

## LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 12-2/23 on December 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	Oncofluor 500	fluorouracil	solution for injection/infusion	50mg/1ml;N5(1x5) glass vial 10ml, N50(10x5) glass vial 10ml,	United Biotech (P) Ltd, Bagbania, Baddi-Nalagarh Road, Distt. Solan (HP)- 174 101	India	Violeta Medical Center LLC, 2/33 Yernzkyan street, Arabkir, Yerevan	Republic of Armenia	PoM	21840 28.12.2023
2	Exforge	amlodipine (amlodipine besilate), valsartan	tablets film-coated	5mg+160mg; (14/1x14) in PVC/PVDC blister, (28/2x14) in PVC/PVDC blister, (14/1x14) in PA/AL/PVC(Alu-Alu) blister, (28/2x14) in PA/AL/PVC(Alu-Alu) blister	Novartis Farma S.p.A, Via Provinciale Schito 131, 80058 Torre Annunziata(NA)	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	21841 28.12.2023
3	Exforge	amlodipine (amlodipine besilate), valsartan	tablets film-coated	10mg+160mg; (14/1x14) in PVC/PVDC blister, (28/2x14) in PVC/PVDC blister, (14/1x14) in PA/AL/PVC(Alu-Alu) blister, (28/2x14) in PA/AL/PVC(Alu-Alu) blister	Novartis Farma S.p.A, Via Provinciale Schito 131, 80058 Torre Annunziata(NA)	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	21842 28.12.2023
4	Galvus	vildagliptin	tablets	50mg; (28/2x14) in blister, (56/4x14) in blister	Novartis Pharmaceuticals Manufacturing LLC, Verovskova Ulica 57, 1000, Ljubljana- bulk manufacturer, packager,quality control (physicochemical), batch releaser, Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana, Slovenia- quality control (microbiological)	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	21843 28.12.2023

5	Privigen	human normal immunoglobulin	solution for infusion	100mg/ml; 25ml glass vial	CSL Behring AG, Wankdorfstrasse 10, CH-3000, Bern 22- bulk manufacturer, primary packager, quality control, batch releaser, according to GMP certificate - CSL Behring AG, Wankdorfstrasse 10, 3014 Bern, Switzerland, CSL Behring AG, Bolligenstrasse 93, 3006 Bern, Switzerland- secondary packager	Switzerland	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	PoM	21844 28.12.2023
6	Privigen	human normal immunoglobulin	solution for infusion	100mg/ml; 50ml glass vial	CSL Behring AG, Wankdorfstrasse 10, CH-3000, Bern 22- bulk manufacturer, primary packager, quality control, batch releaser, according to GMP certificate - CSL Behring AG, Wankdorfstrasse 10, 3014 Bern, Switzerland, CSL Behring AG, Bolligenstrasse 93, 3006 Bern, Switzerland- secondary packager	Switzerland	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	PoM	21845 28.12.2023
7	Privigen	human normal immunoglobulin	solution for infusion	100mg/ml; 100ml glass vial	CSL Behring AG, Wankdorfstrasse 10, CH-3000, Bern 22- bulk manufacturer, primary packager, quality control, batch releaser, according to GMP certificate - CSL Behring AG, Wankdorfstrasse 10, 3014 Bern, Switzerland, CSL Behring AG, Bolligenstrasse 93, 3006 Bern, Switzerland- secondary packager	Switzerland	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	PoM	21846 28.12.2023
8	Privigen	human normal immunoglobulin	solution for infusion	100mg/ml; 200ml glass vial	CSL Behring AG, Wankdorfstrasse 10, CH-3000, Bern 22- bulk manufacturer, primary packager, quality control, batch releaser, according to GMP certificate - CSL Behring AG, Wankdorfstrasse 10, 3014 Bern, Switzerland, CSL Behring AG, Bolligenstrasse 93, 3006 Bern, Switzerland- secondary packager	Switzerland	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	PoM	21847 28.12.2023

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of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 12-2/23 on December 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	Bisoprolol-AKOS	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (30/3x10) in blister, (50/5x10) in blister	Biocom JSC, 54 Chapaevsky Cr., Stavropol, 355016	Russia	Biocom JSC, 54 Chapaevsky Cr., Stavropol, 355016	Russia	PoM	21858 (000792) 28.12.2023
2	Bisoprolol-AKOS	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg; (30/3x10) in blister, (50/5x10) in blister	Biocom JSC, 54 Chapaevsky Cr., Stavropol, 355016	Russia	Biocom JSC, 54 Chapaevsky Cr., Stavropol, 355016	Russia	PoM	21859 (000792) 28.12.2023
3	Cavinton	vinpocetine	concentrate for infusion	5mg/ml; (10/2x5) ampoules 2ml	Sotex PharmFirm» CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region- quality control, batch releaser, «Sotex» PharmFirm» CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, Russia- bulk manufacturer, packager	Russia	Gedeon Richter Plc., Gyomroi ut 19-21, Budapest, 1103	Hungary	PoM	21860 (004388) 28.12.2023
4	Cavinton	vinpocetine	concentrate for infusion	5mg/ml; (10/2x5) ampoules 2ml	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter Plc., Gyomroi ut 19-21, Budapest, 1103	Hungary	PoM	21861 (004388) 28.12.2023
5	Cavinton	vinpocetine	concentrate for infusion	5mg/ml; (10/2x5) ampoules 5ml	Sotex PharmFirm» CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region- quality control, batch releaser, «Sotex» PharmFirm» CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, Russia- bulk manufacturer, packager	Russia	Gedeon Richter Plc., Gyomroi ut 19-21, Budapest, 1103	Hungary	PoM	21862 (004388) 28.12.2023

6	Cavinton	vinpocetine	concentrate for infusion	5mg/ml; (10/2x5) ampoules 5ml	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter Plc., Gyomroi ut 19-21, Budapest, 1103	Hungary	PoM	21863 (004388) 28.12.2023
7	Cavinton	vinpocetine	concentrate for infusion	5mg/ml; (10/2x5) ampoules 10ml	Sotex PharmFirm» CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region- quality control, batch releaser, «Sotex» PharmFirm» CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, Russia- bulk manufacturer, packager	Russia	Gedeon Richter Plc., Gyomroi ut 19-21, Budapest, 1103	Hungary	PoM	21864 (004388) 28.12.2023
8	Cavinton	vinpocetine	concentrate for infusion	5mg/ml; (10/2x5) ampoules 10ml	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter Plc., Gyomroi ut 19-21, Budapest, 1103	Hungary	PoM	21865 (004388) 28.12.2023
9	Tebantin	gabapentin	capsules	300mg; (50/5x10) in blister, (100/10x10) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	21866 (002538) 28.12.2023
10	ViziDol	ketorolac (ketorolac tromethamine)	eye drops	5mg/ml; dropper vial 5ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	21848 (007045) 28.12.2023

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of the medicines recommended for the re-registration by the Center according to the meeting decision N 12-2/23 on December 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	Monosorb XL 60mg Prolonged-Release Tablets	isosorbide mononitrate	tablets prolonged-release	60mg; (28/2x14) in blister	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB- batch releaser, Dexcel Ltd., 1 Dexcel Street, Or-Akiva 3060000, Israel- bulk manufacturer, packager, quality control (physicochemical), The Institute for Food Microbiology and Consumer Goods Ltd., 9 HaShalom Road, Neshet, Israel- quality control (microbiological)	UK	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB	UK	PoM	21849 28.12.2023
2	Sartuzin	fluoxetine (fluoxetine hydrochloride)	capsules hard	20mg; (12/3x4) in blister, (28/4x7) in blister	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., 14452 Metamorphosis, Attica	Greece	PoM	21850 28.12.2023
3	Ermucin	erdosteine	capsules hard	300mg; (10/1x10) in blister, (20/2x10) in blister	Edmond Pharma S.r.l., Strada Statale dei Giovi 131- 20037 Paderno Dugnano (MI)- bulk manufacturer, quality control, batch releaser, Lamp San Prospero S.p.A., Via della Pace, 25/A-41030 San Prospero (MO), Italy- packager	Italy	UAB «MRA», Totoriu str. 20-9, LT-01121 Vilnius	Republic of Lithuania	PoM	21851 28.12.2023
4	Rumizole	metronidazole, miconazole (miconazole nitrate)	suppositories vaginal	500mg+100mg; (14/2x7)	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	PoM	21852 28.12.2023
5	Thyrozol	thiamazole	tablets film-coated	5mg; (50/5x10) in blister, (50/2x25) in blister	Merck Healthcare KgaA, Frankfurter Strasse 250, A18, A31, A32, D2, D3, D11, D12, D15, D39, N79, N80, N90, PH5, PH16, PH23, PH28, PH31, PH33, PH50, PH51, PH52, PH80, 64293 Darmstadt	Germany	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	21853 28.12.2023

6	Thyrozol	thiamazole	tablets film-coated	10mg; (50/5x10/) in blister, (50/2x25/) in blister	Merck Healthcare KgaA, Frankfurter Strasse 250, A18, A31, A32, D2, D3, D11, D12, D15, D39, N79, N80, N90, PH5, PH16, PH23, PH28, PH31, PH33, PH50, PH51, PH52, PH80, 64293 Darmstadt	Germany	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	21854 28.12.2023
7	Herbion ivy syrup	ivy leaf dry extract	syrup	7mg/ml; glass bottle 150ml and measuring spoon	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- quality control (microbiologi- cal), batch releaser, KRKA d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia- bulk manufacturer, packager, quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	21855 28.12.2023
8	Rizoptan	rizatriptane (rizatriptane benzoate)	tablets	10mg; (3/1x3/) in blister, (6/2x3/) in blister, (9/3x3/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	21856 28.12.2023
9	Artrozan	meloxicam	tablets	15mg; (20/1x20) in blister	Pharmstandard-Leksredstva JSC, Kursk, Agre- gatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, Kursk, Agregatnaya 2nd str., 1a/18	Russia	PoM	21857 28.12.2023

## LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-2/23 on December 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	Rumizole	metronidazole, miconazole (miconazole nitrate)	suppositories vaginal	500mg+100mg; (14/2x7)	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	PoM	18164/3/1 28.12.2023
2	Ingavirin	pentanedioic acid (pentanedioic acid imidazolyl ethanamide)	syrup	30mg/5ml; polyethylene bottle 50ml and measuring syringe, polyethylene bottle 90ml and measuring syringe	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2- secondary packager, quality control (physicochemical), batch releaser, ABC Farmaceutici S.p.A, Via Cantone Moretti, 29, 10015, Ivrea, Italy- bulk manufacturer, primary packager, Testing laboratory Centemo Ltd, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 1, housing 1, office 315, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	20758/2/1 28.12.2023

3	Chloropyramine	chloropyramine (chloropyramine hydrochloride)	solution for i/v and i/m injection	20mg/ml; (10) ampoules 1ml	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, No10/1, ul. Chapaeva, Borisov 222518, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	19502/1/1 28.12.2023
4	Tetracycline-Belmed	tetracycline (tetracycline hydrochloride)	tablets film-coated	100mg; (10/1x10) in blister, (20/2x10) 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	20461/1/1 28.12.2023
5	Triderm	betamethasone (betamethasone dipropionate), clotrimazole, gentamicin (gentamicin sulfate)	cream	0,5mg/g+10mg/g+1mg/g; aluminum tube 15g	Organon Heist B.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	18445/7/2 28.12.2023
6	Capecitabine Pharmacare	capecitabine	tablets film-coated	500mg; (120/12x10) in blister	Pharmacare Premium Limited, HHF 003, Hal Far Industrial Estate, Birzebbugia BBg 3000	Malta	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	20110/2/1 28.12.2023



7	Azitrox	azithromycin (azithromycin dihydrate)	capsules	500mg; (2/1x2/) in blister, (3/1x3/) in blister	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTCPharm JSC, 123317, Moscow, Testovskaya str., 10	Russia	PoM	19213/3/1 28.12.2023
8	Artrozan	meloxicam	tablets	15mg; (20/1x20/) in blister	Pharmstandard-Leksredstva JSC, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, Kursk, Agregatnaya 2nd str., 1a/18	Russia	PoM	17525/1/1 28.12.2023

## LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-2/23 on December 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
	Cefazolin	cefazolin	powder for solution for injection	1000mg; (10) glass vials	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	20501/1 28.12.2023
2	Pilfid	minoxidil	spray cutaneous,solution	50mg/ml; 60ml plastic vial	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	17712/3 28.12.2023
3	Ermucin	erdosteine	capsules hard	300mg; (10/1x10) and (20/2x10) in blister	Edmond Pharma S.r.l., Strada Statale dei Giovi 131- 20037 Paderno Dugnano (MI)- batch releaser, bulk manufacturer, Lamp San Prospero S.p.A., Via della Pace, 25/A-41030 San Prospero (MO), Italy- packager	Italy	UAB «MRA», Totoriu str. 20-9, LT-01121 Vilnius	Republic of Lithuania	PoM	18076/4 28.12.2023
4	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	20194/2 28.12.2023
5	Sedropor	ibandronic acid (ibandronic acid sodium monohydrate)	tablets film-coated	150mg; (1/1x1) in blister	Pharmathen S.A., Dervenakion 6, 15351 Pallini, Attiki	Greece	Pharmathen S.A., Dervenakion 6, 15351 Pallini, Attiki	Greece	PoM	21760/1 28.12.2023
6	Phosphogliv	phospholipids (lipoid C 100), glycyrrhizinic acid (glycyrrhizinic acid trisodium)	powder lyophilized for solution for i/v injection	500mg+200mg; (5) glass vials 2,5g and (5) solvent in ampoules 10ml	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	PoM	17989/2 28.12.2023

7	Mezym forte 10000	pancreatin (lipase, amylase, protease)	tablets gastro-resistant	not less than 10000U+not less than 7500U+not less than 375U; (10/1x10) in blister, (20/2x10) 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	20080/3 28.12.2023
8	Sartuzin	fluoxetine (fluoxetine hydrochloride)	capsules hard	20mg; (12/3x4) and (28/4x7) in blister	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorphosis, Attica	Greece	PoM	18042/2 28.12.2023
9	Melarena	melatonin	tablets film-coated	3mg; (10/1x10) in blister, (30/3x10) in blister	Hemofarm LLC, 249035, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	18525/4/2 28.12.2023
10	Amprilan	ramipril	tablets	1,25mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, KRKA, tovarna zdravil, d.d., Novo mesto, Povahova ulica 5, 8501 Novo Mesto, Slovenia-quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	21577/1 28.12.2023
11	Amprilan	ramipril	tablets	2,5mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, KRKA, tovarna zdravil, d.d., Novo mesto, Povahova ulica 5, 8501 Novo Mesto, Slovenia-quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	21578/1 28.12.2023
12	Amprilan	ramipril	tablets	5mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, KRKA, tovarna zdravil, d.d., Novo mesto, Povahova ulica 5, 8501 Novo Mesto, Slovenia-quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	21579/1 28.12.2023

13	Amprilan	ramipril	tablets	10mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, KRKA, tovarna zdravil, d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia-quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	21580/1 28.12.2023
14	Flosteron	betamethasone (betamethasone dipropionate), betamethasone (betamethasone sodium phosphate)	suspension for injection	5mg/ml+2mg/ml; (5) ampoules 1ml	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	20670/1 28.12.2023
15	Siofor 500	metformin (metformin hydrochloride)	tablets film-coated	500mg; (60/6x10) in blister	Berlin-Chemie AG, Glienicker Weg 125, D-12489 Berlin-batch releaser, packager, Berlin-Chemie AG, Tempelhofer Weg 83, D-12347 Berlin,Germany-bulk manufacturer	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	18113/1 28.12.2023
16	Siofor 500	metformin (metformin hydrochloride)	tablets film-coated	500mg; (60/6x10) 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	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	18114/1 28.12.2023
17	Siofor 500	metformin (metformin hydrochloride)	tablets film-coated	500mg; (60/6x10) in blister	Berlin-Chemie AG, 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 AG, Tempelhofer Weg 83, 12347 Berlin, Germany- quality control (physicochemical)	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	21523/1 28.12.2023
18	Siofor 500	metformin (metformin hydrochloride)	tablets film-coated	500mg; (60/6x10) 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	PoM	21525/1 28.12.2023

19	Siofor 850	metformin (metformin hydrochloride)	tablets film-coated	850mg; (60/4x15/) in blister	Berlin-Chemie AG, Glienicker Weg 125, D-12489 Berlin-batch releaser, packager, Berlin-Chemie AG, Tempelhofer Weg 83, D-12347 Berlin,Germany-bulk manufacturer	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	18115/2 28.12.2023
20	Siofor 850	metformin (metformin hydrochloride)	tablets film-coated	850mg; (60/4x15/) blisters	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin-batch releaser, Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden, Germany-bulk manufacturer, packager	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	18116/2 28.12.2023
21	Siofor 850	metformin (metformin hydrochloride)	tablets film-coated	850mg; (60/4x15/) in blister	Berlin-Chemie AG, 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 AG, Tempelhofer Weg 83, 12347 Berlin, Germany- quality control (physicochemical)	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	PoM	21524/1 28.12.2023
22	Siofor 850	metformin (metformin hydrochloride)	tablets film-coated	850mg; (60/4x15/) 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	PoM	21526/1 28.12.2023
23	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	20298/7 28.12.2023

24	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	20299/7 28.12.2023
25	Phlebodia 600	diosmin	tablets film-coated	600mg; (15/1x15) in blister, (18/1x18) in blister, (30/2x15) in blister, (60/4x15) in blister	Innothera Chouzy, Rue Rene Chantereau, Chouzy-sur-Cisse, Valloire-sur-Cisse, 41150	France	Laboratoire Innotech International, 22, Avenue Aristide Briand, 94110 Arcueil	France	OTC	21511/1 28.12.2023
26	Heptral	ademetonine	powder lyophilized for solution for injection	400mg; (5) glass vials and (5) solvent in ampoules 5ml	BIOLOGICI ITALIA LABORATORIES S.R.L., VIA FILIPPO SERPERO, 2- 20060 MASATE (MI)- bulk manufacturer, packager, quality control, batch releaser of powder, BIOLOGICI ITALIA LABORATORIES S.R.L., VIA FILIPPO SERPERO, 2- 20060 MASATE (MI), Italy- solvent manufacturer and primary packager	Italy	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	PoM	19859/1 28.12.2023
27	Azaleptol	clozapine	tablets	100mg; (50/5x10) in blister	PJSC «Technolog», 8, Staraprorizna street, Uman, Cherkassy region, 20300	Ukraine	PJSC «Technolog», 8, Staraprorizna street, Uman, Cherkassy region, 20300	Ukraine	PoM	21470/1 28.12.2023
28	Relantan	progesterone	capsules soft	100mg; (30/3x10) in blister	Aversi-Rational Ltd, Chirmakhuli Str. 14, 0198 Tbilisi- secondary packager, quality control, batch releaser, M/s.Steril-Gene Life Sciences (P) Ltd, No.45 Mangalam Main Road, Mangalam Village, Villianur Commune, Puducherry, 605110, India- bulk manufacturer, primary packager	Georgia	Aversi-Rational Ltd, Chirmakhuli Str. 14, 0198 Tbilisi	Georgia	PoM	21409/1 28.12.2023

29	Relantan	progesterone	capsules soft	200mg; (30/3x10) in blister	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi- secondary packager, quality control, batch releaser, M/s.Steril-Gene Life Sciences (P) Ltd , No.45 Mangalam Main Road, Mangalam Village, Villianur Commune, Puducherry, 605110, India- bulk manufacturer, primary packager	Georgia	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi	Georgia	PoM	21410/1 28.12.2023
30	Ambroxol-Hemofarm	ambroxol (ambroxol hydrochloride)	syrup	15mg/5ml; 100ml glass bottle and 5ml measuring spoon	Hemofarm A.D. 26300, Vrsac, Beogradskii put bb- batch releaser, Hemofarm A.D. Vrsac, branch plant Sabac, 15000, Sabac, Hajduk Veljkova str. No: bb, Serbia- bulk manufacturer, packager, quality control	Serbia	Hemofarm A.D. 26300, Vrsac, Beogradskii put bb	Serbia	OTC	20642/1 28.12.2023
31	Duressa	dexamethasone (dexamethasone sodium phosphate), levofloxacin (levofloxacin hemihydrate)	drops eye	1mg/ml+5mg/ml; 5ml plastic vial-dropper	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, Tubilux Pharma Sp.A., Via Costarica, 20/22, 00071 Pomezia/Rome, Italy- bulk manufacturer, packager, quality control	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	PoM	20402/3/1 28.12.2023
32	Normomed	inosine pranobex	syrup	50mg/ml; 120ml glass bottle and measuring cup, 240ml glass bottle and measuring cup	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2- secondary packager, quality control (physicochemical), batch releaser, ABC Farmaceutici Sp.A, Via Cantone Moretti, 29, 10015, Ivrea, Italy- bulk manufacturer, primary packager, 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	PoM	21678/1 28.12.2023