.2023
23	Cytosar	cytarabine	powder lyophilized for solution for injection	100mg; glass vial	Corden Pharma Latina S.p.A, Via Murillo7, Sermoneta, 04013	Italy	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	20394/1/1 28.02.2023

LIST

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1	Cilapenem	imipenem (imipenem monohydrate), cilastatin (cilastatin sodium)	powder for solution for infusion	500mg+500mg; (1) glass vial, (12) glass vial	Belmedpreparaty RUE, Grodninsky region, 231286, Lida, str. Kachana,19/8- quality control, batch releaser, Belmedpreparaty RUE, Grodninsky region, 231286, Lida, str. Kachana,19/8,N18, Belarus-bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	PoM	17373/2/1 28.02.2023
2	Exforge	amlodipine (amlodipine besilate), valsartan	tablets film-coated	5mg+160mg; (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	19885/3 28.02.2023
3	Exforge	amlodipine (amlodipine besilate), valsartan	tablets film-coated	10mg+160mg; (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	19886/3 28.02.2023

4	Ambroxol	ambroxol (ambroxol hydrochloride)	tablets	30mg; (20/2x10/) in blister	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	OTC	17458/1 28.02.2023
5	Edarbi Clo	azilsartan medoxomil, chlortalidone	tablets film-coated	40mg+12,5mg; (28/2x14/) in blister, (98/7x14/) in blister	Takeda Ireland Ltd., Bray Business Park Kilruddery Co. Wicklow	Ireland	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	18629/3/1 28.02.2023
6	Edarbi Clo	azilsartan medoxomil, chlortalidone	tablets film-coated	40mg +25mg; (28/2x14/) in blister, (98/7x14/) in blister	Takeda Ireland Ltd., Bray Business Park Kilruddery Co. Wicklow	Ireland	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	18630/3/1 28.02.2023
7	Diclofenac	diclofenac (diclofenac sodium)	tablets film-coated gastro-resistant	50mg; (20/2x10/) in blister	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb-packager, batch releaser, Hemofarm d.o.o., Novakovici bb, Banja Luka 78000, Bosnia and Herzegovina-bulk manufacturer	Serbia	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	PoM	18524/1 28.02.2023
8	Pelethrocin Plus	diosmin, hesperidin	tablets film-coated	450mg+50mg; (30/2x15/) and (60/4x15/) in blister	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., 14452 Metamorphosis, Attica	Greece	OTC	16733/1 28.02.2023

9	Nalgesin	naproxen (naproxen sodium)	tablets film-coated	275mg; (10/1x10/) in blister, (20/2x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	19782/1 28.02.2023
10	Privigen	human normal immunoglobulin	solution for infusion	100mg/ml; 25ml glass vial	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	PoM	20325/1 28.02.2023
11	Privigen	human normal immunoglobulin	solution for infusion	100mg/ml; 50ml glass vial	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	PoM	20326/1 28.02.2023
12	Privigen	human normal immunoglobulin	solution for infusion	100mg/ml; 100ml glass vial	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	PoM	20327/1 28.02.2023
13	Privigen	human normal immunoglobulin	solution for infusion	100mg/ml; 200ml glass vial	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	PoM	20328/1 28.02.2023
14	Ingavirin	pentanedioic acid (pentanedioic acid imidazolyl ethanamide)	capsules	90mg; (7/1x7/) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	20120/2/1 28.02.2023

15	Deep Relief	ibuprofen, levomenthol(menthol)	gel for external use	50mg/g+30mg/g; 15g aluminum tube, 50g aluminum tube, 100g aluminum tube	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	OTC	19357/2 28.02.2023
16	Akistan	latanoprost	drops eye (solution)	0,05mg/ml; 2.5ml plastic vial	Bruschettini S.r.l., Via Isonzo, 6, 16147 Genova	Italy	Pharmaselect International Beteiligungs GmbH, Ernst- Melchior-Gasse 20 1020 Vienna	Austria	PoM	17446/1 28.02.2023
17	Tears Naturale II	dextran (dextran 70), hypromellose	drops eye	1mg/ml+3mg/ml; 15ml plastic vial with measuring dropper	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs	Belgium	Alcon Pharmaceuticals Ltd, Route des Arsenaux 41 Case Postale 1701 Fribourg	Switzerland	OTC	17879/1 28.02.2023
18	Mixtard 30	insulin human (recombinant DNA)	suspension for injection	100IU/ml; (1) glass vial 10ml	Novo Nordisk Production SAS, 45 avenue d` Orleans, F-28000, Chartres	France	Novo Nordisk A/S, Novo Alle, DK- 2880 Bagsvaerd	Denmark	PoM	21088/1 28.02.2023
19	Trio Vision	neomycin (neomycin sulfate), polymyxin B (polymyxin B sulfate), dexamethasone	drops eye (suspension)	3500IU/ml+6000IU/ ml+1mg/ml; plastic vial 5ml	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	Antibiotic- Razgrad AD, 68, Aprilsko vastanie Blvd, Razgrad, 7200	Bulgaria	PoM	19559/1 28.02.2023

20	Enap	enalapril (enalapril maleate)	tablets	2,5mg; (20/2x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	18058/1 28.02.2023
21	Aevit	retinol palmitate (vitamin A), alpha-tocopherol acetate (vitamin E)	capsules	100mg+55mg (100000IU); (20/2x10/) in blister	Pharmaceutical company MELIGEN" CJSC, 188676, Leningrad region, Vsevolozhsk district, p.Shcheglovo, 53a	Russia	Pharmaceutical company MELIGEN" CJSC, 188676, Leningrad region, Vsevolozhsk district, p.Shcheglovo, 53a	Russia	OTC	16961/1 28.02.2023
22	Laennec	human placenta hydrolisate	solution for injection	112mg/2ml; (10) and (50) ampoules 2ml	Japan Bio Products Co., Ltd., Aza Edamitsu, Fujimitsu-machi, Kurume-shi, Fukuoka-ken	Japan	LLC Medical Corporation "RHANA", Zoologicheskaya st. 22, Moscow 123242	Russia	PoM	17452/2/1 28.02.2023
23	Ziglip tablets 145mg	fenofibrate	tablets	145mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje-batch releaser, Lupin Limited, 198-202, New Industrial Estate Area No.2 Mandideep-462046 district-Raisen M.P, India-bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	17465/1 28.02.2023

24	A-cnotren	isotretinoin	capsules soft	10mg; (30/3x10/) in blister	Pharmathen International S.A., Industrial Park Sapes, Rodopi Prefecture, Block No 5, 69300 Rodopi-packager, quality control, batch releaser, G.A. Pharmaceuticals S.A., (GAP S.A), 46, Agisilaou str., 17341 Agios Dimitrios Attiki, Greece- bulk manufacturer	Greece	Pharmathen Investments Group Limited, 32, Kritis str., Papachristoforou Bulding, 4th floor, 3087, Limassol	Cyprus	PoM	19663/4/1 28.02.2023
25	A-cnotren	isotretinoin	capsules soft	20mg; (30/3x10/) in blister	Pharmathen International S.A., Industrial Park Sapes, Rodopi Prefecture, Block No 5, 69300 Rodopi-packager, quality control, batch releaser, G.A. Pharmaceuticals S.A., (GAP S.A), 46, Agisilaou str., 17341 Agios Dimitrios Attiki, Greece- bulk manufacturer	Greece	Pharmathen Investments Group Limited, 32, Kritis str., Papachristoforou Bulding, 4th floor, 3087, Limassol	Cyprus	PoM	17645/4/1 28.02.2023
26	Panadol	paracetamol	tablets film-coated	500mg; (12/1x12/) in blister	SmithKline Beecham S.A. Ctra. de Ajalvir, KM-2500-28806, Alcala de Henares, Madrid-packager, batch releaser, GlaxoSmithKline Dungarvan Limited, Knockbrack, Dungarvan, Co Waterford, Ireland-bulk manufacturer, quality control	Spain	GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	OTC	18906/1 28.02.2023

27	Nebilet	nebivolol (nebivolol hydrochloride)	tablets	5mg; (7/1x7/) in blister, (14/1x14/) in blister, (28/2x14/) in blister	Berlin-Chemie AG, Glienicker Weg 125 D-12489 Berlin - granules manufacturer, packager, batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, D-12347 Berlin, Germany - bulk manufacturer	Germany	Menarini International Operations Luxembourg S.A., 1, avenue de la Gare, 1611	Luxembourg	PoM	18554/2 28.02.2023
28	Ondansetron	ondansetron (ondansetron hydrochloride dihydrate)	solution for injection	2mg/ml; (5) ampoules 2ml, (5/1x5/) ampoules 2ml in blister	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	PoM	17170/2 28.02.2023
29	Ondansetron	ondansetron (ondansetron hydrochloride dihydrate)	solution for injection	2mg/ml; (5) ampoules 4ml, (5/1x5/) ampoules 4ml in blister	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	PoM	17169/2 28.02.2023
30	Moxiral	moxifloxacin (moxifloxacin hydrochloride)	tablets film-coated	400mg; (5/1x5/) and (7/1x7/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	17408/4/1 28.02.2023

31	Solpadeine Active	paracetamol, caffeine	tablets soluble	500mg+65mg; (12/3x4/) in strip	GlaxoSmithKline Dungarvan Limited, Knockbrack, Dungarvan, Co Waterford	Ireland	GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	OTC	19195/2 28.02.2023
32	Trifas 5	torasemide	tablets	5mg; (30/3x10/) in blister	Berlin-Chemie AG, Glienicke Weg 125 D- 12489 Berlin-packager, batch releaser, Berlin- Chemie AG, Tempelhofer Weg 83, D-12347 Berlin, Germany-bulk manufacturer	Germany	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, 1611	Luxembourg	PoM	18580/2 28.02.2023
33	Trifas 10	torasemide	tablets	10mg; (30/3x10/) in blister	Berlin-Chemie AG, Glienicke Weg 125 D- 12489 Berlin-packager, batch releaser, Berlin- Chemie AG, Tempelhofer Weg 83, D-12347 Berlin, Germany-bulk manufacturer	Germany	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, 1611	Luxembourg	PoM	18581/2 28.02.2023
34	MONSERA	ivabradine (ivabradine hydrochloride)	tablets film- coated	5mg; (56/8x7/) in blister	LABORATORIOS CINFA, S.A, Ctra. Olaz-Chipi, 10, Pol. Ind. Areta, Huarte, Navarra, 31620	Spain	GM Pharmaceuticals Ltd, Phonicchala 65, 0165 Tbilisi	Georgia	PoM	20053/1 28.02.2023

35	MONSERA	ivabradine (ivabradine hydrochloride)	tablets film-coated	7,5mg; (56/8x7/) in blister	LABORATORIOS CINFA, S.A, Ctra. Olaz-Chipi, 10, Pol. Ind. Areta, Huarte, Navarra, 31620	Spain	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	20054/1 28.02.2023
36	Lodigrel	clopidogrel (clopidogrel hydrosulfate)	tablets film-coated	75mg; (14/2x7/) in blister, (28/4x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	18408/3 28.02.2023
37	Hartil-D	ramipril, hydrochlorothiazide	tablets	5mg+25mg; (28/2x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	18011/3 28.02.2023
38	BC Benzogel	benzocaine	gel	200mg/g; syringe 6g	Bio-Chem LLC Yerevan, Manandyan, 33, 1/1	Republic of Armenia	Bio-Chem LLC Yerevan, Manandyan, 33, 1/1	Republic of Armenia	OTC	14149/1 28.02.2023
39	Spasmalgon	metamizole (metamizole sodium), pitofenone (pitofenone hydrochloride), fempiverinium bromide	tablets	500mg+5mg+0,1mg; (10/1x10/), (20/2x10/) and (50/5x10/) in blister	Balkanpharma-Dupnitsa AD, str."Samokovsko Shosse" N3, Dupnitsa 2600	Bulgaria	Balkanpharma-Dupnitsa AD, str."Samokovsko Shosse" N3, Dupnitsa 2600	Bulgaria	OTC	17265/1 28.02.2023

40	Cymbalta	duloxetine (duloxetine hydrochloride)	capsules gastro-resistant	60mg; (28/4x7/) in blister, (28/2x14/) in blister	Lilly S.A., Avda de la Industria 30, 28108 Alcobendas-Madrid-packager, batch releaser, Lilly del Caribe, Inc., Puerto Rico 00985, 12,6 km 65th Infantry Road, Carolina, USA- bulk manufacturer	Spain	Eli Lilly Nederland B.V.,Grootslag 1-5, NL-3991 RA,Houten	the Netherlands	PoM	18648/3/1 28.02.2023
41	Fluconazole	fluconazole	tablets coated	150mg; (2/1x2) in blister	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PoM	18390/1 28.02.2023
42	Hexaxim	diphtheria toxoid, tetanus toxoid, pertussis toxoid/filamentous haemagglutinin, poliovirus types 1/2/3, hepatitis B surface antigen, haemophilus influenzae type b polysaccharide, haemophilus influenzae type b polysaccharide conjugated to tetanus protein	suspension for injection	20IU/0,5ml+40IU/0,5ml+25/25mcg/0,5ml+40/8/32 DU/0,5ml+10mcg/0,5ml+12mcg/0,5ml+22-36mcg/0,5ml; (10) glass vials 0,5ml	Sanofi Pasteur, Parc Industriel d` Incarville, 27100 Val de Reuil	France	Sanofi Pasteur, 14 Espace Henry Vallee, 69007 Lyon	France	PoM	20298/5 28.02.2023

43	Hexaxim	diphtheria toxoid, tetanus toxoid, pertussis toxoid/filamentous haemagglutinin, poliovirus types 1/2/3, hepatitis B surface antigen, haemophilus influenzae type b polysaccharide, haemophilus influenzae type b polysaccharide conjugated to tetanus protein	suspension for injection	20IU/0,5ml+40IU/0,5ml+25/25mcg/0,5ml+40/8/32 DU/0,5ml+10mcg/0,5ml+12mcg/0,5ml+22-36mcg/0,5ml; pre-filled syringe 0,5ml and (2) needles	Sanofi Pasteur, Parc Industriel d` Incarville, 27100 Val de Reuil	France	Sanofi Pasteur, 14 Espace Henry Vallee, 69007 Lyon	France	PoM	20299/5 28.02.2023
44	Tetracaine	tetracaine (tetracaine hydrochloride)	drops eye	10mg/ml; (1) plastic vial-dropper 10ml, (10) plastic vial-dropper 10ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	20709/1 28.02.2023
45	Ferrum LEK	iron (III) hydroxide with polymaltose complex	syrup	50mg/5ml; 100ml glass bottle and measuring spoon	Genveon Ilac Sanayi ve Ticaret A.S., Inoenue Mahallesi, Gebze Plastikciler Organize Sanayi Boelgesi, Mahallesi 9, Cadde No.2, 41400, Kocaeli	Turkey	Lek d.d., Verovskova str. 57,1526 Ljubljana	Slovenia	PoM	20700/2 28.02.2023
46	Vegtasone	mometasone (mometasone furoate)	cream	1mg/g; aluminium tube 15g	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	Vegapharm LLP, Unit 18, Normon road 53, Greenwich Centre Business park, SE10 9QF, London	United Kingdom	PoM	20066/1 28.02.2023

47	Lamal	lamotrigine	tablets	25mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	17149/3/1 28.02.2023
48	Lamal	lamotrigine	tablets	50mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	17150/3/1 28.02.2023
49	Lamal	lamotrigine	tablets	100mg; (30/2x15/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	17151/3/1 28.02.2023
50	Lamal	lamotrigine	tablets	200mg; (30/2x15/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	17152/3/1 28.02.2023
51	Deep Heat	methyl salicylate, menthol (racemic), eucalyptus oil, turpentine oil	cream for external use	128mg/g+59,1mg/g+19,7mg/g+14,7mg/g; 15g aluminium tube, 67g aluminium tube	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	OTC	18771/3 28.02.2023

52	Lorazepam	lorazepam	tablets	1mg; (24/1x24/) 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	17746/1 28.02.2023
53	Lorazepam	lorazepam	tablets	2mg; (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	17745/2 28.02.2023
54	Ekvator	lisinopril (lisinopril dihydrate), amlodipine (amlodipine besilate)	tablets	20mg+10mg; (10/1x10/) in blister, (30/3x10/) in blister, (60/6x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	19174/2 28.02.2023
55	Nervomix	valerianae radix, melissae folium, lupuli strobilus, hyperici herba	capsules hard	210mg+52,5mg+52,5mg+35mg; (30/3x10/) and (60/3x20/) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza St., 05-152 Czosnow	Poland	OTC	17085/3 28.02.2023
56	Chondroxid	chondroitin sulfat (chondroitin sulfat sodium)	gel for external use	50mg/g; 30g aluminium or plastic tube	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	17841/2 28.02.2023

57	Amoksiklav powder for solution for injection 500mg/100mg	amoxicillin (amoxicillin sodium), clavulanic acid (potassium clavulanate)	powder for solution for injection	500mg+100mg; (5) glass vials	Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl	Austria	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19966/2 28.02.2023
58	Amoksiklav powder for solution for injection 1000mg /200mg	amoxicillin (amoxicillin sodium), clavulanic acid (potassium clavulanate)	powder for solution for injection	1000mg+200mg; (5) glass vials	Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl	Austria	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19967/2 28.02.2023
59	Diclac 75mg/3ml	diclofenac (diclofenac sodium)	solution for injection	75mg/3ml; (5) ampoules 3ml, (10) ampoules 3ml	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	20041/2 28.02.2023
60	Flavamed cough tablets	ambroxol (ambroxol hydrochloride)	tablets	30mg; (20/2x10) in blister	Berlin-Chemie AG, Glienicker Weg 125, D-12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, D-12347 Berlin, Germany- bulk manufacturer, Berlin-Chemie AG, TempelhoferWeg 83, D-12347 Berlin,Germany / Berlin-Chemie AG, GlienickerWeg 125, D-12489 Berlin, Germany- quality control (physicochemical)	Germany	Berlin-Chemie AG, Glienicker Weg 125, D-12489 Berlin	Germany	OTC	19176/3 28.02.2023

61	Flavamed effervescent tablets	ambroxol (ambroxol hydrochloride)	tablets effervescent	60mg; (10) aluminium or plastic container	Berlin-Chemie AG, Glienicker Weg 125, D-12489 Berlin- batch releaser, Hermes Pharma GmbH, Hans-Urmiler Ring 52, 82515 Wolfratshausen, Germany- bulk manufacturer, packager, quality control	Germany	Berlin-Chemie AG, Glienicker Weg 125, D-12489 Berlin	Germany	OTC	19323/3/1 28.02.2023
62	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	19495/2 28.02.2023
63	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	19496/2 28.02.2023
64	Oxivin-DF	oxymetazoline (oxymetazoline hydrochloride)	spray nasal	0,5mg/ml; 10ml plastic vial with pump dispenser	Dosfarm LLP, 050034, Almaty city, Chaplygin str.3	Kazakhstan	Dosfarm LLP, 050034, Almaty city, Chaplygin str.3	Kazakhstan	OTC	17056/3 28.02.2023
65	Bepanthen	dexpanthenol	ointment	50mg/g; aluminium tube 30g, aluminium tube 100g	GP Grenzach Produktions GmbH, Emil-Barell-Strasse 7, D-79639 Grenzach-Wyhlen	Germany	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	18643/7/1 28.02.2023

66	Bepanthen	dexpanthenol	cream	50mg/g; aluminium tube 30g and 100g	GP Grenzach Produktions GmbH, Emil-Barell-Strasse 7, D-79639 Grenzach-Wyhlen	Germany	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	18644/3 28.02.2023
67	Bepanthen Plus	dexpanthenol, chlorhexidine (chlorhexidine dihydrochloride)	cream for topical use	50mg/g+5mg/g; 30g aluminium tube	GP Grenzach Produktions GmbH, Emil-Barell-Strasse 7, D-79639 Grenzach-Wyhlen	Germany	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	17571/4 28.02.2023
68	Galvus	vildagliptin	tablets	50mg; (28/2x14/) in blister, (56/4x14/) 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	19791/4/1 28.02.2023
69	Ascorbic acid with glucose	ascorbic acid, dextrose	tablets	100mg+877mg; (10) in strip, (40) in plastic container	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	OTC	17497/2 28.02.2023
70	Grammidin with anesthetic neo	gramicidin S (gramicidin S dihydrochloride), oxybuprocaine (oxybuprocaine hydrochloride), cetylpyridinium chloride (cetylpyridinium chloride monohydrate)	tablets to be sucked	3mg+0.2mg+1mg; (18/2x9/) in blister	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Centemo LTD, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	15769/4 28.02.2023

71	Betamaks	sulpiride	tablets	50mg; (30/3x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	17476/2 28.02.2023
72	Betamaks	sulpiride	tablets	100mg; (30/3x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	17475/2 28.02.2023
73	Betamaks	sulpiride	tablets	200mg; (30/3x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	17474/2 28.02.2023
74	Trulicity	dulaglutide	solution for injection	0,75mg/0.5ml; (4) pre-filled glass pen 0.5ml	Eli Lilly and Company, Indianapolis, IN 46285	USA	Eli Lilly and Company, Indianapolis, IN 46285	USA	PoM	17836/5 28.02.2023
75	Trulicity	dulaglutide	solution for injection	1,5mg/0.5ml; (4) pre-filled glass pen 0.5ml	Eli Lilly and Company, Indianapolis, IN 46285	USA	Eli Lilly and Company, Indianapolis, IN 46285	USA	PoM	17837/5 28.02.2023
76	Lysobact	lysozyme (lysozyme hydrochloride), pyridoxine (pyridoxine hydrochloride)	lozenges compressed	20mg+10mg; (10/1x10/) and (30/3x10/) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	17078/2 28.02.2023
77	Enterofuryl	nifuroxazide	capsules	100mg; (30/3x10/) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	PoM	20982/1 28.02.2023

78	Enterofuryl	nifuroxazide	capsules	200mg; (16/2x8/) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	PoM	20983/1 28.02.2023
79	Levomicetin-Darnitsa	chloramphenicol	tablets	500mg; (10) in blister	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	PoM	17591/2 28.02.2023
80	Avodart	dutasteride	capsules soft	0,5mg; (30/3x10/) In blister	GlaxoSmithKline Pharmaceuticals S.A.,189 Grunwaldzka street, 60-322 Poznan	Poland	GlaxoSmithKline Export Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	PoM	17340/2 28.02.2023
81	Cipro-Denk 500	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	500mg; (10/1x10/) in blister	Allphamed PHARBIL Arzneimittel GmbH, Hildebrandstr. 12, 37081 Gottingen	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20134/1 28.02.2023
82	Bactox 250mg/5ml	amoxicillin (amoxicillin trihydrate)	powder for oral suspension	250mg/5ml; glass bottle 60ml and measuring spoon	Innothera Chouzy Rue Rene Chantereau, Chouzy-sur-Cisse Valloire-sur-Cisse, 41150- batch releaser, Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl,Tirol, Austria- bulk manufacturer, packager, quality control	France	Laboratoire Innotech International, 22 Avenue Aristide Brand 94110 Arcueil	France	PoM	14161/1 28.02.2023

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 02-1/23 on February 28, 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	ARIFON Retard	indapamide	tablets film-coated prolonged release	1,5mg; (30/1x30/) in blister, (90/3x30/) 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	000156 28.02.2023