

## LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 09-2/22 on September 30, 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	Propofol	propofol	emulsion for i/v injection/infusion	10mg/ml; (5) ampoules 20ml	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111- batch releaser, Kwality Pharmaceuticals Ltd , Plot No. 1-A Industrial Area, Raja Ka Bagh, Tehsil Nurpur, district Kangra, Himachal Pradesh, India- bulk manufacturer, packager, quality control	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	20911 30.09.2022
2	Diosperidin	diosmin, hesperidin	film-coated tablet	450mg+50mg; (30/2x15/) in blister	Help S.A., Pedini Ioanninon, Ioannina	Greece	Spey Medical Ltd, Lynton House 7-12 Tavistock square, WC1H 9LT, London	UK	OTC	20912 30.09.2022
3	KLARUKTAM	cefotaxim (cefotaxim sodium), sulbactam (sulbactam sodium)	powder for solution for i/m and i/v injection and infusion	1000mg+500mg; glass vial 20ml	Ruzpharma LLC, 143132, Moscow Region, Ruzskiy district, Tuchkovo Village 12, Komsomolskaya str., bld. 1	Russia	Farmnovacii LLC, 127055, City Moscow, 27 Sushevskaya Str., Bld. 2, 3rd floor, room III, suit 3, office 39	Russia	PoM	20913 30.09.2022

4	SYBRAVA	inclisiran	solution for subcutaneous injection	189mg/ml; 1.5ml pre-filled syringe	Sandoz GmbH, Biochemiestrasse 10, Langkampfen, 6336- batch releaser, Corden Pharma S.p.A., Reparto UP3, Via G. Galilei, 17, Caponago (MB), 20867, Italy- bulk manufacturer, primary packager, quality control, Corden Pharma S.p.A., viale dell Industria, 3, Caponago (MB), 20867, Italy- secondary packager	Austria	Novartis Overseas Investments AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20914 30.09.2022
5	Ultrix Quadri Tetravalent inactivated split influenza vaccine	influenza virus antigen tipe	solution for i/m injection	15mcg/dose+ 15mcg/dose+ 15mcg/dose+ 15mcg/dose; (1) pre-filled syringes 0,5ml, (10) pre-filled syringes 0,5ml	FORT LLC, Ryazan district, Ryazan Oblast, 1a Okskoye rural settlement, 390540	Russia	FORT LLC, Ryazan district, Ryazan Oblast, 1a Okskoye rural settlement, 390540	Russia	PoM	20915 30.09.2022

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 09-2/22 on September 30, 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	Amiksin	tilorone	tablets film-coated	60mg; (6/1x6/) in blister, (10/1x10/) in blister, (12/2x6/) in blister, (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	20916 30.09.2022
2	Amiksin	tilorone	tablets film-coated	125mg; (3/1x3/) in blister, (6/1x6/) in blister, (6/2x3/) in blister, (10/1x10/) in blister, (12/2x6/) in blister, (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	20917 30.09.2022
3	Fluimucil	acetylcysteine	granules for oral solution	200mg; (20) sachet 1g, (60) sachet 1g	Zambon Switzerland Ltd., Via Industria 13, CH-6814, Cadempino	Switzerland	Zambon S.P.A., Via Lillo Del Duca, 10, Bresso, 20091	Italy	OTC	20918 30.09.2022

4	Heparin-Indar	heparin sodium	solution for injection	5000 IU/ml; (5) glass vial 5ml, (100) glass vial 5ml	PrJSC "On the production of insulin "INDAR", 02099, Kyiv, 5 Zroshuvalna st	Ukraine	PrJSC "On the production of insulin "INDAR", 02099, Kyiv, 5 Zroshuvalna st	Ukraine	PoM	20919 30.09.2022
5	Sulbactacid	ampicillin (ampicillin sodium), sulbactam (sulbactam sodium)	powder for solution for injection	1000mg+500mg; (50) glass vial	ANTIBIOTICE S.A., str. Valea Lupului, 1, lasi, 707410- packager, quality control, batch releaser, ZHUHAI UNITED LABORATORIES CO, LTD., No. 2428, Anji Road Jinwan District, Zhuhai-Sanzao Town, ZHUHAI, GUANGDONG, 519040, China- bulk manufacturer	Romania	ANTIBIOTICE S.A., str. Valea Lupului, 1, lasi, 707410	Romania	PoM	20920 30.09.2022
6	Fluconazole-Inta	fluconazole	capsules	50mg; (30/3x10/) in blister	Incepta Pharmaceuticals Limited, Dewan Idris Road, Bara Rangamatia, Zirabo, Ashulia, Savar, Dhaka-1341	Bangladesh	Incepta Pharmaceuticals Limited, Dewan Idris Road, Bara Rangamatia, Zirabo, Ashulia, Savar, Dhaka-1341	Bangladesh	PoM	20921 30.09.2022
7	Fluconazole-Inta	fluconazole	capsules	150mg; (10/1x10/) blister	Incepta Pharmaceuticals Limited, Dewan Idris Road, Bara Rangamatia, Zirabo, Ashulia, Savar, Dhaka-1341	Bangladesh	Incepta Pharmaceuticals Limited, Dewan Idris Road, Bara Rangamatia, Zirabo, Ashulia, Savar, Dhaka-1341	Bangladesh	PoM	20922 30.09.2022

8	Ketilept	quetiapine (quetiapine fumarate)	tablets film-coated	25mg; (30/3x10/) in blister, (60/6x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	20923 30.09.2022
9	Ketilept	quetiapine (quetiapine fumarate)	tablets film-coated	100mg; (30/3x10/) in blister, (60/6x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	20924 30.09.2022
10	Ketilept	quetiapine (quetiapine fumarate)	tablets film-coated	200mg; (30/3x10/) and (60/6x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	20925 30.09.2022
11	Ketilept	quetiapine (quetiapine fumarate)	tablets film-coated	300mg; (30/3x10/) in blister, (60/6x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	20926 30.09.2022
12	Skopryl	lisinopril (lisinopril dihydrate)	tablets	10mg; (30/3x10/) in blister, (90/9x10/) 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	20927 30.09.2022

13	Skopryl	lisinopril (lisinopril dihydrate)	tablets	20mg; (30/3x10/) in blister, (90/9x10/) 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	20928 30.09.2022
14	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	20929 30.09.2022
15	Ceftonus	ceftriaxone (ceftriaxone sodium)	powder for solution for injection	1000mg; (25) glass vial	Panpharma, ZI du Clairay, Luitre, 35133	France	Panpharma, ZI du Clairay, Luitre, 35133	France	PoM	20930 30.09.2022
16	Carvedilol	carvedilol	tablets	6,25mg; (40/1x40/) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	20931 30.09.2022
17	Carvedilol	carvedilol	tablets	25mg; (40/1x40/) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	20932 30.09.2022

18	Milgamma	benfotiamine, pyridoxine (pyridoxine hydrochloride)	tablets coated	100mg+100mg; (30/2x15/) in blister, (60/4x15/) in blister	Mauermann-Arzneimittel KG Heinrich-Knote-Strasse 2, Poecking, Bayern, 82343- bulk manufacturer, batch releaser, Mauermann- Arzneimittel KG, Sankt- Sebastian-Strasse 13, Aschering, 82343, Germany- packager	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boblingen	Germany	PoM	20933 30.09.2022
19	Clemastine	clemastine (clemastine fumarate)	solution for injection	1mg/ml; (10) label banderol ampoules 2ml, (10) dividella ampoules 2ml	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	20934 30.09.2022
20	DISTREPTAZA	streptokinase, streptodornase	suppositories rectal	15000IU+1250IU; (6/1x6/)	BIOMED-LUBLIN Wytwornia Surowic i Szczepionek Spolka Akcyjna, ul. Uniwersytecka 10, 20-029, Lublin	Poland	BIOMED-LUBLIN Wytwornia Surowic i Szczepionek Spolka Akcyjna, ul. Uniwersytecka 10, 20-029, Lublin	Poland	PoM	20935 30.09.2022

## LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 09-2/22 on September 30, 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	TheraFlu	paracetamol, pheniramine (pheniramine maleate), phenylephrine (phenylephrine hydrochloride), ascorbic acid	powder for oral solution with lemon flavour	325mg+20mg+10mg+50mg; (10) sachets 22,1g	Delpharm Orleans, 5 avenue de Concyr, 45071 Orleans Cedex 02	France	GSK Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon	Switzerland	OTC	18194/2/2 30.09.2022
2	Panthenol Pharmstandard	dexpanthenol	aerosol	50mg/g; aluminium container 58g	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	19070/1/1 30.09.2022
3	Xalatan	latanoprost	drops eye	50mcg/ml; 2,5ml plastic container	Pfizer Manufacturing Belgium N.V., Rijksweg 12, B-2870 Puurs	Belgium	Upjohn US 1 LLC, 1209 Orange street, Wilmington DE 19801,	USA	PoM	17980/4/1 30.09.2022



4	Fentanyl Kalceks	fentanyl (fentanyl citrate)	solution for injection	0,05mg/ml; (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, quality control	Latvia	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057	Latvia	PoM	19795/1/1 30.09.2022
5	Cordarone	amiodarone (amiodarone hydrochloride)	solution for i/v injection	50mg/ml; (6) ampoules 3ml	Sanofi Winthrop Industrie, 1, rue de la Vierge, Ambares et Lagrave, 33565 Carbon Blanc cedex	France	Sanofi-Aventis France, 82 avenue Raspail, 94250 Gentilly	France	PoM	17436/2/1 30.09.2022
6	Artraxicam	meloxicam, peper siliculose fruits tincture	cream	30mg/g+100mg/g; aluminium or plastic tube 30g	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	18481/2/1 30.09.2022
7	Distem	paracetamol, methocarbamol	tablets	300mg+ 380mg; (50/5x10/) in blister	FAES FARMA S.A., C/Maximo Aguirre, 14, Lejona-Leioa, 48940 Vizcaya/Bizkaia	Spain	FAES FARMA S.A., C/Maximo Aguirre, 14, Lejona-Leioa, 48940 Vizcaya/Bizkaia	Spain	PoM	18868/2/1 30.09.2022

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 09-2/22 on September 30, 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	Broncho-munal P	lyophilized bacterial lysate	capsules hard	3,5mg; (10/1x10/) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- packager, quality control, batch releaser, OM Pharma SA, 22, rue du Bois-du-Lan, 1217 Meyrin 2/Geneva, Switzerland- bulk manufacturer	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19713/2 30.09.2022
2	Broncho-munal	lyophilized bacterial lysate	capsules hard	7mg; (10/1x10/) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- packager, quality control, batch releaser, OM Pharma SA, 22, rue du Bois-du-Lan, 1217 Meyrin 2/Geneva, Switzerland- bulk manufacturer	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19712/2 30.09.2022

3	Eliquis	apixaban	tablets film-coated	2,5mg; (20/2x10/) in blister, (60/6x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstätte Freiburg, Mooswaldallee 1, 79090 Freiburg- packager, quality control, batch releaser, Pfizer Ireland Pharmaceuticals, Little Conell Newbridge, Co. Kildare, Ireland- bulk manufacturer	Germany	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	PoM	19625/2 30.09.2022
4	Eliquis	apixaban	tablets film-coated	5mg; (20/2x10/) in blister, (60/6x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstätte Freiburg, Mooswaldallee 1, 79090 Freiburg- packager, quality control, batch releaser, Pfizer Ireland Pharmaceuticals, Little Conell Newbridge, Co. Kildare, Ireland- bulk manufacturer	Germany	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	PoM	19626/2 30.09.2022
5	Peritol	cyproheptadine (cyproheptadine hydrochloride)	tablets	4mg; (20/2x10/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	20016/2 30.09.2022

6	Fraxiparine	nadroparin calcium	solution for injection	2850IU AXa/0,3ml; (10) pre-filled syringes 0,3ml	Aspen Notre Dame de Bondeville, 1 rue de l' Abbaye, 76960 Notre Dame de Bondeville	France	Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24	Ireland	PoM	19030/2 30.09.2022
7	Fraxiparine	nadroparin calcium	solution for injection	5700IU AXa/0,6ml; (10) pre-filled syringes 0,6ml	Aspen Notre Dame de Bondeville, 1 rue de l' Abbaye, 76960 Notre Dame de Bondeville	France	Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24	Ireland	PoM	19031/2 30.09.2022
8	Panadol Baby	paracetamol	suppositories rectal	125mg (10/2x5/)	Farmaclair, 440 Avenue du General de Gaulle, 14200 Herouville Saint Clair	France	GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	OTC	19598/1 30.09.2022
9	Fluimucil	acetylcysteine	granules for oral solution	200mg; (20) and (60) sachet 1g	Zambon Switzerland Ltd., Via Industria 13, CH-6814, Cadempino	Switzerland	Zambon S.P.A., Via Lillo Del Duca, 10, Bresso, 20091	Italy	OTC	16216/4 30.09.2022

10	Actovegin	deproteinised haemoderivate of calf blood	tablets coated	200mg (50) in glass container	Takeda Pharmaceuticals LLC, Yaroslavl city, 9 Tekhnoparkovaya street	Russia	Takeda Pharmaceuticals LLC, Usacheva str 2, bld. 1, Moscow 119048	Russia	PoM	19450/1 30.09.2022
11	Pimafucort	natamycin, neomycin (neomycin sulfate), hydrocortisone (hydrocortisone micronized)	ointment for external use	10mg/g+3500U/g+10mg/g; aluminium tube 15g	Temmler Italia S.r.L., Via delle Industrie 2, 20061 Carugate (MI)	Italy	LEO Pharma A/S, Industriparken 55, DK-2750 Ballerup	Denmark	PoM	19259/1 30.09.2022
12	Strepsils Intensive	flurbiprofen	lozenges with honey and lemon flavour	8,75mg; (24/3x8/) 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	19549/2 30.09.2022

13	Nanotropil novo	fonturacetam	tablets	100mg; (10/1x10/) in blister, (30/3x10/) in blister	Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 107- bulk manufacturer, packager, batch releaser, Obninsk Chemical Pharmaceutical Company CJSC, 249036, Kaluga region, Obninsk, str. Kiev highway, 3a/3, Russia- quality control (physical/chemical), Federal State Budgetary Healthcare Institution "Center for Hygiene and Epidemiology No. 8 of the Federal Medical and Biological Agency", Kaluga region, Obninsk, pr-kt. Lenin, 85, 249030, Russia- quality control (microbiological)	Russia	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo city, Fabrichnaya St., 2	Russia	PoM	20086/2/1 30.09.2022
14	Flucona-Denk 100	fluconazole	capsules hard	100mg; (10/1x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	18141/2 30.09.2022

15	Metformin Denk 500	metformin (metformin hydrochloride)	tablets film-coated	500mg; (30/3x10/) in blister, (100/10x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, packager, quality control (physico-chemical), 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	19249/2/1 30.09.2022
16	Heparin-Indar	heparin sodium	solution for injection	5000 IU/ml; (5), (100) glass vial 5ml	PrJSC "On the production of insulin "INDAR", 02099, Kyiv, 5 Zroshuvalna st	Ukraine	PrJSC "On the production of insulin "INDAR", 02099, Kyiv, 5 Zroshuvalna st	Ukraine	PoM	16855/2/1 30.09.2022
17	Panto-Denk 20	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	20mg; (28/2x14/) in blister	Advance Pharma GmbH, Wallenroder str. 8-14, 13435 Berlin	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	17853/2 30.09.2022

18	AmoxiClav-Denk 1000/125	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	powder for oral suspension	1000mg+125mg; (8) sachets 3g, (12) sachets 3g	PenCef Pharma GmbH, Breitenbachstrasse 13-14, 13509 Berlin- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Allphamed Pharbil Arzneimittel GmbH, Hildebrandstr. 10-12, 37081 Gottingen, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20172/1 30.09.2022
19	Toras-Denk 5	torasemide	tablets	5mg; (30/3x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, packager, quality control(phisicochemical), 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	20481/1 30.09.2022
20	Morfina hidrochlorids- Kalceks	morphine (morphine hydrochloride)	solution for injection	10mg/ml; (10/2x5/) ampoules 1ml 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, quality control	Latvia	Kalceks JSC, 53 Krustpils Street, Riga, LV-1057	Latvia	PoM	19003/3 30.09.2022



21	Sentor	losartan (losartan potassium)	tablets film-coated	50mg; (10/1x10/) in blister, (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest - batch releaser, Gedeon Richter Poland Sp.z o.o., ul.Graniczna 35,Grodzisk Mazowiecki, 05-825, Poland - bulk manufacturer, packager	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	18374/3 30.09.2022
22	Sentor	losartan (losartan potassium)	tablets film-coated	100mg; (10/1x10/) in blister, (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest - batch releaser, Gedeon Richter Poland Sp.z o.o., ul.Graniczna 35,Grodzisk Mazowiecki, 05-825, Poland - bulk manufacturer, packager	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	18375/3 30.09.2022
23	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	20846/1 30.09.2022

24	Letrozole Denk 2.5	letrozole	tablets film- coated	2,5mg; (30/3x10/) in blister	Haupt Pharma Muenster GmbH, Schleebrueggenkamp 15, 48159 Muenster- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Umweltlabor ACB GmbH, Albrecht- Thaer-Strasse 14, 48147 Muenster, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	PoM	19943/1 30.09.2022
25	Atorvastatin Alkaloid	atorvastatin (atorvastatin calcium trihydrate)	tablets film- coated	10mg; (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	20439 /1 30.09.2022
26	Atorvastatin Alkaloid	atorvastatin (atorvastatin calcium trihydrate)	tablets film- coated	20mg; (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	20440 /1 30.09.2022
27	Atorvastatin Alkaloid	atorvastatin (atorvastatin calcium trihydrate)	tablets film- coated	40mg; (30/2x15/) 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	20441/1 30.09.2022

28	Atorvastatin Alkaloid	atorvastatin (atorvastatin calcium trihydrate)	tablets film-coated	80mg; (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	20442 /1 30.09.2022
29	Dalacin	clindamycin (clindamycin hydrochloride)	capsules	150mg; (16/2x8/) 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	18181/3 30.09.2022
30	Dalacin	clindamycin (clindamycin hydrochloride)	capsules	300mg; (16/2x8/) 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	18182/2 30.09.2022
31	Janumet	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+850mg (56/4x14/) in blister	Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem- packager, quality control, batch releaser, Aesica Queenborough Limited, Queenborough Kent ME 11 5EL, UK- bulk manufacturer	the Netherlands	Merck Sharp & Dohme Corp., One Merck Drive, Whitehouse Station, New Jersey, 08889	USA	PoM	19550/2 30.09.2022

32	Janumet	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+1000mg (56/4x14/) in blister	Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem- packager, quality control, batch releaser, Aesica Queenborough Limited, Queenborough Kent ME 11 5EL, UK- bulk manufacturer	the Netherlands	Merck Sharp & Dohme Corp., One Merck Drive, Whitehouse Station, New Jersey, 08889	USA	PoM	19551/2 30.09.2022
33	Janumet	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+1000mg; (56/4x14/) in blister	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem-batch releaser, packager, Patheon Puerto Rico, Inc., State Road 670 Km. 2,7 Manati, Puerto Rico, 00674, USA- bulk manufacturer	the Netherlands	Merck Sharp & Dohme Corp., One Merck Drive, Whitehouse Station, New Jersey, 08889	USA	PoM	17069/3/1 30.09.2022
34	Janumet	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+500mg; (56/4x14/) in blister	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem-batch releaser, packager, Patheon Puerto Rico, Inc., State Road 670 Km. 2,7 Manati, Puerto Rico, 00674, USA- bulk manufacturer	the Netherlands	Merck Sharp & Dohme Corp., One Merck Drive, Whitehouse Station, New Jersey, 08889	USA	PoM	17070/4/1 30.09.2022

35	Janumet	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+850mg; (56/4x14/) in blister	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem-batch releaser, packager, Patheon Puerto Rico, Inc., State Road 670 Km. 2,7 Manati, Puerto Rico, 00674, USA-bulk manufacturer	the Netherlands	Merck Sharp & Dohme Corp., One Merck Drive, Whitehouse Station, New Jersey, 08889	USA	PoM	17071/4/1 30.09.2022
36	Levicitam	levetiracetam	tablets film-coated	250mg (30/3x10/) in blister, (60/6x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	18675/3/1 30.09.2022
37	Levicitam	levetiracetam	tablets film-coated	500mg (30/3x10/) in blister, (60/6x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	18676/3/1 30.09.2022
38	Norditropin NordiFlex	somatropin	solution for s/c injection	6,7mg/ml; pre-filled pen 1,5ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd-batch releaser, Novo Nordisk A/S, Hagedornsvej 1, DK-2820 Gentofte, Denmark- bulk manufacturer, primary packager, quality control, Novo Nordisk A/S Kirke Vaerloesevej 30, Vaerloese, 3500, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	20413/1 30.09.2022

39	Lamisil	terbinafine (terbinafine hydrochloride)	cream	10mg/g; 15g aluminium tube, 15g laminated tube	GlaxoSmithKline Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon	Switzerland	GlaxoSmithKline Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon	Switzerland	OTC	16653/2/1 30.09.2022
40	Strepsils with Menthol and Eucalyptus	dichlorobenzyl alcohol, amylmetacresol, levomenthol	lozenges	1,2mg+0,6mg+8mg; (24/2x12/) in blister, (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	19461/2 30.09.2022
41	Strepsils with vitamin C	dichlorobenzyl alcohol, amylmetacresol, ascorbic acid	lozenges with orange flavour	1,2mg+0,6mg+100mg; (24/2x12/) 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	19616/2 30.09.2022
42	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	500mg+125mg; (14/2x7/) in blister	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	PoM	17633/6 30.09.2022

43	DISTREPTAZA	streptokinase, streptodornase	suppositories rectal	15000IU+1250IU; (6/1x6/) in blister	BIOMED-LUBLIN Wytownia Surowic i Szczepionek Spolka Akcyjna, ul. Uniwersytecka 10, 20-029, Lublin	Poland	BIOMED-LUBLIN Wytownia Surowic i Szczepionek Spolka Akcyjna, ul. Uniwersytecka 10, 20-029, Lublin	Poland	PoM	17138/2 30.09.2022
44	Amoksiklav powder for solution for injection 500mg/100mg	amoxicillin (amoxicillin sodium), clavulanic acid (potassium clavulanate)	powder for solution for injection	500mg+100mg; (5) glass vials	Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl	Austria	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19966/1 30.09.2022
45	Amoksiklav powder for solution for injection 1000mg /200mg	amoxicillin (amoxicillin sodium), clavulanic acid (potassium clavulanate)	powder for solution for injection	1000mg+200mg; (5) glass vials	Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl	Austria	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	19967/1 30.09.2022
46	Carvedilol	carvedilol	tablets	6,25mg; (40/1x40/) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro- District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	17287/2 30.09.2022

47	Carvedilol	carvedilol	tablets	12,5mg; (40/1x40/), in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	19913/1 30.09.2022
48	Carvedilol	carvedilol	tablets	25mg; (40/1x40/) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	17286/2 30.09.2022
49	Celebrex	celecoxib	capsules	100mg; (20/2x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Baden-Wuerttemberg, Mooswaldallee 1, 79090 Freiburg- packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	Upjohn US 1 LLC, 1209 Orange street, Wilmington DE 19801	USA	PoM	19390/3/1 30.09.2022



50	Celebrex	celecoxib	capsules	200mg; (20/2x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Baden-Wuerttemberg, Mooswaldallee 1, 79090 Freiburg- packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	Upjohn US 1 LLC, 1209 Orange street, Wilmington DE 19801	USA	PoM	19391/3/1 30.09.2022
51	Mixtard 30	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	17159/7 30.09.2022
52	Diclo-Denk 75 Injection	diclofenac (diclofenac sodium)	solution for injection	25mg/ml; (10) ampoules 3ml	Haupt Pharma Wulfing GmbH, Bethelner Landstrasse 18, Gronau/Leine 31028	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	PoM	17460/3
53	Dimedrol-Darnitsa	diphenhydramine (diphenhydramine hydrochloride)	tablets	50mg; (10/1x10/) and (10) in blister	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	PoM	17685/1 30.09.2022

54	Metypred	methylprednisolone (methylprednisolone sodium succinate)	powder for solution for injection	250mg; glass vial	Orion Corporation, Orionintie 1, 02200 Espoo-secondary packager, batch releaser, Hikma Farmaceutica, Estrada do Rio da Mo n.8, 8A e 8B, Fervenca, 2705-906 Terrugem SNT, Portugal-bulk manufacturer, primary packager	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	PoM	20540/1 30.09.2022
55	Ovitrelle	choriogonadotropin alfa	solution for s/c injection	250mcg/0,5ml; glass pre-filled syringe with needle in plastic pack	Merck Serono S.p.A., Via delle Magnolie 15, 70026 Modugno (BA)	Italy	Merck LLC, 35 Valovaya Street, Moscow 115054	Russia	PoM	17878/2/1 30.09.2022
56	Enterogermina	spores of polyantibiotic-resistant Bacillus clausii	suspension oral	2x10 <sup>9</sup> /5ml; (10) plastic vials 5ml	Sanofi S.P.A., Viale Europa, 11, 21040 Origgio	Italy	Sanofi S.P.A., Viale Europa, 11, 21040 Origgio	Italy	OTC	19188/1 30.09.2022
57	Enterogermina Forte	spores of polyantibiotic-resistant Bacillus clausii	suspension oral	4x10 <sup>9</sup> /5ml; (10) plastic vial 5ml	Sanofi S.P.A., Viale Europa,11, 21040 Origgio	Italy	Sanofi S.P.A., Viale Europa,11, 21040 Origgio	Italy	OTC	17306/2/1 30.09.2022
58	Adenuric 80mg	febuxostat	tablets film-coated	80mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister, (84/6x14/) in blister	Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden	Germany	Menarini International O. L. S.A., 1, Avenue de la Gare, 1611	Luxembourg	PoM	20300/1 30.09.2022

59	Adenuric 120mg	febuxostat	tablets film-coated	120mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister, (84/6x14/) in blister	Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden	Germany	Menarini International O. L. S.A., 1, Avenue de la Gare, 1611	Luxembourg	PoM	20301/1 30.09.2022
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