

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 05-1/23 on May 16, 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	Nizoral	ketoconazole	shampoo medicinal	20mg/g; plastic bottle 60ml	Janssen Pharmaceutica N.V., Turnhoutseweg 30, 2340 Beerse	Belgium	STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel	Germany	OTC	21362 16.05.2023
2	Revolade	eltrombopag (eltrombopag-olamine)	tablets film-coated	25mg; (28/4x7/) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, Ljubljana, 1526	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	21363 16.05.2023
3	Revolade	eltrombopag (eltrombopag-olamine)	tablets film-coated	50mg; (28/4x7/) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, Ljubljana, 1526	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	21364 16.05.2023
4	Halidor	bencyclane (bencyclane fumarate)	solution for injection	25mg/ml; (10/2x5/) ampoules 2ml in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	21365 16.05.2023

LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 05-1/23 on May 16,
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	Detraproct	lidocaine (lidocaine hydrochloride monohydrate), fluocinolone acetonide	cream rectal	21,2mg/g+0,1mg/g; 15g aluminium tube and applicator	Simvis Pharmaceuticals S.A., 14568, Asklipiou 4-6, Kryoneri, Attiki	Greece	Servier JSC, 125196, Lesnaya str., 7, floor 7/8/9, Moscow	Russia	PoM	21361 (000736) 16.05.2023

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 05-1/23 on May 16, 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	Sevoflurane	sevoflurane	liquid for inhalation	100%; 250ml glass bottle	Piramal Pharma Limited, Sy.Nos.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	21366 16.05.2023
2	Rinza	paracetamol, caffeine, phenylephrine (phenylephrine hydrochloride), chlorphenamine (chlorphenamine maleate)	tablets	500mg+30mg+10mg+2mg; (4/1x4) in blister, (10/1x10) in blister, (20/2x10) in blister	Unique Pharmaceutical Laboratories (a division of J. B. Chemicals & Pharmaceuticals Ltd.), Survey No. 101/2 & 102/1, Daman Industrial Estate, Kadaiya, Daman-396 210	India	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	OTC	21367 16.05.2023
3	Enap	enalaprilat	solution for injection	1,25mg/ml; (5/1x5) ampoules 1ml 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	21368 16.05.2023
4	Lysobact DUO	lysozyme (lysozyme hydrochloride), cetylpyridinium (cetylpyridinium chloride)	lozenges compressed	20mg+1,5mg; (20/2x10) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	21369 16.05.2023
5	Colchicina Lirca	colchicine	tablets	1mg; (60/2x30) in blister	Haupt Pharma Amareg GmbH, Donaustauer Strasse 378, 93055 Regensburg	Germany	Acarpia Farmaceutici S.r.l., Viale L. Majno 18, 20129 Milano	Italy	PoM	21370 16.05.2023

6	Calcium gluconate-Darnitsa (stabilized)	calcium gluconate	solution for injection	100mg/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	21371 16.05.2023
7	Erythromycin	erythromycin (erythromycin ethylsuccinate)	tablets	400mg; (10/1x10) 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	21372 16.05.2023
8	Betaserc	betahistine (betahistine dihydrochloride)	tablets	8mg; (30/1x30) in blister	Mylan Laboratories SAS, Route de Belleville, Lieu-dit Maillard, 01400 Chatillon sur Chalaronne	France	Abbott Healthcare Products B.V., C.J. van Houtenlaan 36, NL-1381 CP Weesp	the Netherlands	PoM	21373 16.05.2023
9	Betaserc	betahistine (betahistine dihydrochloride)	tablets	16mg; (30/2x15) in blister	Mylan Laboratories SAS, Route de Belleville, Lieu-dit Maillard, 01400 Chatillon sur Chalaronne	France	Abbott Healthcare Products B.V., C.J. van Houtenlaan 36, NL-1381 CP Weesp	the Netherlands	PoM	21374 16.05.2023
10	Betaserc	betahistine (betahistine dihydrochloride)	tablets	24mg; (20/1x20) in blister, (60/3x20) in blister	Mylan Laboratories SAS, Route de Belleville, Lieu-dit Maillard, 01400 Chatillon sur Chalaronne	France	Abbott Healthcare Products B.V., C.J. van Houtenlaan 36, NL-1381 CP Weesp	the Netherlands	PoM	21375 16.05.2023
11	Metronidazole	metronidazole	suppositories vaginal	500mg; (10/2x5)	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	PoM	21376 16.05.2023
12	Enalapril	enalapril (enalapril maleate)	tablets	5mg; (20/2x10) in blister, (30/3x10) in blister, (60/6x10) 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	21377 16.05.2023
13	Enalapril	enalapril (enalapril maleate)	tablets	10mg; (20/2x10) in blister, (30/3x10) in blister, (60/6x10) 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	21378 16.05.2023

14	Genferon	interferon alfa-2b, benzocaine, taurine	suppositories rectal and vaginal	500000IU+55mg+10mg; (10/2x5/)	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	21379 16.05.2023
15	Genferon	interferon alfa-2b, benzocaine, taurine	suppositories vaginal and rectal	1000000IU+55mg+10mg; (10/2x5/)	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	21380 16.05.2023
16	Oxolin	oxolin	ointment nasal	2,5mg/g; 15g aluminium tube	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	OTC	21381 16.05.2023
17	Calcium chloride-Darnitsa	calcium chloride (calcium chloride dihydrate)	solution for injection	50,7mg/ml; (10/2x5/) ampoules 5ml in blister	PrJSC «Pharmaceutical firm «Darnitsa», 02093, Kyiv, Boryspilska Str.,13	Ukraine	PrJSC «Pharmaceutical firm «Darnitsa», 02093, Kyiv, Boryspilska Str.,13	Ukraine	PoM	21382 16.05.2023
18	AnGriMax Neo	paracetamol, phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate)	capsules	325mg+10mg+20mg; (20/2x10/) in blister, (28/2x14/) in blister, (30/3x10/) in blister	Minskintercaps U.V., 26/3, Inzhenernaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Republic of Belarus	PoM	21383 16.05.2023
19	Herticad	trastuzumab	powder lyophilized for concentrate for solution for infusion	150mg; glass vial	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422- quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422, Russia- bulk manufacturer, packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	21384 16.05.2023

20	Herticad	trastuzumab	powder lyophilized for concentrate for solution for infusion	440mg; glass vial and glass vial with 20ml solvent	<p>BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422- quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422, Russia- bulk manufacturer, packager</p>	Russia	<p>BIOCAD JSC, Intracity Municipality the Settlement of Strelna, the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515</p>	Russia	PoM	<p>21385 16.05.2023</p>
21	Kostarox	etoricoxib	tablets film-coated	60mg; (28/2x14) in blister	<p>Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben- batch releaser, Cadila Pharmaceuticals LTD, Plot No. 1389, Trasad Road, Dholka- 382 225, Ahmedabad, Gujarat State, India- bulk manufacturer, packager, Pharmacare Premium Ltd., HHF003 Hal Far Industrial Estate, Birzebbugia, BBG3000, Malta- quality control</p>	Germany	<p>Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana</p>	Slovenia	PoM	<p>21386 16.05.2023</p>
22	Kostarox	etoricoxib	tablets film-coated	90mg; (28/2x14) in blister	<p>Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben- batch releaser, Cadila Pharmaceuticals LTD, Plot No. 1389, Trasad Road, Dholka- 382 225, Ahmedabad, Gujarat State, India- bulk manufacturer, packager, Pharmacare Premium Ltd., HHF003 Hal Far Industrial Estate, Birzebbugia, BBG3000, Malta- quality control</p>	Germany	<p>Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana</p>	Slovenia	PoM	<p>21387 16.05.2023</p>
23	Liniment Vishnevsky	birch tar, xeroform	liniment	30mg/g+30mg/g; aluminium tube 25g	<p>ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079</p>	Republic of Armenia	<p>ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079</p>	Republic of Armenia	OTC	<p>21388 16.05.2023</p>

24	Lansoptol	lansoprazole	capsules	30mg; (14/2x7) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Nacionalni laboratorij za zdravje, okolje in hrano (NLZOH), Dalmatinova ulica 3, Novo mesto, 8000, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	21389 16.05.2023
25	Clonazepam	clonazepam	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	21390 16.05.2023
26	Magnetab	magnesium (magnesium lactate dihydrate), pyridoxine (pyridoxine hydrochloride)	tablets	34mg+5mg; (30/3x10) in blister, (50/5x10) in blister	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Republic of Belarus	OTC	21391 16.05.2023
27	Vitaprost Forte	samprost (dry extract of calf prostate)	suppositories rectal	100mg; (10/2x5) in blister	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	21392 16.05.2023
28	Nucleo CMP Forte	cytidine-5-disodium monophosphate + (uridine-5-trisodium triphosphate, uridine-5-disodium diphosphate, uridine-5-disodium monophosphate)	powder lyophilized for solution for injection	10mg+6mg; (3) ampoules, (3) solvent in ampoules 2ml	Ferrer International, S.A., Joan Buscalla,1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer International, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	PoM	21393 16.05.2023
29	Polcortolon TC	tetracycline (tetracycline hydrochloride), triamcinolone (triamcinolone acetonide)	aerosol for external use	23,12mg/g+0,58mg/g; aluminium container 17,3g	Tarchomin Pharmaceutical Works «Polfa» S.A., 2,A. Fleminga str., 03-176 Warsaw	Poland	Tarchomin Pharmaceutical Works «Polfa» S.A., 2,A. Fleminga str., 03-176 Warsaw	Poland	PoM	21394 16.05.2023
30	Biprol	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (30/3x10) in blister	Hemofarm LLC, 249032, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	21395 16.05.2023

31	Biprol	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg; (30/3x10) in blister	Hemofarm LLC, 249032, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	21396 16.05.2023
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LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 05-1/23
on May 16, 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	Codelac Broncho	ambroxol (ambroxol hydrochloride), sodium glycyrrhizinate (glycyrrhizinic acid trisodium), thermopsis extract, sodium hydrocarbonate	tablets	20mg+30mg+10mg+200mg; (10/1x10) in blister, (20/2x10) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	«OTCPharm» JSC, Testovskaya street, 10, flr. 12, apartment II, room. 29, Moscow 123112	Russia	OTC	19250/1/1 16.05.2023
2	Roxera	rosuvastatin (rosuvastatin calcium)	tablets film-coated	40mg; (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	18129/1/1 16.05.2023
3	Herbion ivy lozenges	ivy leaf dry extract	lozenges	35mg; (16/2x8) in blister, (32/4x8) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- quality control (physicochemical- HPLC test Assay and identification of ivy leaf dry extract and microbiological), batch releaser, KRKA d.d., Novo mesto, Ulica Rada Pusenjakova 10, Ljutomer, 9240, Slovenia- bulk manufacturer, packager, KRKA d.d., Novo mesto, Povhovaulica 5, 8501 Novo Mesto, Slovenia- quality control (physicochemical- GC test Residual solvents: ethanol)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	19527/1/1 16.05.2023
4	Oxolin	oxolin	ointment nasal	2,5mg/g; 15g aluminium tube	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Republic of Belarus	OTC	17695/1/1 16.05.2023
5	Enalapril	enalapril (enalapril maleate)	tablets	5mg; (20/2x10), (30/3x10) and (60/6x10) in blister	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64A, No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	17639/2/1 16.05.2023

6	Enalapril	enalapril (enalapril maleate)	tablets	10mg; (20/2x10), (30/3x10/) and (60/6x10/) in blister	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64A, No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company «Borisovskiy zavod medicinskih preparatov», 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	17638/2/1 16.05.2023
7	Cetirizine	cetirizine (cetirizine dihydrochloride)	tablets film-coated	10mg; (20/2x10) in blister	Chanelle Medical Unlimited Company, Dublin Road, Loughrea, H62 FH90 - bulk manufacturer, packager, quality control (physicochemical), batch releaser, Complete Laboratory Solutions, Units 3A & 8, Small Business Park, Tuam Road, Galway, Ireland- quality control (microbiological)	Ireland	ARGO-PHARM LLC, 13/9 Sundukyan str., 0012 Yerevan	Republic of Armenia	OTC	20862/1/1 16.05.2023
8	Omeprazole 20mg gastro-resistant capsules	omeprazole	capsules gastro-resistant	20mg; (100/10x10) in strip	Medicamen Biotech Ltd., SP-1192 A&B, Phase-IV, Industrial Area, Bhiwadi, Dist. Alwar(Rajasthan)	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	17613/1/1 16.05.2023

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 05-1/23
on May 16, 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	Isoflurane	isoflurane	liquid for inhalation	100%; 250ml glass bottle	Piramal Enterprises Limited, Sy.No.7-70, 70/1 & 70/2, Digwal Village, Kohir Mandal, Sangareddy District - 502 321, Telangana	India	Piramal Enterprises Limited, Piramal Towers, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400013	India	PoM	16781/2 16.05.2023
2	Roxera	rosuvastatin (rosuvastatin calcium)	tablets film-coated	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	18126/1 16.05.2023
3	Roxera	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (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	18127/1 16.05.2023
4	Roxera	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (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	18128/1 16.05.2023
5	Glucophage XR	metformin (metformin hydrochloride)	tablets prolonged-release	500mg; (30/2x15) in blister, (60/4x15) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400, Semoy	France	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	19451/2/1 16.05.2023
6	Glucophage XR	metformin (metformin hydrochloride)	tablets prolonged-release	1000mg; (60/6x10) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400, Semoy- packager, batch releaser, Merck Healthcare KGaA, Frankfurter Strasse 250, 64 293 Darmstadt, Germany- bulk manufacturer, quality control	France	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	19452/2/1 16.05.2023
7	Clariscan	gadoteric acid	solution for injection	0,5mmol/ml; (10) glass vials 10ml	GE Healthcare AS-Oslo Plant, Nycoveien 1, NO-0485 Oslo	Norway	GE Healthcare AS, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	PoM	20610/1 16.05.2023

8	Clariscan	gadoteric acid	solution for injection	0,5mmol/ml; (10) glass vials 15ml	GE Healthcare AS-Oslo Plant, Nycoveien 1, NO-0485 Oslo	Norway	GE Healthcare AS, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	PoM	20611/1 16.05.2023
9	Clariscan	gadoteric acid	solution for injection	0,5mmol/ml; (10) glass vials 20ml	GE Healthcare AS-Oslo Plant, Nycoveien 1, NO-0485 Oslo	Norway	GE Healthcare AS, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	PoM	20612/1 16.05.2023
10	Clariscan	gadoteric acid	solution for injection	0,5mmol/ml; (10) plastic bottles 50ml	GE Healthcare AS-Oslo Plant, Nycoveien 1, NO-0485 Oslo	Norway	GE Healthcare AS, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	PoM	20613/1 16.05.2023
11	Clariscan	gadoteric acid	solution for injection	0,5mmol/ml, (10) plastic bottles 100ml	GE Healthcare AS-Oslo Plant, Nycoveien 1, NO-0485 Oslo	Norway	GE Healthcare AS, P.O. Box 4220 Nydalen, NO-0401 Oslo	Norway	PoM	20615/1 16.05.2023
12	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	19288/3 16.05.2023
13	Calcium gluconate-Darnitsa (stabilized)	calcium gluconate	solution for injection	100mg/ml; (10/2x5) ampoules 5ml in blister and (10) am- poules 5ml	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	PoM	17494/1 16.05.2023
14	Calcium gluconate-Darnitsa (stabilized)	calcium gluconate	solution for injection	100mg/ml; (10/2x5) ampoules 10ml in blister	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	PoM	17495/1 16.05.2023
15	Lysobact DUO	lysozyme (lysozyme hydrochloride), cetylpyridinium (cetylpyridinium chloride)	lozenges compressed	20mg+1,5mg; (20/2x10) In blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	17492/3 16.05.2023
16	Warfarin STADA	warfarin (warfarin sodium)	tablets	2,5mg; (50) and (100) in plastic container, (50/1x50/) and (100/1x100) in plastic container	Orifarm Manufacturing Poland Sp.z o.o., 12 Ksiestwa Lowickiego st., 99-420 Lyszkowice	Poland	STADA Arzneimittel AG, Stadas- trasse 2-18, 61118 Bad Vilbel	Germany	PoM	16936/3/1 16.05.2023
17	Xefocam	lornoxicam	powder lyophilized for solution for i/v and i/m injection	8mg; (5) glass vials	Takeda Austria GmbH, St. Peter Strasse 25, A-4020 Linz- secondary packager, quality control, batch releaser, Wasserburger Arzneimittelwerk GmbH, Herderstrasse 2, D-83512 Wasserburg, Germany- bulk manufacturer, primary packager	Austria	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	21045/1 16.05.2023

18	AmoxiClav-Denk 1000/125	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	powder for oral suspension	1000mg+125mg; (8) sachets 3g, (12) sachets 3g	PenCef Pharma GmbH, Breitenbachstrasse 13-14, 13509 Berlin- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Allphamed Pharbil Arzneimittel GmbH, Hildebrandstr. 10-12, 37081 Göttingen, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20172/2 16.05.2023
19	Diprosan	betamethasone (betamethasone dipropionate), betamethasone (betamethasone sodium phosphate)	suspension for injection	5mg/ml+2mg/ml; (5) ampoules 1ml	Schering-Plough Labo N.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	19021/4/1 16.05.2023
20	Hepathrombin H	heparin sodium, prednisolone (prednisolone acetate), polidocanol	ointment for rectal and external use	65IU/g+2,233mg/g+30mg/g; 20g aluminium tube	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	20516/1 16.05.2023
21	Hepathrombin H	heparin sodium, prednisolone (prednisolone acetate), polidocanol	suppositories rectal	120IU+1,675mg+30mg; (10/2x5) in blister	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	20515/1 16.05.2023
22	Herbion plantain syrup	liquid aqueous extract of the narrowleaf plantain leaves, liquid aqueous extract of the common mallow flower, ascorbic acid	syrup	1250mg/5ml+1250mg/5ml+65mg/5ml; 150ml glass bottle and measuring spoon	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- batch releaser, KRKA, tovarna zdravil, d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia- bulk manufacturer, packager, 1. KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto, Slovenia, 2. KRKA, tovarna zdravil, d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia- quality control (physicochemical), KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto, Slovenia- quality control (microbiological)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	20778/1 16.05.2023
23	Argosulfan	silver sulfathiazole	cream for external use	20mg/g; 15g aluminium tube, 40g 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	20710/1 16.05.2023

24	Plavix	clopidogrel (clopidogrel hydrosulfate)	tablets film- coated	75mg; (14/1x14) in blister, (28/2x14) in blister	Sanofi Winthrop Industrie, 1, rue de la Vierge, Ambares et Lagrave, 33565 Carbon Blanc cedex	France	Sanofi-Aventis Group, 54, rue La Boetie 75008 Paris	France	PoM	20848/2/1 16.05.2023
25	Levemir FlexPen	insulin detemir (recombinant)	solution for injection	100U/ml; (5) pre-filled pen 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	Novo Nordisk A/S, Novo Alle, DK- 2880 Bagsvaerd	Denmark	PoM	17819/4 16.05.2023
26	NovoMix 30 FlexPen	insulin aspart (recombinant)	suspension for injection	100U/ml; (5) pre-filled pen 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	Novo Nordisk A/S, Novo Alle, DK- 2880 Bagsvaerd	Denmark	PoM	17660/2 16.05.2023
27	Actrapid	insulin human (recombinant DNA)	solution for injection	100IU/ml; 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	21316/1 16.05.2023
28	Dimex	diphenhydramine (diphenhydramine hydrochloride), ammonium chloride	syrup	1.992mg/ml+19.92mg/ml; 125ml plastic bottle and mea- suring cup	Sopharma JSC, Vrabovo vlg. 5660, district of Lovetch	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	19426/1 16.05.2023
29	Bronchobos	carbocisteine	capsules	375mg; (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	19990/3 16.05.2023
30	Avastin	bevacizumab	concentrate for solution for infusion	25mg/ml; (1) glass vial 16ml	Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim- bulk manufac- turer, primary packager, quality control, batch releaser, F. Hoffmann-La Roche Ltd., Wurmisweg CH-4303 Kaiseraugst, Switzer- land- secondary packager	Germany	F. Hoffmann-La Roche Ltd., Gren- zacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	19095/2 16.05.2023
31	Avastin	bevacizumab	concentrate for solution for infusion	25mg/ml; (1) glass vial 4ml	Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim- bulk manufac- turer, primary packager, quality control, batch releaser, F. Hoffmann-La Roche Ltd., Wurmisweg CH-4303 Kaiseraugst, Switzer- land- secondary packager	Germany	F. Hoffmann-La Roche Ltd., Gren- zacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	19096/2 16.05.2023
32	Avastin	bevacizumab	concentrate for solution for infusion	25mg/ml; glass vial 4ml	F. Hoffmann-La Roche Ltd., Wurmisweg CH-4303 Kaiseraugst	Switzerland	F. Hoffmann-La Roche Ltd., Gren- zacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	20006/2 16.05.2023

33	Avastin	bevacizumab	concentrate for solution for infusion	25mg/ml; glass vial 16ml	F. Hoffmann-La Roche Ltd., Wurmisweg CH-4303 Kaiseraugst- secondary packager, batch releaser, Roche Diagnostics GmbH, Sandhofer strasse 116, 68305 Mannheim, Germany- bulk manufacturer, primary packager, quality control	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	20007/2 16.05.2023
34	Avastin	bevacizumab	concentrate for solution for infusion	25mg/ml; glass vial 16ml	F. Hoffmann-La Roche Ltd., Wurmisweg CH-4303 Kaiseraugst	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	20008/2 16.05.2023
35	Avastin	bevacizumab	concentrate for solution for infusion	25mg/ml; glass vial 4ml	F. Hoffmann-La Roche Ltd., Wurmisweg CH-4303 Kaiseraugst- secondary packager, batch releaser, Roche Diagnostics GmbH, Sandhofer strasse 116, 68305 Mannheim, Germany- bulk manufacturer, primary packager, quality control	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	20009/2 16.05.2023
36	Efferalgan	paracetamol	solution oral	30mg/ml; plastic bottle 90ml and measuring spoon	UPSA SAS, 304, avenue du Docteur Jean Bru, 47000 AGEN- bulk manufacturer, packager, batch releaser, UPSA SAS, 979, avenue des Pyrenees, 47520 Le Passage, France- quality control	France	UPSA SAS, 3, rue Joseph Monier- 92500 Rueil- Malmaison	France	OTC	19162/1 16.05.2023
37	Macmiror Complex	nifuratel, nystatin	capsules vaginal soft	500mg+200 000IU; (8/1x8) in blister	Doppel Farmaceutici S.r.l., Via Volturmo, 48-Quinto de` Stampi-20089 Rozzano (MI)- packager, quality control, batch releaser, Catalent Italy S.p.A., Via Nettunense Km. 20, 100-04011 Aprilia (LT), Italy- bulk manufacturer	Italy	Polichem S.r.l., Via Giuseppe Marcora, 11-20121 Milan	Italy	PoM	19786/2 16.05.2023
38	Macmiror Complex	nifuratel, nystatine	cream vaginal	10g/100g+4000000IU/100g; 30g aluminium tube and dosing syringe applicator	Doppel Farmaceutici S.r.l., Via Martiri delle Foibe, 1-29016 Cortemaggiore (PC)	Italy	Polichem S.r.l., Via Giuseppe Marcora, 11-20121 Milan	Italy	PoM	19816/2 16.05.2023
39	Macmiror	nifuratel	tablets coated	200mg; (20/2x10) in blister	Doppel Farmaceutici S.r.l., Via Volturmo, 48 Quinto de` Stampi- 20089 Rozzano (MI)	Italy	Polichem S.r.l., Via Giuseppe Marcora, 11- 20121 Milan	Italy	PoM	19640/1 16.05.2023

40	Clomentin	escitalopram (escitalopram oxalate)	tablets film-coated	10mg; (28/2x14) in blister	Delorbis Pharmaceuticals Ltd., 17 Athinon Street, Ergates Industrial Area, 2643 Ergates, Lefkosia- secondary packaging, batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, primary packaging, quality control	Cyprus	Delorbis Pharmaceuticals Ltd., 17 Athinon Street, Ergates Industrial Area, 2643 Ergates, P.O. Box 28629, 2081 Lefkosia	Cyprus	PoM	20640/1 16.05.2023
41	Clomentin	escitalopram (escitalopram oxalate)	tablets film-coated	20mg (28/2x14) in blister	Delorbis Pharmaceuticals Ltd., 17 Athinon Street, Ergates Industrial Area, 2643 Ergates, Lefkosia-secondary packager, batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia-bulk manufacturer, primary packager, quality control	Cyprus	Delorbis Pharmaceuticals Ltd., 17 Athinon Street, Ergates Industrial Area, 2643 Ergates, P.O. Box 28629, 2081 Lefkosia	Cyprus	PoM	18723/4 16.05.2023
42	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	17722/2/1 16.05.2023
43	Indometacin	indometacin	suppositories rectal	50mg; (10/2x5/)	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis.,MD-4829	Moldova	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis.,MD-4829	Moldova	PoM	17847/1 16.05.2023
44	Indometacin	indometacin	suppositories rectal	100mg; (6/1x6/)	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis.,MD-4829	Moldova	PoM	17848/1 16.05.2023
45	Metोजect	methotrexate (methotrexate disodium)	solution for s/c injection	7.5mg/0.15ml; pre-filled syringe 0,15ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel-secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany-bulk manufacturer, primary packager	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	18461/3 16.05.2023
46	Metोजect	methotrexate (methotrexate disodium)	solution for s/c injection	10mg/0.2ml; pre-filled syringe 0,2ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel-secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany-bulk manufacturer, primary packager	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	18462/3 16.05.2023
47	Metोजect	methotrexate (methotrexate disodium)	solution for s/c injection	12.5mg/0.25ml; pre-filled syringe 0,25ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel-secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany-bulk manufacturer, primary packager	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	18463/3 16.05.2023

48	Metoject	methotrexate (methotrexate disodium)	solution for s/c injection	15mg/0.3ml; pre-filled syringe 0,3ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel-secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany-bulk manufacturer, primary packager	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	18464/3 16.05.2023
49	Metoject	methotrexate (methotrexate disodium)	solution for s/c injection	17.5mg/0.35ml; pre-filled syringe 0,35ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel-secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany-bulk manufacturer, primary packager	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	18465/3 16.05.2023
50	Metoject	methotrexate (methotrexate disodium)	solution for s/c injection	20mg/0.4ml; pre-filled syringe 0,4ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel-secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany-bulk manufacturer, primary packager	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	18466/3 16.05.2023
51	Metoject	methotrexate (methotrexate disodium)	solution for s/c injection	22.5mg/0.45ml; pre-filled syringe 0,45ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel-secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany-bulk manufacturer, primary packager	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	18467/3 16.05.2023
52	Metoject	methotrexate (methotrexate disodium)	solution for s/c injection	25mg/0.5ml; pre-filled syringe 0,5ml in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel-secondary packager, batch releaser, Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany-bulk manufacturer, primary packager	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	PoM	18468/3 16.05.2023
53	Nalgesin	naproxen (naproxen sodium)	tablets film-coated	220mg (10/1x10) in blister, (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, KRKA 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	OTC	19477/1 16.05.2023

54	Norditropin Nordiflex	somatropin	solution for s/c injection	6,7mg/ml; pre-filled pen 1,5ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd- batch releaser, Novo Nordisk A/S, Hagedornsvej 1, DK-2820 Gentofte, Denmark- bulk manufacturer, primary packager, quality control, Novo Nordisk A/S Kirke Vaerloesevej 30, Vaerloese, 3500, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	20413/3 16.05.2023
55	Clonazepam	clonazepam	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	17748/1 16.05.2023
56	Diclac gel 5%	diclofenac (diclofenac sodium)	gel for external use	50mg/g; 50g aluminium tube	Salutas Pharma GmbH, Lange Goehren 3, 39171 Osterweddingen- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben, Germany- quality control (microbiological)	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	OTC	20114/2 16.05.2023
57	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	21205/1 16.05.2023
58	Aripirazol	aripirazole	tablets	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	18388/4/1 16.05.2023
59	Aripirazol	aripirazole	tablets	15mg; (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	18389/4/1 16.05.2023
60	Levocom	levodopa, carbidopa	tablets	250mg+25mg; (30/3x10) in blister, (100/10x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	18602/4/1 16.05.2023
61	Metronidazole	metronidazole	suppositories vaginal	500mg; (10/2x5)	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829	Moldova	PoM	17789/1 16.05.2023
62	Liniment Vishnevsky	birch tar, xeroform	liniment	30mg/g+30mg/g; 25g aluminium tube	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	OTC	17481/2 16.05.2023

63	Erythromycin	erythromycin (erythromycin ethylsuccinate)	tablets	400mg; (10/1x10) 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	17662/1 16.05.2023
64	Exoderil	naftifine (naftifine hydrochloride)	solution for external use	10mg/ml; glass vial 10ml, glass vial 20ml	Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl- batch releaser, Globopharm Pharmazeutische Produktions-und Handels GmbH, Breitenfurter Strasse 251, 1230 Wien, Austria- bulk manufacturer, packager, quality control	Austria	Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl	Austria	OTC	21257/1 16.05.2023
65	Hexoral	hexetidine	pressurised inhalation solution	2mg/ml; 40ml aluminium container with pump dispenser	Delpharm Orleans, 5 avenue de Concyr, 45071 Orleans, Cedex 2	France	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	OTC	17209/3/1 16.05.2023
66	Phlogenzym	bromelain, trypsin, rutin	tablets gastro-resistant	450FIP-U+1440FIP-U(24mck-at)+100mg; (40/2x20) in blister, (100/5x20) in blister, (200/10x20) in blister, (800) in plastic container	Mucos Emulsions GmbH, Mirastrasse 17, D-13509 Berlin	Germany	Mucos Pharma GmbH & Co. KG, Mirastrasse 17, D-13509 Berlin	Germany	OTC	18978/5/1 16.05.2023
67	Rinza	paracetamol, caffeine, phenylephrine (phenylephrine hydrochloride), chlorphenamine (chlorphenamine maleate)	tablets	30mg+500mg+10mg+2mg; 4(1x4) blister, 10(1x10) blisters, 20(2x10) blisters	Unique Pharmaceutical Laboratories (a division of J. B. Chemicals & Pharmaceuticals Ltd.), Survey No. 101/2 and 102/1, Daman Industrial Estate, Kadaiya, Daman-396 210	India	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	OTC	16884/2 16.05.2023
68	Biprol	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (30/3x10) in blister	Hemofarm LLC, 249032, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	17885/3 16.05.2023
69	Biprol	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg; (30/3x10) in blister	Hemofarm LLC, 249032, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	17886/3 16.05.2023
70	Genferon	interferon alfa-2b, benzocaine, taurine	suppositories rectal and vaginal	500000IU+55mg+10mg; (10/2x5)	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515	Russia	PoM	17542/3/1 16.05.2023

71	Genferon	interferon alfa-2b, benzocaine, taurine	suppositories vaginal and rectal	1000000IU+55mg+10mg; (10/2x5/)	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, the Settle- ment of Strelna, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515	Russia	PoM	17541/3/1 16.05.2023
72	Herticad	trastuzumab	powder lyophilized for concentrate for solution for infusion	150mg; (1) glass vial	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Re- gion, 143422- quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422, Russia- bulk manufacturer, packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, the Settle- ment of Strelna, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515	Russia	PoM	17890/3/2 16.05.2023
73	Herticad	trastuzumab	powder lyophilized for concentrate for solution for infusion	440mg; (1) glass vial and (1) glass vial with 20ml solvent	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk, Moscow Re- gion, 143422- quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk, Moscow Region, 143422, Russia- bulk manufacturer, package	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, the Settle- ment of Strelna, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515	Russia	PoM	17891/3/2 16.05.2023
74	Lansoptol	lansoprazole	capsules	30mg; (14/2x7) 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	17411/3 16.05.2023

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 05-1/23 on May 16, 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	Metadon Alkaloid	methadone (methadone hydrochloride)	solution oral	10mg/ml; 100ml glass bottle and graduated pipette, 1000ml glass bottle	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	000653 16.05.2023