

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 08-1/22 on August 15, 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	Otofa	rifamycin (rifamycin sodium)	drops ear	26mg (20000IU)/ml; 10ml glass bottle with dropper	Pharmaster, Zone Industrielle de Krafft, 67150 Erstein- bulk manufacturer, packager, batch releaser, QUALI CONTROLE, 29 rue Paul Vaillant Couturier, 60110 MERU, France- quality control (physicochemical), CONFARMA FRANCE-HOMBOURG, Zone Industrielle, rue du Canal d` Alsace, 68490 HOMBOURG, France	France	Laboratoires Bouchara-Recordati, Immeuble le Wilson, 70 avenue du General de Gaulle, 92800 Puteaux	France	PoM	20832 15.08.2022
2	Folic Acid	folic acid	tablets	5mg; (30/3x10/) in blister	Akriti Pharmaceuticals Pvt. Ltd., Plot No. D-10, D-11, M.I.D.C. Indl. Estate, Nira Road, Jejuri, Tal. Purandar (Saswad), Dist. Pune-412 303, Maharashtra	India	Akriti Pharmaceuticals Pvt. Ltd., Office N205, Thane mint, Indiabulls, Behind Hiranandani Meadows, Near Hyde Park, off. Gladys Alvaris Road, Thane (W), 400 610	India	PoM	20833 15.08.2022

3	Benzilor	chlorhexidine dihydrochloride, benzocaine	compressed lozenges with orange flavour	5mg+5mg; (20/2x10/) In blister	Laboratorios Alcala Farma, S.L., Avenida de Madrid, 82, Alcala de Henares 28802-Madrid	Spain	GM Pharmaceuticals Ltd, Phonicchala 65, Tbilisi	Georgia	OTC	20834 15.08.2022
4	Dolgit	ibuprofen	cream for external use	5g/100g; 20g aluminium tube, 50g aluminium tube, 100g aluminium tube	Dolorgiet GmbH & Co.KG, Otto-von-Guericke-Strasse 1 Sankt Augustin- bulk manufacturer, packager, batch releaser, Dolorgiet GmbH & Co.KG, Otto-von-Guericke-Strasse 1 Sankt Augustin, Germany, 2.GBA Pharma GmbH, Anna-Sigmund-Strasse 82061 Neuried, Germany-quality control (physicochemical), BAV INSTITUT fur Hygiene und Qualitatssicherung GmbH ,Hanns-Martin-Schleyer-Str. 25, D-77656 Offenburg, Germany-quality control (microbiological)	Germany	Dolorgiet GmbH & Co.KG, Otto-von-Guericke Str. 1 Sankt Augustin	Germany	PoM	20835 15.08.2022

5	Dolgit	ibuprofen	gel for external use	5g/100g; 20g aluminium tube, 50g aluminium tube, 100g aluminium tube	Dolorgiet GmbH & Co.KG, Otto-von-Guericke-Strasse 1 Sankt Augustin- bulk manufacturer, packager, batch releaser, 1. Dolorgiet GmbH & Co.KG, Otto-von-Guericke-Strasse 1 Sankt Augustin, Germany, 2.GBA Pharma GmbH, Anna-Sigmund-Strasse 82061 Neuried, Germany-quality control (physicochemical), BAV INSTITUT fur Hygiene und Qualitätssicherung GmbH ,Hanns-Martin-Schleyer-Str. 25, D-77656 Offenburg, Germany-quality control (microbiological)	Germany	Dolorgiet GmbH & Co.KG, Otto-von-Guericke Str. 1 Sankt Augustin	Germany	PoM	20836 15.08.2022
6	Sandostatin	octreotide (octreotide acetate)	solution for injection	0,05mg/ml; (5) ampoules 1ml	Delpharm Dijon, 6, Boulevard de l'Europe 21800	France	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20837 15.08.2022
7	Sandostatin	octreotide (octreotide acetate)	solution for injection	0,1mg/ml; (5) ampoules 1ml	Delpharm Dijon, 6, Boulevard de l'Europe 21800	France	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20838 15.08.2022
8	Amoksiklav 2x625mg	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	500mg+125mg; 10(2x5) in blister, 15(3x5) in blister	Sandoz GmbH, Biochemiestrasse 10, A-6250, Kundl	Austria	Lek Pharmaceuticals d.d. Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	20839 15.08.2022

9	Amoksiklav 625mg	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	500mg+125mg; 10(2x5) in blister, 15(3x5) in blister	Sandoz GmbH, Biochemiestrasse 10, A-6250, Kundl	Austria	Lek Pharmaceuticals d.d. Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	20840 15.08.2022
10	Amoksiklav 2x1000mg	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	875mg+125mg; 10(2x5) in blister, 14(2x7) in blisters	Sandoz GmbH, Biochemiestrasse 10, A-6250, Kundl	Austria	Lek Pharmaceuticals d.d. Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	20841 15.08.2022

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 08-1/22 on August 15, 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	Enalapril	enalapril (enalapril maleate)	tablets	5mg; (20/2x10/) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway-bulk manufacturer, packager, quality control (physicochemical), batch releaser, Farmoborona Test Center, Ltd., 141074, Korolyov, Moscow Region, Gagarin St., 46A, Russia-quality control (microbiological)	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	PoM	20842 15.08.2022
2	Enalapril	enalapril (enalapril maleate)	tablets	10mg; (20/2x10/) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway-bulk manufacturer, packager, quality control (physicochemical), batch releaser, Farmoborona Test Center, Ltd., 141074, Korolyov, Moscow Region, Gagarin St., 46A, Russia-quality control (microbiological)	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	PoM	20843 15.08.2022

3	Enalapril	enalapril (enalapril maleate)	tablets	20mg; (20/2x10/) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway-bulk manufacturer, packager, quality control (physicochemical), batch releaser, Farmoborona Test Center, Ltd., 141074, Korolyov, Moscow Region, Gagarin St., 46A, Russia-quality control (microbiological)	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	PoM	20844 15.08.2022
4	Losar-Denk 50	losartan (losartan potassium)	tablets film-coated	50mg; (28/2x14/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, Tittmoning, 84529, Bayern-bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany-quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20845 15.08.2022

5	Losar-Denk 100	losartan (losartan potassium)	tablets film-coated	100mg; (28/2x14/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, Tittmoning, 84529, Bayern- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20846 15.08.2022
6	Octolipen	thioctic acid (alfa-lipoic acid)	concentrate for solution for infusion	30mg/ml; (10/2x5/) ampoules 10ml	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	PoM	20847 15.08.2022
7	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	20848 15.08.2022
8	Emsibel	methylethylpyridinol hydrochloride	solution for i/v and i/m injection	30mg/ml; (5/1x5/) ampoules 5ml, (10/2x5/) ampoules 5ml	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30- quality control, batch releaser, Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30, N2, Belarus- bulk manufacturer, packager	Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	PoM	20849 15.08.2022

9	Pneumovax 23	pneumococcal polysaccharide vaccine	solution for injection	25mcg/0,5ml; 0,5ml glass vial	Merck Sharp & Dohme B.V. Waarderweg 39,2031 BN Haarlem- secondary packager, batch releaser, Merck Sharp & Dohme Corp., Sumneytown Pike P.O. Box West Point, Pennsylvania 19486-0004, USA- bulk manufacturer, primary packager	the Netherlands	Merck Sharp & Dohme IDEA GmbH, Tribschenstrasse 60, 6005 Luzern	Switzerland	PoM	20850 15.08.2022
10	Klerimed	clarithromycin	tablets film-coated	250mg; (14/2x7/) in blister	Medochemie Ltd (Factory AZ), 2 Michael Erakleous street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupolos street, 3011 Limassol	Cyprus	PoM	20851 15.08.2022
11	Klerimed	clarithromycin	tablets film-coated	500mg; (14/2x7/) in blister	Medochemie Ltd (Factory AZ), 2 Michael Erakleous street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupolos street, 3011 Limassol	Cyprus	PoM	20852 15.08.2022

12	Topiramate Canon	topiramate	tablets film-coated	25mg; (28/4x7/) 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, packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	PoM	20853 15.08.2022
13	Topiramate Canon	topiramate	tablets film-coated	100mg; (28/4x7/) 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, packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	PoM	20854 15.08.2022

14	Doloforte Denk	tramadol (tramadol hydrochloride), paracetamol	tablets film-coated	37,5mg+325mg; (20/2x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20855 15.08.2022
15	Regulon	desogestrel, ethinylestradiol	tablets coated	0,15mg+0,03mg; (21/1x21/) in blister, (63/3x21/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	20856 15.08.2022

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 08-1/22 on August 15, 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	GONAL-f	follitropin alfa	solution for s/c injection	300IU(22mcg)/0,5ml; pre-filled syringe 0,5ml and (8) needles	Merck Serono S.p.A., Via delle Magnolie 15, 70026 Modugno (BA)	Italy	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	20173/1/1 15.08.2022
2	GONAL-f	follitropin alfa	solution for s/c injection	450IU(33mcg)/0,75ml; pre-filled pen-syringe 0,75ml and (12) needles	Merck Serono S.p.A., Via delle Magnolie 15, 70026 Modugno (BA)	Italy	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	20174/1/1 15.08.2022
3	GONAL-f	follitropin alfa	solution for s/c injection	900IU(66mcg)/1,5ml; (1) pre-filled pen-syringe 1,5ml and (20) needles	Merck Serono S.p.A., Via delle Magnolie 15, 70026 Modugno (BA)	Italy	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	20175/1/1 15.08.2022

4	Concor COR	bisoprolol (bisoprolol fumarate)	tablets film-coated	2,5mg; (30/1x30/) 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	18410/1/1 15.08.2022
5	Bridion	sugammadex (sugammadex sodium)	solution for i/v injection	100mg/ml; (10) glass vials 2ml	N.V. Organon, Kloosterstraat 6, 5349 AB Oss- secondary packager, quality control, batch releaser, Patheon Manufacturing Services LLC, 5900 Martin Luther King Jr. Higway, Greenville, North Carolina 27834, USA- bulk manufacturer, primary packager	the Netherlands	Merck Sharp & Dohme IDEA GmbH, Tribschenstrasse 60, 6005 Luzern	Switzerland	PoM	19993/2/1 15.08.2022
6	Bridion	sugammadex (sugammadex sodium)	solution for i/v injection	100mg/ml; (10) glass vial 2ml	N.V. Organon, Kloosterstraat 6, 5349 AB Oss- batch releaser, secondary packager, Patheon Manufacturing Services LLC, 5900 Martin Luther King Jr. Higway, Greenville, North Carolina 27834, USA- bulk manufacturer, primary packager	the Netherlands	Merck Sharp & Dohme IDEA GmbH, Tribschenstrasse 60, 6005 Luzern	Switzerland	PoM	17793/4/2 15.08.2022

7	Maalox	aluminium hydroxide, magnesium hydroxide	suspension oral	525mg/15ml+600mg/15 ml; (30) sachets 15ml	Pharmatis, Zone d'activites Est No.1, BP 60190 Estress Saint Denis	France	Opella Healthcare France SAS, 82 avenue Raspail ,94250 Gentilly	France	OTC	20130/1/1 15.08.2022
8	Maalox	aluminium hydroxide, magnesium hydroxide	tablets chewable	400mg+400mg; (40/4x10/) in blister	Sanofi S.R.L., Strada Statale N17 km 22, 67019 Scoppito	Italy	Opella Healthcare France SAS, 82 avenue Raspail ,94250 Gentilly	France	OTC	20192/1/1 15.08.2022
9	Genferon light	interferon alfa-2b, taurine	suppositories rectal	125000IU+5mg; (10/2x5/) Alu / Alu in strip, (10/2x15/) PVC / PVC in strip	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	20309/1/1 15.08.2022
10	Genferon light	interferon alfa-2b, taurine	suppositories vaginal and rectal	250000IU+5mg; (10/2x5/) Alu / Alu in strip, (10/2x15/) PVC / PVC in strip	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	20310/1/1 15.08.2022

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of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 08-1/22 on August 15, 2022

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1	Propofol Kabi	propofol	emulsion for injection/infusion	10mg/ml; (1) glass vial 50ml in blister, (10) glass vial 50ml in blister	Fresenius Kabi Austria GmbH, Hafnerstrasse 36, Graz, 8055-bulk manufacturer, primary packager, quality control, batch releaser, Fresenius Kabi Austria GmbH, Estermannstrasse 17, Linz, 4020, Austria-secondary packager	Austria	Fresenius Kabi Deutschland GmbH, Else-Kroener-Strasse,1,61352 Bad Homburg	Germany	PoM	18776/3 15.08.2022
2	Rovastat Duo	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets	20mg+10mg; (30/3x10/) in blister, (30/2x15/) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego st., 95-200 Pabianice, Lodzkie	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza st., 05-152 Czosnow, Mazowieckie	Poland	PoM	20523/1 15.08.2022

3	Rovastat Duo	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets	10mg+10mg; (30/3x10/) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego st., 95-200 Pabianice, Lodzkie	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza st., 05-152 Czosnow, Mazowieckie	Poland	PoM	20467/1 15.08.2022
4	Lamisil	terbinafine (terbinafine hydrochloride)	tablets	250mg; (14/1x14/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	17442/5 15.08.2022
5	Lamisil	terbinafine (terbinafine hydrochloride)	tablets	250mg; (14/1x14/) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, quality control (microbiological), batch releaser, Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr, Germany- bulk manufacturer, Pharmanalytica SA., Via Balestra, Locarno, 6600, Switzerland- quality control (physicochemical)	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20246/2 15.08.2022
6	Anti-Cold	paracetamol, phenylephrine (phenylephrine hydrochloride), chlorpheniramine (chlorpheniramine maleate)	tablets	325mg+5mg+2mg; (20/2x10/) 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	OTC	17191/1 15.08.2022

7	Voltaren Retard	diclofenac (diclofenac sodium)	tablets prolonged-release	75mg; (20/2x10/) in blister	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20294/1 15.08.2022
8	Minidiab	glipizide	tablets	5mg (30/2x15/) in blister	Pfizer Italia S.r.l. Localita Marino del Tronto, 63100 Ascoli Piceno for Pfizer H.C.P. Corporation, 235, East 42nd Street, New York, 10017, USA	Italy			PoM	19547/3 15.08.2022
9	Ipigrix 5mg/ml	ipidacrine (ipidacrine hydrochloride)	solution for injection	5mg/ml; (10/2x5/) ampoules 1ml	Grindeks JSC, Krustpils street 53, LV-1057, Riga - batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680, Martin, Slovak Republic - bulk manufacturer, packager	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	16896/2 15.08.2022
10	Ipigrix 15mg/ml	ipidacrine (ipidacrine hydrochloride)	solution for injection	15mg/ml; (10/2x5/) ampoules 1ml	Grindeks JSC, Krustpils street 53, LV-1057, Riga - batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680, Martin, Slovak Republic - bulk manufacturer, packager	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	16895/1 15.08.2022

11	Tantum Verde	benzydamine (benzydamine hydrochloride)	spray for local use	0,255mg/dose (150mg/100ml); 30ml (176 doses) plastic container with pump dispenser	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. Via Vecchia Del Pinocchio, 22, 60100 Ancona	Italy	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. Viale Amelia, 70, Rome	Italy	OTC	20024 /2 15.08.2022
12	Tantum Verde	benzydamine (benzydamine hydrochloride)	solution for local use	150mg/100ml; 120ml glass bottle and measuring cup	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. Via Vecchia Del Pinocchio, 22, 60100 Ancona	Italy	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. Viale Amelia, 70, Rome	Italy	OTC	20031/2/1 15.08.2022
13	Topiramate Canon	topiramate	tablets film-coated	100mg; (28/4x7/) 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	16439/3/1 15.08.2022

14	Topiramate Canon	topiramate	tablets film-coated	25mg; (28/4x7/) 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	16438/3/1 15.08.2022
15	Regulon	desogestrel, ethinylestradiol	tablets film-coated	0,15mg+0,03mg; (21/1x21/) and (63/3x21/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	17136/2 15.08.2022
16	Clexane	enoxaparin (enoxaparin sodium)	solution for injection	20mg/0,2ml; (2) pre-filled syringe 0,2ml	SANOFI WINTHROP INDUSTRIE, MAISONS-ALFORT, 180 rue Jean Jaures, 94700	France	Sanofi-Aventis France, 82 avenue Raspail, 94250 Gentilly	France	PoM	17471/1 15.08.2022
17	Clexane	enoxaparin (enoxaparin sodium)	solution for injection	40mg/0,4ml; N10(5x2) pre-filled syringe 0,4ml	SANOFI WINTHROP INDUSTRIE, MAISONS-ALFORT, 180 rue Jean Jaures, 94700	France	Sanofi-Aventis France, 82 avenue Raspail, 94250 Gentilly	France	PoM	17470/2 15.08.2022

18	Octanine F	human blood coagulation factor IX	powder and solvent for solution for injection	500IU; glass vial, 5ml solvent in glass vial, disposable syringe, transfer set (double-ended needle, filter needle), infusion set, (2) alcohol swabs	Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A-1100 Vienna	Austria	Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A-1100 Vienna	Austria	PoM	16708/2 15.08.2022
19	Glivec	imatinib (imatinib mesylate)	tablets film-coated	100mg; (60/6x10/) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr, Germany-bulk manufacturer, quality control (physicochemical), Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland- quality control (microbiological)	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	19866/2 15.08.2022
20	Glivec	imatinib (imatinib mesylate)	tablets film-coated	400mg; (30/3x10/) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr, Germany-bulk manufacturer, quality control (physicochemical), Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland- quality control (microbiological)	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	19867/2 15.08.2022

21	Glivec	imatinib (imatinib mesylate)	tablets film-coated	100mg; (60/6x10/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	17496/5/1 15.08.2022
22	Glivec	imatinib (imatinib mesylate)	tablets film-coated	400mg; (30/3x10/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	16976/5/1 15.08.2022
23	Ascophen-P	paracetamol, acetylsalicylic acid, caffeine	tablets	200mg+200mg+40mg; (10) and 10(1x10) and 20(2x10) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18 f	Russia	OTCPharm JSC, Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	17913/3/1 15.08.2022
24	Sindranol	ropinirol (ropinirol hydrochloride)	tablets prolonged-release	2mg; (28/2x14/), (56/4x14/) and (84/6x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, Pharmathen International S.A., Industrial Park Sapes, Rodopi Prefecture, Block No5, Rodopi 69300, Greece - bulk manufacturer, packager	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	17432/1 15.08.2022

25	Sindranol	ropinirol (ropinirol hydrochloride)	tablets prolonged-release	3mg; (28/2x14/), (56/4x14/) and (84/6x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, Pharmathen International S.A., Industrial Park Sapés, Rodopi Prefecture, Block No5, Rodopi 69300, Greece - bulk manufacturer, packager	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	17433/1 15.08.2022
26	Sindranol	ropinirol (ropinirol hydrochloride)	tablets prolonged-release	4mg; (28/2x14/), (56/4x14/) and (84/6x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, Pharmathen International S.A., Industrial Park Sapés, Rodopi Prefecture, Block No5, Rodopi 69300, Greece - bulk manufacturer, packager	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	17434/1 15.08.2022
27	Sindranol	ropinirol (ropinirol hydrochloride)	tablets prolonged-release	8mg; (28/2x14/), (56/4x14/) and (84/6x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, Pharmathen International S.A., Industrial Park Sapés, Rodopi Prefecture, Block No5, Rodopi 69300, Greece - bulk manufacturer, packager	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	17435/1 15.08.2022

28	Clemastine	clemastine (clemastine fumarate)	solution for injection	1mg/ml; (10) ampoules 2ml label banderol, (10) ampoules 2ml dividella	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, No11/1, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	PoM	17536/2/1 15.08.2022
29	Octolipen	thioctic acid (alfa-lipoic acid)	concentrate for solution for infusion	30mg/ml; (10/2x5/) ampoules 10ml	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	PoM	16761/1 15.08.2022
30	Exoderil	naftifine (naftifine hydrochloride)	solution for external use	10mg/ml; 10ml and 20ml glass vial	Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl - batch releaser, Globopharm Pharmazeutische Produktions-und Handels GmbH., Breitenfurter Strasse 251, 1230 Wien, Austria- bulk manufacturer, packager	Austria	Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl	Austria	OTC	17187/4 15.08.2022
31	Metronidazole	metronidazole	tablets	250mg; (10) in blister, (300) blister/10/	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	16975/1 15.08.2022

32	Nebilet	nebivolol (nebivolol hydrochloride)	tablets	5mg; (7/1x7/) in blister, (14/1x14/) in blister, (28/2x14/) in blister	Berlin-Chemie A.G., Glienicker Weg 125 D-12489 Berlin - granules manufacturer, packager, batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, D-12347 Berlin, Germany - bulk manufacturer	Germany	Menarini International Operations Luxembourg S.A., 1, avenue de la Gare, 1611	Luxembourg	PoM	18554/1 15.08.2022
33	Hydrochlorothiazide	hydrochlorothiazide	tablets	25mg; (20/2x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, No3, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	PoM	17181/1 15.08.2022
34	Dysport	clostridium botulinum type A toxin-haemagglutinin complex	powder lyophilized for solution for injection	300U; glass vial 3ml	Ipsen Biopharm Limited, Ash Road, Wrexham Industrial Estate, Wrexham, LL13 9UF	UK	Ipsen Pharma, 65 quai Georges Gorse, 92100 Boulogne-Billancourt	France	PoM	18383/1 15.08.2022

35	Bactrim	sulfamethoxazole, trimethoprim	suspension oral	200mg/5ml+40mg/5ml; 100ml glass bottle	Eumetica Pharmaceuticals AG, Arnold Bocklin-Strasse 1, 4051 Basel- batch releaser, Cenexi SAS, Rue Marcel et Jacques Gaucher, 52, Fontenay sous Bois, 94120, France- bulk manufacturer, packager, quality control	Switzerland	Eumetica Pharmaceuticals AG, Arnold Bocklin-Strasse 1, 4051 Basel	Switzerland	PoM	20232/1 15.08.2022
36	Bactrim	sulfamethoxazole, trimethoprim	suspension oral	200mg/5ml+40mg/5ml; 100ml glass bottle	F. Hoffmann-La Roche AG, Viadukstrasse 33, CH-4051 Basel- batch releaser, Cenexi SAS, Rue Marcel et Jacques Gaucher, 52, Fontenay sous Bois, 94120, France- bulk manufacturer, packager	Switzerland	Eumetica Pharmaceuticals AG, Arnold Bocklin-Strasse 1, 4051 Basel	Switzerland	PoM	17724/3/1 15.08.2022
37	Bactrim forte	sulfamethoxazole, trimethoprim	tablets	800mg+160mg; (10/1x10/) in blister	F. Hoffmann-La Roche Ltd, 4303 Kaiseraugst- batch release, packager, - Produtos Roche Quimicos e Farmaceuticos S/A, Estrada dos Bandeirantes 2020 Taquara, RJ, 22775- 109, Brazil- bulk manufacturer, DELPHARM MILANO S.R.L. VIA CARNEVALE, 1 - 20090 SEGRATE (MI), Italy- quality control	Switzerland	Eumetica Pharmaceuticals AG, Arnold Bocklin-Strasse 1, 4051 Basel	Switzerland	PoM	18954/4/2 15.08.2022

38	Bactrim forte	sulfamethoxazole, trimethoprim	tablets	800mg+160mg; (10/1x10/) in blister	Eumedita Pharmaceuticals AG, Arnold Bocklin-Strasse 1, 4051 Basel- batch releaser, Produtos Roche Quimicos e Farmaceuticos S/A, Estrada dos Bandeirantes 2020 Taquara, RJ, 22775-109, Brazil- bulk manufacturer, F. Hoffmann La Roche AG, Wurmisweg CH-4303 Kaiseraugst, Switzerland- packager, DELPHARM MILANO S.R.L. VIA CARNEVALE, 1 - 20090 SEGRATE (MI), Italy- quality control	Switzerland	Eumedita Pharmaceuticals AG, Arnold Bocklin-Strasse 1, 4051 Basel	Switzerland	PoM	20289/1 15.08.2022
39	Edarbi Clo	azilsartan medoxomil, chlortalidone	tablets film- coated	40mg+12,5mg; (28/2x14/) in blister, (98/7x14/) in blister	Takeda Ireland Ltd., Bray Business Park Kilruddery Co. Wicklow	Ireland	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	18629/2/1 15.08.2022
40	Edarbi Clo	azilsartan medoxomil, chlortalidone	tablets film- coated	40mg +25mg; (28/2x14/) in blister, (98/7x14/) in blister	Takeda Ireland Ltd., Bray Business Park Kilruddery Co. Wicklow	Ireland	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	18630/2/1 15.08.2022
41	Methotrexat Ebewe	methotrexate	solution for injection/ infusion	10mg/ml; glass vial 5ml	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	18162/1 15.08.2022

42	Next	ibuprofen, paracetamol	tablets film-coated	400mg+200mg; (2/1x2/) in blister, (4/2x2/) in blister, (6/1x6/) in blister, (10/1x10/) in blister, (12/1x12/) in blister, (12/2x6/) in blister, (20/2x10/) in blister, (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	16627/1/1 15.08.2022
43	Klerimed	clarithromycin	tablets film-coated	250mg; (14/2x7/) in blister	Medochemie Ltd (Factory AZ), 2 Michael Erakleous street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupoli os street, 3011 Limassol	Cyprus	PoM	16740/1 15.08.2022
44	Klerimed	clarithromycin	tablets film-coated	500mg; (14/2x7/) in blister	Medochemie Ltd (Factory AZ), 2 Michael Erakleous street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd., 1-10 Constantinoupoli os street, 3011 Limassol	Cyprus	PoM	16739/1 15.08.2022
45	Lysobact DUO	lysozyme (lysozyme hydrochloride), cetylpyridinum (cetylpyridinum 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	17492/2 15.08.2022

46	Tablets for cough Tatpharm	thermopsis herb, sodium hydrocarbonate	tablets	6,7mg+250mg; (10) in strip	Tatchempharmpreparaty JSC, 420091 Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091 Kazan, str. Belomorskaya 260	Russia	OTC	17094/1 15.08.2022
47	Ferrum LEK	iron (III) hydroxide with polymaltose complex	syrup	50mg/5ml; 100ml glass bottle and measuring spoon	Genveon Ilac Sanayi ve Ticaret A.S., Inoenue Mahallesi, Gebze Plastikciler Organize Sanayi Boelgesi, Mahallesi 9, Cadde No.2, 41400, Kocaeli	Turkey	Lek d.d., Verovskova str. 57,1526 Ljubljana	Slovenia	PoM	20700/1 15.08.2022
48	Lordestin	desloratadine (desloratadine hemisulfate)	tablets film-coated	5mg; (10/1x10/) in blister, (30/3x10/) in blister	Gedeon Richter-RUS JSC, Lesnaya st. 40, Shuvoye, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, packager, batch releaser, Gedeon Richter-RUS JSC, Lesnaya st. 40, b. 1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), Gedeon Richter-RUS JSC, Lesnaya st. 40, b. 2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia)- quality control (microbiological)	Russia	Gedeon Richter-RUS JSC, Lesnaya st. 40, Shuvoye, Moscow region, Yegoriyevsky district, 140342	Russia	PoM	16718/4 15.08.2022