

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 09-1/22 on September 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	Novocain-Zdorovye	procaine (procaine hydrochloride)	solution for injection	5mg/ml; (10) ampoules 5ml, (10/2x5/) ampoules 5ml in blister	Limited Liability Company "Pharmaceutical Company "Zdorovye", 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	Limited Liability Company "Pharmaceutical Company "Zdorovye", 22 Shevchenko str., Kharkiv, 61013, Kharkiv Region	Ukraine	PoM	20891 15.09.2022
2	Kosentyx	seculnumab	lyophilisate for solution for subcutaneous injection	150mg; glass vial	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20892 15.09.2022
3	Kosentyx	secukinumab	solution for injection	150mg/ml; (1) pre-filled pen, (2) pre-filled pen	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20893 15.09.2022

4	Kosentyx	secukinumab	solution for injection in syringe	150mg/ml; (1) pre-filled syringes, N2 pre-filled syringes	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20894 15.09.2022
5	Salbutamol Pharmstandard VCH	salbutamol (salbutamol sulfate)	aerosol for inhalation dosed	100mcg/dose; 200 doses in aluminium container with metering valve and inhaler	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	PoM	20895 15.09.2022
6	Amoksiklav 156.25mg/5ml	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	powder for oral suspension	125mg/5ml+ 31,25mg/5ml; 7.88g powder containing 100ml amber glass bottle and 5ml dosing syringe	Sandoz GmbH, Biochemiestrasse 10, A-6250, Kundl	Austria	Lek Pharmaceuticals d.d. Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	20896 15.09.2022
7	Amoksiklav 312,5mg/5ml	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	powder for oral suspension	250mg/5ml+ 62,5mg/5ml; 15.8g powder containing 100ml amber glass bottle and a 5ml dosing syringe	Sandoz GmbH, Biochemiestrasse 10, A-6250, Kundl	Austria	Lek Pharmaceuticals d.d. Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	20897 15.09.2022
8	Amoksiklav 2x 400mg+57mg/5ml	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	powder for oral suspension	400mg/5ml+ 57mg/5ml; 5.7mg powder containing 35ml amber glass bottle and a 5ml dosing syringe, 11g powder containing 70ml amber glass bottle and 5ml dosing syringe	Sandoz GmbH, Biochemiestrasse 10, A-6250, Kundl	Austria	Lek Pharmaceuticals d.d. Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	20898 15.09.2022

9	Lasolvan syrup 15mg/5ml	ambroxol (ambroxol hydrochloride)	syrup	15mg/5ml; 100ml glass bottle and measuring cup	Sanofi S.P.A., Viale Europa, 11, 21040 Origgio	India	Sanofi-Aventis Deutschland GmbH, Industriepark Hoechst, D-65926 Frankfurt am Main	Germany	OTC	20899 15.09.2022
10	Anastrozole	anastrozole	tablets film-coated	1mg: (30/3x10/) in blister	Pharmacare Premium Limited, HHF 003, Hal Far Industrial Estate, Birzebbugia BBg 3000	Malta	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	20900 15.09.2022
11	Alfaxan Multidose	alfaxalone	solution for injection	10mg/ml; glass vial 10ml , glass vial 20ml	Jurox (Ireland) Limited, The Black Church, St. Marys Place, Dublin, D07P4AX- batch releaser, Jurox Pty Limited, 85 Gardiner street, Rutherford, New South Wales, 2320, Australia- bulk manufacturer, packager, quality control (physicochemical), Eurofins ams laboratories Pty Ltd., 8 Rachael Close Silverwater NSW 2128, Australia- quality control (microbiological)	Ireland	Jurox (Ireland) Limited, The Black Church, St. Marys Place, Dublin, D07P4AX	Ireland	OTC	20910 15.09.2022

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 09-1/22 on September 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	Validol-Pharmstandard	levomenthol solution in menthyl isovalerate	tablets sublingual	60mg; (10/1x10/) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	20901 15.09.2022
2	Diphenin	phenytoin	tablets	117mg; (10/1x10/) blister	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	20902 15.09.2022
3	Efferalgan	paracetamol	tablets effervescent	500mg; (16/4x4/) in blister	UPSA SAS, 979, avenue des Pyrenees, 47520 Le Passage	France	UPSA SAS, 3, rue Joseph Monier-92500 Rueil-Malmaison	France	OTC	20903 15.09.2022

4	Ascorutin	rutoside (rutoside trihydrate), ascorbic acid	tablets	50mg+50mg; (50/5x10/) in blister	PJSC "Technolog", 8, Stara prorizna street, Uman city,, Cherkassy region, 20300	Ukraine	PJSC "Technolog", 8, Stara prorizna street, Uman city,, Cherkassy region, 20300	Ukraine	OTC	20904 15.09.2022
5	Clopidol	clopidogrel (clopidogrel bisulfate)	tablets film-coated	75mg; (20/2x10/) in blister	A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan- packager, batch releaser, Zim Laboratories Ltd., B-21/22, MIDC Area, Kalmeshwar-441 501, Dist. Nagpur (M.S.), India- bulk manufacturer, quality control	Republic of Armenia	A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan	Republic of Armenia	PoM	20905 15.09.2022
6	Dexamethason	dexamethasone (dexamethasone sodium phosphate)	solution for injection	4mg/ml; (25/5x5/) ampoules 1ml	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	20906 15.09.2022
7	Omeprazol	omeprazole	capsules gastro-resistant, hard	20mg; (30/3x10/) in blister	Balkanpharma-Razgrad AD, 68, Aprilsko vastanie Blvd, 7200 Razgrad	Bulgaria	Balkanpharma-Dupnitsa AD, (ACTAVIS GROUP), str."Samokovsko Shosse" N3, Dupnitsa 2600	Bulgaria	PoM	20907 15.09.2022

8	Rotarix	human rotavirus vaccine live	suspension oral	not less than 10 <sup>6</sup> CCID <sup>50</sup> /dose; (50) plastic tube 1.5ml (1 dose)	GlaxoSmithKline Biologicals s.a., Rue de l' Institut, 89 B-1330 Rixensart-batch releaser, GlaxoSmithKline Biologicals SA, Parc de la Noire Epine Rue Fleming, 20,1300 Wavre, Belgium- bulk manufacturer, quality control, packager	Belgium	GlaxoSmithKline Biologicals s.a., Rue de l' Institut, 89 B-1330 Rixensart	Belgium	PoM	20908 15.09.2022
9	Cialis	tadalafil	tablets film- coated	20mg; (1), (2), (4/2x2/ and (8/4x2) in blister	Lilly S.A., Avda de la Industria 30, 28108 Alcobendas-Madrid- quality control, batch releaser, packager, Lilly del Caribe, Inc., Puerto Rico 00985, 12,6 km 65th Infantry Road, Carolina, USA- bulk manufacturer	Spain	Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht	the Netherlands	PoM	20909 15.09.2022

## LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 09-1/22 on September 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	Kestine	ebastine	tablets film-coated	10mg; (5/1x5/) in blister, (10/1x10/) in blister	Industrias Farmaceuticas Almirall S.A., Ctra. De Martorell 41-61, 08740 Sant Andreu de la Barca, Barcelona	Spain	Almirall, S.A., Ronda General Mitre, 151, 08022 Barcelona	Spain	PoM	19442/1/1 15.09.2022
2	Hemomycin	azithromycin (azithromycin dihydrate)	lyophilizate for concentrate for solution for infusion	500mg; (1) glass vial	Hemofarm A.D., 26300 Vrsac, Beogradskii put bb	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradskii put bb	Serbia	PoM	17399/1/1 15.09.2022
3	Lactodepantol	lactic acid	suppositories vaginal	100mg; (10/2x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	18158/3/2 15.09.2022
4	Olazol	hippopheae oil, chloramphenicol, benzocaine, boric acid	aerosol for external use	0,09g/g+0,027g/g+0,027g/g+0,0045g/g; 80g aluminium container	Altayvitaminy JSC, 659325, Altay region, Biysk, st. Zavodskaya, 69	Russia	Altayvitaminy JSC, 659325, Altay region, Biysk, st. Zavodskaya, 69	Russia	OTC	18745/1/1 15.09.2022

5	Phlebodia 600	diosmin	tablets film-coated	600mg; (15/1x15/), (18/1 x18/), (30/2x15/), (60/4x15/) in blister	Innothera Chouzy, Rue Rene Chantereau, Chouzy-sur-Cisse, Valloire-sur-Cisse, 41150	France	Laboratoire Innotech International, 22, Avenue Aristide Briand, 94110 Arcueil	France	OTC	17556/3/2 15.09.2022
6	Emsibel	methylethylpyridinol hydrochloride	solution for injection	10mg/ml; (5/1x5/) ampoules 1ml in blister, (10/2x5/) ampoules 1ml in blister, (10) ampoules 1ml label banderol	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	19306/1/1 15.09.2022
7	Eksportal	lactitol monohydrate	powder for oral solution	5g, (6/3x2/) sachets 5g (6) sachets 5g	PharmVilar LLC SPA, Communiststreet 115, bldg., Maloyaroslavets, Kaluga region, Maloyaroslavetsky district	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	19946/2/1 15.09.2022
8	Eksportal	lactitol monohydrate	powder for oral solution	10g, (10/5x2/) sachets 10g, (20/10x2/) sachets 10g, (10) sachets 10g, (20) sachets 10g	PharmVilar LLC SPA, Communiststreet 115, bldg., Maloyaroslavets, Kaluga region, Maloyaroslavetsky district	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	19947/2/1 15.09.2022



9	Revolade	eltrombopag (eltrombopag olamine)	tablets film-coated	25mg; (28/4x7/) in blister	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos- packager, batch releaser, Glaxo Operations UK Ltd, Priory Street, Ware, Hertfordshire, SG12 0DJ, UK- bulk manufacturer, quality control	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20568/1/1 15.09.2022
10	Revolade	eltrombopag (eltrombopag olamine)	tablets film-coated	50mg; (28/4x7/) in blister	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos-batch releaser, packager, Glaxo Wellcome Operations, Priory Street, Ware, Hertfordshire, SG12 0DJ, UK- bulk manufacturer	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	17502/1/1 15.09.2022
11	Noradrenaline	noradrenaline tartrate	concentrate for solution for infusion	1mg/ml; (5/1x5/) ampoules 4ml in plastic liner, (10/2x5/) ampoules 4ml in plastic liner	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, 1. HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia 2. Grindeks JSC, Krustpils street 53, LV-1057, Riga, Latvia- quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	19569/1/1 15.09.2022

12	Noradrenaline	noradrenaline (noradrenaline tartrate)	concentrate for solution for infusion	1mg/ml; (5/1x5/) ampoules 2ml in plastic liner, (10/2x5/) ampoules 2ml in plastic liner	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, 1. HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia 2.Grindeks JSC, Krustpils street 53, LV-1057, Riga, Latvia- quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	19568 /1/1 15.09.2022
13	Theraflu Extra Lemon	paracetamol, phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate)	powder for oral solution with lemon flavour	650mg+10mg+20mg; (10) sachets 15g	Delpharm Orleans, 5 avenue de Concyr, 45071 Orleans Cedex 02	France	GSK Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon	Switzerland	OTC	18569/2/2 15.09.2022

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 09-1/22 on September 15, 2022

President \_\_\_\_\_ E. Amroyan

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1	Actrapid	insulin human (recombinant DNA)	solution for injection	100IU/ml; (1) glass vial 10ml	Novo Nordisk Production SAS, 45 avenue d` Orleans, F-28000, Chartres	France	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	17514/5 15.09.2022
2	Flavamed cough tablets	ambroxol (ambroxol hydrochloride)	tablets	30mg; (20/2x10/) in blister	Berlin-Chemie A.G., Glienicker Weg 125, D-12489 Berlin- packager, quality control, batch releaser, Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden, Germany- bulk manufacturer	Germany	Berlin-Chemie A.G., Glienicker Weg 125, D-12489 Berlin	Germany	OTC	19190/2 15.09.2022

3	Flavamed cough tablets	ambroxol (ambroxol hydrochloride)	tablets	30mg; (20/2x10/) in blister	Berlin-Chemie A.G.,Glienicker Weg 125, D-12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie A.G., Tempelhofer Weg 83, D-12347 Berlin, Germany- bulk manufacturer, Berlin-Chemie A.G., TempelhoferWeg 83, D-12347 Berlin,Germany / Berlin-Chemie A.G.,GlienickerWeg 125, D-12489 Berlin, Germany- quality control (physicochemical)	Germany	Berlin-Chemie A.G.,Glienicker Weg 125, D-12489 Berlin	Germany	OTC	19176/2 15.09.2022
4	Eslidin	lipoid PPL-400 (phospholipids), methionine	capsules	300mg+100mg; (30/3x10/) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	17139/2 15.09.2022
5	Sydnofarm	molsidomine	tablets	2mg; (30/3x10/) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	17380/1 15.09.2022
6	Nakom	levodopa, carbidopa	tablets	250mg+25mg; (100/10x10/) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	18638/4 15.09.2022

7	Orgalutran	ganirelix (ganirelix acetate)	solution for s/c injection	0,25mg/0,5ml; (5) pre-filled syringes 0,5ml	N.V. Organon, Kloosterstraat 6, 5349 AB Oss- batch releaser, secondary packager, Vetter Pharma-Fertigung GmbH & Co. KG, Schutzenstrasse 87 and 99/101, D-88212 Ravensburg, Germany- bulk manufacturer, primary packager, quality control	the Netherlands	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	18830/6/1 15.09.2022
8	Decaris	levamisole (levamisole hydrochloride)	tablets	50mg; (2/1x2/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest-batch releaser, S.C. Gedeon Richter Romania S.A., 99-105 Guza Voda str.,Targu-Mures, Romania-bulk manufacturer, packager, quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	18810/2 15.09.2022
9	Decaris	levamisole (levamisole hydrochloride)	tablets	150mg; (1) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest-batch releaser, S.C. Gedeon Richter Romania S.A., 99-105 Guza Voda str.,Targu-Mures, Romania-bulk manufacturer, packager, quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	18811/2 15.09.2022

10	Metoclopramide	metoclopramide (metoclopramide hydrochloride)	solution for i/v and i/m injection	5mg/ml; (10) ampoules 2ml label banderol, (10) ampoules 2ml dividella, (10) ampoules 2ml CAMA	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	16946/1 15.09.2022
11	Milgamma	benfotiamine, pyridoxinbe (pyridoxine hydrochloride)	tablets coated	100mg+100mg; (30/2x15/) blisters, (60/4x15/) blisters	Mauermann - Arzneimittel KG Heinrich-Knote-Strasse 2, Poecking, Bayern, 82343 - batch releaser, bulk manufacturer, Mauermann - Arzneimittel KG, Sankt-Sebastian-Strasse 13, Aschering, 82343, Germany - primary packager, secondary packager	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boblingen	Germany	PoM	16905/2/1 15.09.2022
12	Glycerin	glycerol	suppositories rectal	1,24g; (10/2x5/) in blister	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	17035/3 15.09.2022
13	Glycerin	glycerol	suppositories rectal	2.11g; (10/2x5/) in blister	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	17036/3 15.09.2022

14	Kestine	ebastine	tablets film-coated	20mg; (10/1x10/) in blister	Industrias Farmaceuticas Almirall S.A., Ctra. De Martorell 41-61, 08740 Sant Andreu de la Barca, Barcelona	Spain	Almirall, S.A., Ronda General Mitre, 151, 08022 Barcelona	Spain	PoM	16992/3/1 15.09.2022
15	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, Pharanalytica SA., Via Balestra, Locarno, 6600, Switzerland- quality control (physicochemical)	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20246/3 15.09.2022
16	Retinol acetate	retinol (retinol acetate)	solution oily for oral and external use	34,4mg/ml; 10ml and 50ml glass vial, 10ml glass vial-dropper	Marbiopharm JSC, 424006, the Republic of Mari El, Yoshkar-Ola, st. Karl Marx 121	Russia	Marbiopharm JSC, 424006, the Republic of Mari El, Yoshkar-Ola, st. Karl Marx 121	Russia	OTC	17391/1 15.09.2022
17	Diflucan	fluconazole	capsules	50mg; (7/1x7/) in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	PoM	18201/5 15.09.2022

18	Diflucan	fluconazole	capsules	150mg; (1) blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	PoM	18202/5 15.09.2022
19	Analgin	metamizole (metamizole sodium)	solution for i/v and i/m injection	500mg/ml; (10) ampules 2ml CAMA, (10) ampules 2ml label banderol, (10) ampules 2ml dividella	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	PoM	19759/1 15.09.2022
20	Amiksin	tilorone	tablets film-coated	60mg; (6/1x6/), (10/1x10/), (12/2x6/) and (20/2x10/) 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	16878/1/1 15.09.2022
21	Amiksin	tilorone	tablets film-coated	125mg; (3/1x3/), (6/1x6/), (6/2x3/), (10/1x10/), (12/2x6/) and (20/2x10/) 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	16877/1/1 15.09.2022



22	CellCept	mycophenolate mofetil	capsules	250mg; (100/10x10/) in blister	F. Hoffmann-La Roche Ltd.,4303, Kaiseraugust-packager, batch releaser, Delpharm Milano S.R.L, Via Carnevale,1, Segrate (MI), 20090, Italy-bulk manufacturer, quality control	Switzerland	F. Hoffmann-La Roche Ltd., Greenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	18692/2 15.09.2022
23	CellCept	mycophenolate mofetil	capsules	250mg; (100/10x10/) in blister	F. Hoffmann-La Roche AG, Viaduktstrasse 33, Basel, 4051- batch releaser, Delpharm Milano S.R.L, Via Carnevale,1, Segrate (MI), 20090, Italy- bulk manufacturer, packager, quality control	Switzerland	F. Hoffmann-La Roche Ltd., Greenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	20242/1 15.09.2022
24	Sileo	dexmedetomidine (dexmedetomidine hydrochloride)	gel oromucosal	0,1mg/ml; (1) pre-filled syringe 3ml	Orion Corporation, Orionintie 1, 02200 Espoo-quality control (microbiological), batch releaser, Orion Corporation, Tengstrominkatu 8, 20360 Turku, Finland- bulk manufacturer, packager, quality control (phisicochemical)	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	OTC	20001/1 15.09.2022
25	Efferalgan	paracetamol	tablets effervescent	500mg; (16/4x4/) in strip	UPSA SAS, 979, Avenue des Pyrenees, 47520 Le Passage	France	UPSA SAS, 3, rue Joseph Monier-92500 Rueil-Malmaison	France	OTC	17032/1 15.09.2022

26	Moxiral	moxifloxacin (moxifloxacin hydrochloride)	tablets film-coated	400mg; (5/1x5/) and (7/1x7/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	17408/3/1 15.09.2022
27	Milurit	allopurinol	tablets	100mg; (30), (40), (50), (60), (70), (80), (90), (100) and (120) in glass bottle	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	17483/4 15.09.2022
28	Milurit	allopurinol	tablets	300mg; (30), (40), (50), (60), (70), (80), (90), (100) and (120) in glass bottle	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65 -batch releaser, packager, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary-bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	17484/4 15.09.2022
29	Validol-Pharmstandard	levomenthol solution in menthyl isovalerate	tablets sublingual	60mg; (10) in blister	Pharmstandard-Leksredstva JSC, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	16760/2 15.09.2022

30	Zerkalin	clindamycin (clindamycin hydrochloride)	solution for external use	10mg/ml; 30ml glass vial-dropper	JADRAN-GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	JADRAN-GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	PoM	18168/2 15.09.2022
31	Cialis	tadalafil	tablets film-coated	20mg; (1), (2), (4/2x2/) and (8/4x2) in blister	Lilly S.A., Avda de la Industria 30, 28108 Alcobendas-Madrid- batch releaser, packager, Lilly del Caribe, Inc., Puerto Rico 00985, 12,6 km 65th Infantry Road, Carolina, USA- bulk manufacturer	Spain	Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht	the Netherlands	PoM	17077/1 15.09.2022
32	Enalapril	enalapril (enalapril maleate)	tablets	5mg; (20/2x10/), (30/3x10/) and (60/6x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64a, No4, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	PoM	17639/1 15.09.2022
33	Enalapril	enalapril (enalapril maleate)	tablets	10mg; (20/2x10/), (30/3x10/) and (60/6x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64a, No4, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	PoM	17638/1 15.09.2022

34	Clopidol	clopidogrel (clopidogrel bisulfate)	tablets film-coated	75mg; (20/2x10/) 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	16643/1/1 15.09.2022
35	Omeprazol	omeprazole	capsules gastro-resistant, hard	20mg; (30/3x10/) in blister	Balkanpharma-Razgrad AD, 68, Aprilsko vastanie Blvd, 7200 Razgrad	Bulgaria	Balkanpharma-Dupnitsa AD, (ACTAVIS GROUP), str."Samokovsko Shosse" N3, Dupnitsa 2600	Bulgaria	PoM	16827/1 15.09.2022
36	Diphenin	phenytoin	tablets	117mg; (10) 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	16874/1 15.09.2022
37	Fungoterbin	terbinafine (terbinafine hydrochloride)	cream for external use	10mg/g; aluminium or plastic laminated tube 15g	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	18992/1 15.09.2022

38	Rotarix	human rotavirus vaccine live	suspension oral	not less than 10 <sup>6</sup> CCID <sub>50</sub> /dose; (50) plastic tube 1.5ml (1 dose)	GlaxoSmithKline Biologicals s.a., Rue de l' Institut, 89 B-1330 Rixensart-batch releaser, GlaxoSmithKline Biologicals SA, Parc de la Noire Epine Rue Fleming, 20 1300 Wavre, Belgium- (bulk manufacturer, packager	Belgium	GlaxoSmithKline Biologicals s.a., Rue de l' Institut, 89 B-1330 Rixensart	Belgium	PoM	16854/1 15.09.2022
39	Diclac 75mg/3ml	diclofenac (diclofenac sodium)	solution for injection	75mg/3ml; (5) ampoules 3ml, (10) ampoules 3ml	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	20041/1 15.09.2022
40	Tisercin	levomepromazine (levomepromazine maleate)	tablets film-coated	25mg; (50) in glass container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	20183/1 15.09.2022
41	Hartil	ramipril	tablets	5mg; (14/2x7/) in blister, (28/4x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	18395/5 15.09.2022

42	Hartil	ramipril	tablets	10mg; (14/2x7/) in blister, (28/4x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	18396/5 15.09.2022
43	Tulosin	tamsulosin (tamsulosin hydrochloride)	capsules modified-release	0,4mg; (10/1x10/) and (30/3x10/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	17587/2 15.09.2022
44	Zalain	sertaconazole (sertaconazole nitrate)	suppositories vaginal	300mg; (1)	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- batch releaser, Trommsdorff GmbH & Co. KG, Arzneimittel, Trommsdorffstrasse 2-6, 52477, Alsdorf, Germany- bulk manufacturer, packager, quality control (physicochemical), Allphamed PHARBIL Arzneimittel GmbH, Hildebrandstr. 10-12, 37081 Gottingen, Niedersachsen, Germany- quality control (microbiological)	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	20096/1 15.09.2022

45	Zalain	sertaconazole (sertaconazole nitrate)	suppositories vaginal	300mg; (1)	Trommsdorff GmbH & Co. KG, Arzneimittel, Trommsdorffstrasse 2-6, 52477, Alsdorf- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Allphamed PHARBIL Arzneimittel GmbH, Hildebrandstr. 10-12, 37081 Gottingen, Niedersachsen, Germany- quality control (microbiological)	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	20097/1 15.09.2022
46	Traumeel	achillea millefolium D3, napellus D2, arnica montana D2, atropa bella-donna D2, bellis perennis D2, calendula officinalis D2, echinacea D2, echinacea purpurea D2, hamamelis virginiana D1, hepar sulfuris D6, hypericum perforatum D2, matricaria recutita D3, mercurius solubilis Hahnemanni D6, symphytum officinale D6	solution for injection	2,2mg/2,2ml+ 1,32mg/2,2ml+ 2,2mg/2,2ml+ 2,2mg/2,2ml+ 1,1mg/2,2ml+ 2,2mg/2,2ml+ 0,55mg/2,2ml+ 0,55mg/2,2ml+ 0,22mg/2,2ml+ 2,2mg/2,2ml+ 0,66mg/2,2ml+ 2,2mg/2,2ml+ 1,1mg/2,2ml+ 2,2mg/2,2ml (10) ampoules 2,2ml, (100) ampoules 2,2ml	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	PoM	19591/1 15.09.2022

47	Puregon	follitropin beta (recombinant)	solution for s/c injection	300IU/0,36ml; cartridge 0,42ml, (6/2x3/) needles	N.V. Organon, Molenstraat 110, 5342 CC OSS- secondary packager, quality control, batch releaser (legal address- N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands), Vetter Pharma-Fertigung GmbH & Co. KG, Mooswiesen 2, Ravensburg, Baden-Wuerttemberg, 88214, Germany- bulk manufacturer, primary packager	the Netherlands	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	19260/4/1 15.09.2022
48	Puregon	follitropin beta (recombinant)	solution for s/c injection	600IU/0,72ml; cartridge 0,78ml, (6/2x3/) needles	N.V. Organon, Molenstraat 110, 5342 CC OSS- secondary packager, quality control, batch releaser (legal address- N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands), Vetter Pharma-Fertigung GmbH & Co. KG, Mooswiesen 2, Ravensburg, Baden-Wuerttemberg, 88214, Germany- bulk manufacturer, primary packager	the Netherlands	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	19261/4/1 15.09.2022



49	Vermox	mebendazole	tablets	100mg (6/1x6/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Romania S.A., 99-105 Guza Voda str., 540306, Targu-Mures, Romania- bulk manufacturer, packager, quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	19595 /1 15.09.2022
50	Dexamethason	dexamethasone (dexamethasone sodium phosphate)	solution for injection	4mg/ml; (25/5x5/) ampoules 1ml	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	16713/2 15.09.2022
51	Anastrozole Denk 1mg	anastrozole	tablets film- coated	1mg; (30/3x10/) in blister	Haupt Pharma Muenster GmbH, Schleebrueggenkamp 15, 48159 Muenster	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	PoM	18777/3 15.09.2022
52	Glimepiride Denk 3	glimepiride	tablets	3mg; (30/3x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	PoM	17344/2 15.09.2022

53	Captopril+HCT Denk 50/25	captopril, hydrochlorothiazide	tablets	50mg+25mg; (30/3x10/) and (100/10x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	17814/5 15.09.2022
54	Toras-Denk 10	torasemide	tablets	10mg; (30/3x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	18590/4 15.09.2022
55	Salbutamol Sopharma	salbutamol (salbutamol sulfate)	syrup	2mg/5ml; 125ml glass or plastic bottle and measuring cup	Sopharma JSC, Vrabevo vlg. 5660, district of Lovetch	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	17132/2 15.09.2022
56	Acyclovir Denk 200	aciclovir	tablets	200mg; (25/5x5/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	17984/3 15.09.2022

57	Metformin Denk 1000	metformin (metformin hydrochloride)	tablets film-coated	1000mg; (30/2x15/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor L+S AG, 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	20334/1 15.09.2022
58	Ascorutin	rutoside (rutoside trihydrate), ascorbic acid	tablets	50mg+50mg (50/5x10/) in blister	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	OTC	17276/3/1 15.09.2022
59	Sodium chloride	sodium chloride	solution for injection	9mg/ml; (10) ampoules 5ml, (10/2x5/) ampoules 5ml in blister	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	PoM	16706/2 15.09.2022
60	Sodium chloride	sodium chloride	solution for injection	9mg/ml; (10) ampoules 10ml, (10/2x5/) ampoules 10ml in blister	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	PoM	16705/2 15.09.2022

61	Strepsils	dichlorobenzyl alcohol, amylmetacresol	lozenges with honey and lemon flavour	1,2mg+0,6mg; (24/2x12/), (36/3x12/), in blister	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	OTC	19410/2 15.09.2022
62	Abrobion	ambroxol (ambroxol hydrochloride)	syrup	6mg/ml; 125ml glass bottle	Help S.A. Pedini, Ioanninon, Ioannina, 45500	Greece	Help S.A ,10 Valaoritou str., GR 144 52, Metamorphosis, Attika	Greece	OTC	19933/1 15.09.2022
63	Phosphogliv URSO	ursodeoxycholic acid, sodium glycyrrhizinate (glycyrrhizinic acid trisodium)	capsules	250mg+35mg; (50/5x10/) in blister	Pharmstandard- Leksredstva JSC, 305022, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard- Leksredstva JSC, 305022, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	PoM	20358/1 15.09.2022
64	Dicloton 75mg/3ml	diclofenac (diclofenac sodium)	solution for injection/ infusion	25mg/ml (5) ampoules 3ml	Medochemie Ltd. (Ampoule Injectable Facility) 48 Iapetou street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd.,1-10 Constantinoupole os street, 3011 Limassol	Cyprus	PoM	19403/1 15.09.2022

65	Insulatard	insulin human (recombinant DNA)	suspension for injection	100IU/ml; (1) glass vial 10ml	Novo Nordisk Production SAS, 45 avenue d` Orleans, F-28000, Chartres	France	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	17160/5 15.09.2022
66	Oftagel	carbomer 974P	gel eye	2,5mg/g; plastic vial-dropper 10g	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, Ursapharm Arzneimittel GmbH, Industriestrasse 35, 66129 Saarbrucken, Germany- bulk manufacturer, packager, quality control	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	OTC	19860/2 15.09.2022
67	Strepsils Intensive	flurbiprofen	spray dosed for topical use	8,75mg; (1) plastic container with dosing device, 15ml (at least 15 dose)	Reckitt Benckiser Healthcare Manufacturing (Thailand) Ltd, 65 Lardkrabang-Bangplee Road Moo 12, Bangplee, Samutprakarn, 10540	Thailand	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	OTC	20726/1 15.09.2022
68	Lorinden A	flumetasone (flumetasone pivalate), salicylic acid	ointment for external use	0,2mg/g+30mg/g; 15g 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	PoM	20427/1 15.09.2022