

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 06-2/22 on June 29, 2022

President _____ E. Amroyan

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 50 Berlin-Chemie	levothyroxine sodium	tablets	50mcg; (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	20790 29.06.2022

2	L-Thyroxin 75 Berlin-Chemie	levothyroxine sodium	tablets	75mcg; (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	20791 29.06.2022
3	L-Thyroxin 100 Berlin-Chemie	levothyroxine sodium	tablets	100mcg; (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	20792 29.06.2022

4	L-Thyroxin 125 Berlin-Chemie	levothyroxine sodium	tablets	125mcg; (100/4x25/) in blister	<p>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)</p>	Germany	Berlin-Chemie A.G.,Glienicker Weg 125, 12489 Berlin	Germany	PoM	20793 29.06.2022
5	L-Thyroxin 150 Berlin-Chemie	levothyroxine sodium	tablets	150mcg; (100/4x25/) in blister	<p>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)</p>	Germany	Berlin-Chemie A.G.,Glienicker Weg 125, 12489 Berlin	Germany	PoM	20794 29.06.2022

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 06-2/22 on June 29, 2022

President _____ E. Amroyan

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	Diclofenac	diclofenac (diclofenac sodium)	gel for external use	10mg/g; 40g 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- bulk manufacturer, packager, quality control	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradskii put bb	Serbia	OTC	20775 29.06.2022
2	Clotrimazol	clotrimazole	spray	10mg/ml; 20g plastic container with pump dispenser	Rompharm Company SRL, Eroilor Str., No. 1A, Otopeni city, Ilfov county, 075100, buildings Rompharm 1 and Rompharm 2	Romania	Rompharm Company SRL, Eroilor Str., No. 1A, Otopeni city, Ilfov county, 075100	Romania	OTC	20776 29.06.2022
3	Troxevasin 2%	troxerutin	gel for external use	20mg/g; 40g aluminium tube, 40g plastic tube	Balkanpharma-Troyan AD, Krayrechna Str. N1, 5600, Troyan	Bulgaria	Balkanpharma-Troyan AD, (ACTAVIS GROUP) Krayrechna Str. N1, 5600, Troyan	Bulgaria	OTC	20777 29.06.2022

4	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 29.06.2022
5	Lucentis	ranibizumab	solution for injection	10mg/ml; glass vial 0.23ml and fitler needle	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20779 29.06.2022
6	Dimedrol	diphenhydramine (diphenhydramine hydrochloride)	solution for i/m and i/v injection	10mg/ml; (10) ampoules 1ml label banderol, (10) ampoules 1ml dividella, (10) ampoules 1ml CAMA	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	PoM	20780 29.06.2022

7	RHINO-TON	xylometazoline (xylometazoline hydrochloride)	spray nasal	0.5mg/ml; 10ml plastic bottle with pump dispenser	Pharmtechnology LLC, Korzhenevskogo str., 22, 220024, Minsk	Belarus	Giga Farm LLC, Gogunca str.3/5, Gyumri	Republic of Armenia	OTC	20781 29.06.2022
8	RHINO-TON	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; 10ml plastic bottle with pump dispenser	Pharmtechnology LLC, Korzhenevskogo str., 22, 220024, Minsk	Belarus	Giga Farm LLC, Gogunca str.3/5, Gyumri	Republic of Armenia	OTC	20782 29.06.2022
9	Amelotex	meloxicam	solution for i/m injection	10mg/ml; (3) ampoules 1.5ml, (5) ampoules 1.5ml	SotexPharmFirm" 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	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	PoM	20783 29.06.2022
10	Heparin ointment	heparin (heparin sodium), benzocaine, benzyl nicotinate	ointment for external use	100IU/g+40mg/g+0,8mg /g; 25g aluminium or plastic tube	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	20784 29.06.2022
11	Xylo-Nazal	xylometazoline (xylometazoline hydrochloride)	drops nasal	1mg/ml; 10ml 10ml plastic bottle-dropper	Rompharm Company SRL, Eroilor Str., No. 1A, Otopeni city, Ilfov county, 075100, buildings Rompharm 1 and Rompharm 2	Romania	Rompharm Company SRL, Eroilor Str., No. 1A, Otopeni city, Ilfov county, 075100	Romania	OTC	20785 29.06.2022

12	Panangin Forte	potassium asparaginate (potassium asparaginate hemihydrate), magnesium asparaginate (magnesium asparaginate tetrahydrate)	tablets film-coated	316mg+280mg; (30/2x15/) in blister, (60/4x15/) in blister, (90/6x15/) in blister	Gedeon Richter Plc., Gyomroi ut 19-21, 1103, Budapest- bulk manufacturer, packager, batch releaser, Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825, Poland- quality control	Hungary	Gedeon Richter Plc, Gyomroi ut 19-21, 1103 Budapest	Hungary	OTC	20786 29.06.2022
13	Miropriston	mifepristone	tablets	200mg; (3/1x3/) in blister	Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 107- bulk manufacturer, packager, Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 3a/3, Russia- quality control (physical/chemical), batch releaser, Test center «Farmoborona» LTD., 46A, Gagarin st., Korolyov, Moscow Region, 141074, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	20787 29.06.2022

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 06-2/22 on June 29, 2022

President _____ E. Amroyan

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	Influvac	A/Victoria/2570/2019 (H1N1) pdm09-like strain (A/Victoria/2570/2019, IVR-215), A/Cambodia/e0826360/2020 (H3N2)-like strain (A/Cambodia/e0826360/2020, IVR-224), B/Washington/02/2019-like strain(B/Washington/02/2019, wild type)	suspension for injection	0.5ml; 15mcg haemagglutinin/dose+1 5mcg haemagglutinin/dose+1 5mcg haemagglutinin/dose; pre-filled syringe 0,5ml	ABBOTT Biologicals B.V. Veerweg 12, 8121 AA Olst-packer, batch releaser, Abbott Biologicals B.V., C.J. van Houtenlaan 36, WEESP, 1381CP, the Netherlands-bulk manufacturer, quality control for	the Netherlands	ABBOTT Biologicals B.V. C.J. van Houtenlaan 36, 1381 CP Weesp	the Netherlands	PoM	18823/2/1 29.06.2022
2	Aevit	retinol palmitate (vitamin A), alfa-tocopherol acetate (vitamin E)	capsules	55,036mg (100000IU)+100mg; (15/1x15/) in blister	Minskintercaps U.V., 26/3, Inzhenernaya str., 220075, Minsk for Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk, Belarus	Belarus	Minskintercaps U.V., 26/3, Inzhenernaya str., 220075, Minsk for Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk, Belarus	Belarus	OTC	17184/1/1 29.06.2022

3	Mirtazapine Canon	mirtazapine	tablets film-coated	30mg; (30/3x10/) in blister, (30/1x30/) in blister	CJSC Canonpharma production, 105B bldg., 11, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, 141100- quality control, batch releaser, CJSC Canonpharma production, 105, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, 141100, Russia- bulk manufacturer, primary and secondary packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	PoM	20148/1/1 29.06.2022
4	Mirtazapine Canon	mirtazapine	tablets film-coated	45mg; (30/3x10/) in blister	CJSC Canonpharma production, 105B bldg., 11, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, 141100- quality control, batch releaser, CJSC Canonpharma production, 105, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, 141100, Russia- bulk manufacturer, primary and secondary packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	PoM	20149/1/1 29.06.2022

5	Paracetamol	paracetamol	tablets	500mg; (10/1x10/) in blister, (20/2x10/) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	18975/1/1 29.06.2022
6	Januvia	sitagliptin (sitagliptin phosphate hydrate)	tablets film-coated	100mg; (28/2x14/) in blister	Organon Pharma (UK) Limited, Shotton Lane, Cramlington, Northumberland NE23 3JU	UK	Merck Sharp & Dohme IDEA GmbH, Tribschenstrasse 60, 6005 Luzern	Switzerland	PoM	18855/3/3 29.06.2022
7	ACC Extra	acetylcysteine	tablets effervescent	600mg; (10/5x2/) in aluminium laminated sachets, (20/10x2/) in aluminium laminated sachets	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben-batch releaser, Hermes Pharma GmbH, Hans-Urmiler Ring 52, Wolftratshausen, Germany-bulk manufacturer, packager	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	OTC	18240/5/1 29.06.2022
8	Plavix	clopidogrel (clopidogrel hydrosulfate)	tablets film-coated	75mg; (14/1x14/) in blister, (28/1x28/) 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	16916/2/1 29.06.2022

9	Pentalgin	paracetamol, naproxen, caffeine, drotaverine (drotaverine hydrochloride), pheniramine (pheniramine maleate)	tablets film-coated	325mg+100mg+50mg+40mg+10mg; (12/1x12/) and (24/2x12/) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTCPharm JSC, Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	17053/1/1 29.06.2022
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LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 06-2/22 on June 29, 2022

President _____ E. Amroyan

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	Tyrosur	tyrothricin	gel for topical use	1mg/g; 5g aluminium tube	Engelhard Arzneimittel GmbH& Co. KG, Herzbergstrasse 3, 61138 Niederdorfelden	Germany	Engelhard Arzneimittel GmbH& Co. KG, Herzbergstrasse 3, 61138 Niederdorfelden	Germany	OTC	16046/3 29.06.2022
2	Myramistin	benzyltrimethyl (3-(myristoilamine) propyl) ammonium chloride monohydrate	solution for topical application	0,1mg/ml; 50ml plastic container with urological applicator, 50ml plastic container with urological applicator and pump dispenser, 50ml plastic container with urological applicator and gynecological device, 150ml plastic container with pump dispenser	INFAMED K LLC, ul. Kommunalnaya., build.12, g. Bagrationovsk, Bagrationovsky dist., Kaliningrad region, 238420	Russia	INFAMED LLC., Promzona ter., bulid. 473, g.Vidnoe, Leninsky dist., Moscow region, 142704	Russia	OTC	17466/2/1 29.06.2022

3	Diovan	valsartan	tablets film-coated	80mg; (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	18658/8/1 29.06.2022
4	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	17819/2 29.06.2022
5	Levemir Penfill	insulin detemir (recombinant)	solution for injection	100U/ml; (5) cartridges 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	17820/2 29.06.2022
6	Ipigrix	ipidacrine (ipidacrine hydrochloride)	tablets	20mg; (50/2x25/) in blister, (100/4x25/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia			PoM	17091/2/1 29.06.2022
7	Amelotex	meloxicam	solution for i/m injection	10mg/ml; (3) and (5) ampoules 1.5ml	SotexPharmFirm" 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	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	PoM	16803/2/1 29.06.2022

8	Wobenzym	pancreatin, trypsin, chymotrypsin, bromelain, papain, amylase, lipase, rutoside trihydrate	tablets gastro-resistant	300 prot.UA+360FIP-U+300FIP-U+225FIP-U+90FIP-U+50FIP-U+34FIP-U+50mg (40/2x20/) and (200/10x20/) in blister, (800) in plastic bottle	Mucos Emulsionsgesellschaft mbH, Miraustrasse 17, D-13509 Berlin	Germany	Mucos Pharma GmbH & Co. KG, Miraustrasse 17, D-13509 Berlin	Germany	OTC	17623/4 29.06.2022
9	Xylo-Nazal	xylometazoline (xylometazoline hydrochloride)	drops nasal	1mg/ml; 10ml plastic bottle	Rompharm Company SRL, Eroilor Str., No. 1A, Otopeni city, Ilfov county, 075100, buildings Rompharm 1 and Rompharm 2	Romania	Rompharm Company SRL, Eroilor Str., No. 1A, Otopeni city, Ilfov county, 075100	Romania	OTC	16712/2 29.06.2022
10	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	19791/2/1 29.06.2022
11	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	19816/1 29.06.2022

12	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	19786/1 29.06.2022
13	Hartil Amlo	ramipril, amlodipine (amlodipine besilate)	capsules	5mg+5mg; (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (90/9x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	20251/2 29.06.2022
14	Hartil Amlo	ramipril, amlodipine (amlodipine besilate)	capsules	10mg+10mg; (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (90/9x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	20254/2 29.06.2022
15	Dibazol-Darnitsa	bendazol (bendazol hydrochloride)	solution for injection	10mg/ml; (10/2x5/) ampoules 1ml, in blister	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	PoM	17343/1 29.06.2022

16	Floxaval	levofloxacin (levofloxacin hemihydrate)	tablets film-coated	500mg (10/1x10/) in blister	Delorbis Pharmaceuticals Ltd, 17 Athinon str.,Ergates Industrial Area, 2643 Ergates, Lefkosia	Cyprus	Delorbis Pharmaceuticals Ltd, 17 Athinon str.,Ergates Industrial Area,2643 Ergates, P.O. Box 28629,2081 Lefkosia	Cyprus	PoM	19062/1 29.06.2022
17	Zindolin	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	500mg (10/1x10/) in blister	Remedica Ltd, Aharnon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	Remedica Ltd, Aharnon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	PoM	18476/3 29.06.2022
18	Enterofuryl	nifuroxazide	suspension oral	200mg/5ml; 90ml suspension in 125ml glass bottle and plastic measuring spoon (2,5ml/5ml)	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	PoM	20382/2 29.06.2022
19	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	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	16497/3 29.06.2022

20	Lantus	insulin glargine	solution for s/c injection	100U/ml; (5) cartridges 3ml, in SoloStar pen-syringes	Sanofi-Aventis Deutschland GmbH, Industriepark Hoechst, Bruningstrasse 50, D-65926, Frankfurt am Main	Germany	Sanofi-Aventis Deutschland GmbH, Industriepark Hoechst, Bruningstrasse 50, D-65926, Frankfurt am Main	Germany	PoM	18144/3 29.06.2022
21	Codelac Neo	butamirate (butamirate citrate)	syrup	7.5mg/5ml; 100ml glass bottle and measuring spoon	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk city, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, room II, flr.12, h.10, off. 29, Moscow 123112	Russia	OTC	16209/1 29.06.2022
22	Codelac Neo	butamirate (butamirate citrate)	drops oral	5mg/ml; 20ml glass vial-dropper	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk city, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, room II, flr.12, h.10, off. 29, Moscow 123112	Russia	OTC	16210/1 29.06.2022
23	BoriVit	thiamine (thiamine hydrochloride), pyridoxine (pyridoxine hydrochloride), cyanocobalamin, lidocaine (lidocaine hydrochloride)	solution for i/m injection	100mg/2ml+100mg/2ml+1mg/2ml+20mg/2ml; (10) ampoules 2ml	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	PoM	16978/2/1 29.06.2022

24	Spasmalgon 500mg/2mg/0,02mg/ml solution for injection	metamizole (metamizole sodium), pitofenone (pitofenone hydrochloride), fempiverinium bromide	solution for i/m injection	500mg/ml+2mg/ml+0,02mg/ml; (10/1x10/) ampoules 2ml in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	20177/1 29.06.2022
25	Spasmalgon 500mg/2mg/0,02mg/ml solution for injection	metamizole (metamizole sodium), pitofenone (pitofenone hydrochloride), fempiverinium bromide	solution for i/m injection	500mg/ml+2mg/ml+0,02mg/ml; (5/1x5/) ampoules 5ml in blister, (10/1x10/) ampoules 5ml in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	20178/1 29.06.2022
26	Celex	celecoxib	capsules	200mg; (10/1x10/) in blister	A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan- batch releaser, packager, Zim Laboratories Ltd., B-21/22, MIDC Area, Kalmeshwar-441 501, Dist. Nagpur (M.S.), India- bulk manufacturer	Republic of Armenia	A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan	Republic of Armenia	PoM	16642/1/1 29.06.2022
27	Diclofenac	diclofenac (diclofenac sodium)	gel for external use	10mg/g; 40g 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	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradskii put bb	Serbia	OTC	16278/2 29.06.2022

28	Actilyse	alteplase	powder lyophilized for solution for infusion with solvent	50mg; glass vial and glass vial with solvent 50ml	Boehringer Ingelheim Pharma GmbH & Co. KG, Birkendorfer str. 65, 88397 Biberach a.d.R.	Germany	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein	Germany	PoM	17517/2 29.06.2022
29	Indapafon	indapamide	tablets coated	2,5mg; (30/3x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	PoM	17320/2 29.06.2022
30	Recreol	dexpanthenol	cream	50mg/g; 30g and 50g aluminium tube	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	OTC	17713/3 29.06.2022
31	Losar-Denk 50	losartan (losartan potassium)	tablets film-coated	50mg; (28/2x14/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	16140/3 29.06.2022

32	Losar-Denk 100	losartan (losartan potassium)	tablets film-coated	100mg; (28/2x14/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	16139/3 29.06.2022
33	Gemcitabin Ebewe	gemcitabine (gemcitabine hydrochloride)	concentrate for solution for i/v infusion	10mg/ml; glass vial 20ml	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	20430/1 29.06.2022
34	Gemcitabin Ebewe	gemcitabine (gemcitabine hydrochloride)	concentrate for solution for i/v infusion	10mg/ml; glass vial 100ml	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	20431/1 29.06.2022
35	Clotrimazol	clotrimazole	spray	10mg/ml; 20g plastic container with pump dispenser	Rompharm Company SRL, Eroilor Str., No. 1A, Otopeni city, Ilfov county, 075100, buildings Rompharm 1 and Rompharm 2	Romania	Rompharm Company SRL, Eroilor Str., No. 1A, Otopeni city, Ilfov county, 075100	Romania	OTC	16780/2/1 29.06.2022

36	Kisqali	ribociclib(ribociclib succinate)	tablets film-coated	200mg; (21/1x21/) in blister, (63/3x21/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr -batch releaser, packager, Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd., 10 Tuas Bay Lane, 637461 Singapore, Singapore-bulk manufacturer	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18535/5/1 29.06.2022
37	KISQALI	ribociclib (ribociclib succinate)	tablets film-coated	200mg; (21/1x21/) in blister, (63/3x21/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein AG, 4332- packager, batch releaser, Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd., 10 Tuas Bay Lane, 637461 Singapore, Singapore- bulk manufacturer, quality control	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20278/1 29.06.2022
38	Neurexan	Avena sativa D2, Coffea Arabica D12, Passiflora incarnataD2, Zincum isovalerianicum D4	tablets	0.6mg+0.6mg+0.6mg+0.6mg; (25) plastic container, (50) plastic container	Biologische Heilmittel Heel GmbH, Dr.-Reckeweg-Strasse 2-4, 76532 Baden-Baden	Germany	Biologische Heilmittel Heel GmbH, Dr.-Reckeweg-Strasse 2-4, 76532 Baden-Baden	Germany	OTC	18289/1 29.06.2022

39	Skopryl plus	lisinopril (lisinopril dihydrate), hydrochlorothiazide	tablets	20mg+12,5mg; (20/2x10/) and (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	17412/2/1 29.06.2022
40	Miropriston	mifepristone	tablets	200mg; (3/1x3/) in blister	Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 107- bulk manufacturer, packager, Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 3a/3, Russia- quality control (physical/chemical), batch releaser, Test center «Farmoborona» LTD., 46A, Gagarin st., Korolyov, Moscow Region, 141074, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	16423/2 29.06.2022