

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 04-3/22 on April 29, 2022

President_____E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Energair Breezhaler	indacaterol (indacaterol maleate), glycopyrronium bromide, mometasone fuora	powder for inhalation, capsules hard	150mcg+50mcg+160mcg; (30/3x10/) in blister and inhaler	Ziegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona-packager, batch releaser, Novartis Pharma Stein AG Novartis Technical Operations Schweiz, Stein Solids, Schaffhauserstrasse, 4332 Stein AG, Switzerland-bulk manufacturer, quality control (microbial/biological), Novartis Pharma Stein AG Novartis Technical Operations Schweiz, Stein Solids, Schaffhauserstrasse, 4332 Stein AG, Switzerland; 2.Solvias AG, Romerpark 2, 4303 Kaiseraugst 4303, Switzerland; 3.Pharmanalytica SA., Via Balestra, Locarno, 6600, Switzerland- quality control (physicochemical)	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	29.04.2022

2	ATRACURIUM-NOVO	atracurium (atracurium besylate)	solution for injection	10mg/ml; (5/1x5/) ampoules 2.5ml in blister	Firm "Novofarm-BiosynteZ" LLC, 11700, Zhytomyr region, town Novograd-Volynskyi, Zhytomyrska street, building 38	Ukraine	Firm "Novofarm-BiosynteZ" LLC, 11700, Zhytomyr region, town Novograd-Volynskyi, Zhytomyrska street, building 38	Ukraine	PoM	29.04.2022
3	ATRACURIUM-NOVO	atracurium (atracurium besylate)	solution for injection	10mg/ml; (5/1x5/) ampoules 5ml in blister	Firm "Novofarm-BiosynteZ" LLC, 11700, Zhytomyr region, town Novograd-Volynskyi, Zhytomyrska street, building 38	Ukraine	Firm "Novofarm-BiosynteZ" LLC, 11700, Zhytomyr region, town Novograd-Volynskyi, Zhytomyrska street, building 38	Ukraine	PoM	29.04.2022
4	Lidocaine-Zdorovye	lidocaine (lidocaine hydrochloride)	solution for injection	100mg/ml; (10/1x10/) ampoules 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	29.04.2022

5	Smectica med	diosmectite (smectite dioctaedric)	powder for oral suspension	3g; (10) sachets 3g	Foreing manufacturing unitary enterpriser Med-interplast, Leninslcaya str., 115, off. 204, Nesvizh, Minsk region, 222603- bulk manufacturer, packager, batch releaser, Foreing manufacturing unitary enterpriser Med-interplast, Inzhinernaya str, 18-3 Minsk, Belarus- Foreing manufacturing unitary enterpriser Med-interplast, Inzhinernaya str, 18-3 Minsk, Belarus- quality control (phsycochemical), AmantsiMed LLC, Minsk region, district Logoisk, city Logoisk, str. Minsk 2I, Belarus- quality control (microbiological)	Belarus	Foreing manufacturing unitary enterpriser Med-interplast, Leninslcaya str., 115, off. 204, Nesvizh, Minsk region, 222603	Belarus	OTC	29.04.2022
6	Fentavera	fentanyl	patch transdermal	50mcg/h; (5) patches	Acino AG, Leopoldstrasse 115, 80804 Munich- batch releaser, Luye Pharma AG, Am Windfeld 27 und 35, 83714 Miesbach, Germany- balk manufacturer, packager, quality control (physicochemical), Eurofins Biopharma Product Testing Munich GmbH, Robert-Koch-str. 3a, 82152 Planegg, Germany- quality control (microbiological)	Germany	Acino AG, Leopoldstrasse 115, 80804 Munich	Germany	PoM	29.04.2022

7	Fentavera	fentanyl	patch transdermal	75mcg/h; (5) patches	Acino AG, Leopoldstrasse 115, 80804 Munich- batch releaser, Luye Pharma AG, Am Windfeld 27 und 35, 83714 Miesbach, Germany- balk manufacturer, packager, quality control (physicochemical), Eurofins Biopharma Product Testing Munich GmbH, Robert-Koch-str. 3a, 82152 Planegg, Germany- quality control (microbiological)	Germany	Acino AG, Leopoldstrasse 115, 80804 Munich	Germany	PoM	29.04.2022
8	Cefotaxime	cefotaxime (cefotaxime sodium)	powder for solution for i/m and i/v injection	1000mg; (10)glass vial, (50)glass vial, (270) glass vial	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64/3, Chapaev str., Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	PoM	29.04.2022
9	Forcorium	mometasone (mometasone furoate), gentamicin sulphate, dexpantenol, econazole (econazole nitrate)	cream	0.5mg+1mg+50,0mg+10,0mg; aluminium tube 15g	Werteks JSC, 199106, Saint Petersburg, Vasilevski Ostrov, Lane 24, bld. 27A- bulk manufacturer, packager, batch releaser, Werteks JSC, Saint Petersburg, 197350, Doroga v Kamenku, 62A, Russia- quality control	Russia	Werteks JSC, 197350, Saint Petersburg, Doroga v Kamenku, 62A	Russia	PoM	29.04.2022

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 04-3/22 on April 29, 2022

President_____E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Carbalex 300mg retard	carbamazepine	tablets prolonged-release	300mg; (50/5x10/) in blister, (100/10x10/) in blister	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach- batch releaser, G.L. Pharma GmbH, Industriestrasse 1, 8502 Lannach, Austria- bulk manufacturer, packager, G.L. Pharma GmbH, Arnethgasse 3, 1160 Vienna, Austria- quality control	Austria	Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	PoM	29.04.2022
2	Carbalex 600mg retard	carbamazepine	tablets prolonged-release	600mg; (50/5x10/) in blister, (100/10x10/) in blister	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach- batch releaser, G.L. Pharma GmbH, Industriestrasse 1, 8502 Lannach, Austria- bulk manufacturer, packager, G.L. Pharma GmbH, Arnethgasse 3, 1160 Vienna, Austria- quality control	Austria	Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	PoM	29.04.2022

3	Cholisal	choline salicylate, cetalkonium chloride	gel dental	87,1mg/g+0,1mg/g; 10g aluminium tube	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	OTC	29.04.2022
4	Papaverin	papaverine (papaverine hydrochloride)	suppositories rectal	20mg; (10/2x5/)	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	29.04.2022
5	Tamoxifen	tamoxifen (tamoxifen citrate)	tablets film- coated	20mg; (30/3x10/) in blister	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	29.04.2022
6	Cordarone	amiodarone (amiodarone hydrochloride)	tablets	200mg; (30/2x15/) in blister	Chinoin Pharmaceutical and Chemical Works Private Co. Ltd., 2112 Veresegyhaz, Levai u. 5- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Chinoin Pharmaceutical and Chemical works Private Co. Ltd (Chinoin Private Co. Ltd), 1. Telephely / Site1, To utca 1-5, Budapest, 1045, Hungary- quality control (microbiological)	Hungary	Sanofi-Aventis France, 1-13, boulevard Romain Rolland, 75014 Paris	France	PoM	29.04.2022

7	Alte	marshmallow root extract	syrup	2360mg/5ml; glass or plastic bottle 125g and measuring cup	Pharmaceutical Manufacturing Enterprise GEMI, 05-480 Karczew, Mickiewicza 36 str.	Poland	Pharmaceutical Manufacturing Enterprise GEMI, 05-480 Karczew, Mickiewicza 36 str.	Poland	OTC	29.04.2022
8	Fluimucil	acetylcysteine	solution for i/m and i/v injection and inhalation	100mg/ml; (5) ampoules 3ml	Zambon S.P.A., Via della Chimica, 9, Vicenza, 36100	Italy	Zambon S.P.A., Via Lillo del Duca, 10, Bresso, 20091	Italy	PoM	29.04.2022
9	Vit-B-Denk	thiamine (thiamine hydrochloride)(vitaminB1), pyridoxine (pyridoxine hydrochloride)(vitaminB6)	tablets film-coated	100mg+200mg; (20/2x10/) and (100/10x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, packager, quality control (physicochemical), batch releaser, GBA Pharma GmbH, Ernst-Abbe-Str. 40 Ulm Baden-Wuerttemberg, 89079, Germany- quality control(microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	29.04.2022
10	Flosteron	betamethasone (betamethasone dipropionate), betamethasone (betamethasone sodium phosphate)	suspension for injection	5mg/ml+2mg/ml; (5) 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	29.04.2022

11	Risperidone	risperidone	tablets coated	2mg; (30/3x10/) in 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	29.04.2022
12	Otrepin-Arpi	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; 15ml plastic bottle with pump dispenser	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	29.04.2022
13	Femara	letrozole	tablets film-coated	2,5mg; (30/3x10/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	29.04.2022
14	Herpevir	aciclovir	ointment	25mg/g; 5g aluminium tube, 15g aluminium tube	Kievmedpreparat PJSC, 03115, Kiev, Peremogy avenue, 120- bulk manufacturer, packager, batch releaser, Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139, Ukraine-quality control	Ukraine	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	OTC	29.04.2022

15	Aquadetrim Vitamin D3 Medana	colecalfiferol	drops oral	15000IU/ml; 10ml glass bottle	Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 10 Wladyslawa Lokietka St. 98-200 Sieradz- batch releaser, Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 57 Polskiej Organizacji Wojskowej st. 98-200 Sieradz, Poland- bulk manufacturer, packager, quality control	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	PoM	29.04.2022
16	Pentatrop	cyclopentolate (cyclopentolate hydrochloride)	drops eye	10mg/ml; (1) plastic vial- dropper 5ml, (10) plastic vial-dropper 5ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	29.04.2022
17	Tramadol	tramadol (tramadol hydrochloride)	capsules	50mg; (20/2x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	29.04.2022
18	Rocephin	ceftriaxone (ceftriaxone sodium)	powder for solution for injection	1000mg; (143/1x143/) glass vial	F.Hoffmann-La Roche Ltd. Wurmisweg, CH-4303 Kaiseraugst	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124 Basel, CH- 4070	Switzerland	OTC	29.04.2022

19	IMMUNOMAX BIO	peptidoglycan	powder lyophilized for solution for i/m injection	200IU; (3) glass vial	IMMAPHARMA LLC, 18/11, st. Gamaleya, Moscow, 123098- batch releaser, bulk manufacturer, packager, quality control (physicochemical), Avexima Sibir LLC, 7, st. Hercen, Kemerovskaya region, Kuzbass, Anjero- Sudjensk, 652473, Russia- quality control (microbiological)	Russia	Avexima OJSC, 31A/1, Leningradsky pr., Moscow, 125284	Russia	PoM	29.04.2022
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LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 04-3/22 on April 29, 2022

President_____E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Crinone	progesterone	gel vaginal	80mg/g; (6) pre-filled plastic applicators 1,125g, (15) pre-filled plastic applicators 1,125g	Central Pharma (Contract Packing) Limited, Caxton Road, Bedford, Bedfordshire, MK41 0XZ - secondary packager, batch releaser, Dendron Brands Limited, 94 Rickmansworth Road, Watford, Hertfordshire, WD18 7JJ, UK - bulk manufacturer, Maropack AG, Industriestrasse Briseck 4, 6144 Zell, Switzerland-primary packager, Herd Mundy Richardson Limited, Oak House, Bredbury Parkway Ashton Road, Bredbury Stockport Cheshire SK62SN, UK- quality control	UK	Merck LLC, Valovaya Street 35, 115054 Moscow	Russia	PoM	18229/4/2 29.04.2022

2	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 Böcklin-Strasse 1, 4051 Basel	Switzerland	PoM	18954/3/2 29.04.2022
3	Miconazole	miconazole (miconazole nitrate)	cream for external use	20mg/g; aluminium tube 15g	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	OTC	19974/1/1 29.04.2022
4	Thiogamma	thioctic acid	tablets film- coated	600mg; (30/3x10/) in blister, (60/6x10/) in blister, (100/10x10/) in blister	Dragenopharm Apotheker Puschl GmbH, Gollstrasse 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	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boblingen	Germany	PoM	20418/1/1 29.04.2022

5	Thiogamma	thioctic acid	solution for infusion	12mg/ml; (1) glass vial 50ml, (10) glass vial 50ml	Solupharm Pharmazeutische Erzeugnisse GmbH, Industriestrasse 3, D-34212 Melsungen	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boblingen	Germany	PoM	18870/2/1 29.04.2022
6	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 PHARMACEUTICA LS LLC, Kochinyan 13/16, Yerevan	Republic of Armenia	PoM	16643/1/1 29.04.2022

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 04-3/22 on April 29, 2022

President_____E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Magrilan	fluoxetine (fluoxetine hydrochloride)	capsules	20mg (30/3x10/) 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	17327/1 29.04.2022
2	Venolex	diosmin, flavonoids	tablets	450mg+50mg; (30/3x10/) in blister, (60/6x10/) in blister, (120/12x10/) in blister	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk- bulk manufacturer, packager, batch releaser, "Rubicon" LLC, 62-2, M. Gorky street, 210002, Vitebsk, Belarus- quality control	Belarus	Rubicon LLC, 62B, M. Gorky street, 210002, Vitebsk	Belarus	PoM	20488/1 29.04.2022

3	Dicynone	etamsylate	tablets	250mg; (100/10x10/) in blister	Lek Pharmaceuticals d.d.,Trimlini 2D, Lendava, 9220 -batch releaser, packager, Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana, Slovenia-bulk manufacturer	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	17275/3 29.04.2022
4	Tamsol	tamsulosin (tamsulosin hydrochloride)	capsules modified-release	0,4mg; (10/1x10/) and (30/3x10/) 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	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	16796/1 29.04.2022
5	Nicorandil 10mg Tablets	nicorandil	tablets	10mg; (60/6x10/) in blister	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB- batch releaser, Dexcel Ltd., 1 Dexcel Street, Or-Akiva 3060000, Israel- bulk manufacturer, packager, quality control (physicochemical), The Institute for Food Microbiology and Consumer Goods Ltd.,9 HaShalom Road, POB 291, Nesher, Israel- quality control (microbiological)	UK	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire , NN11 8PB	UK	PoM	19638/3 29.04.2022

6	Nicorandil 20mg Tablets	nicorandil	tablets	20mg; (60/6x10/) in blister	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB- batch releaser, Dexcel Ltd., 1 Dexcel Street, Or-Akiva 3060000, Israel- bulk manufacturer, packager, quality control (physicochemical), The Institute for Food Microbiology and Consumer Goods Ltd.,9 HaShalom Road, POB 291, Nesher, Israel- quality control (microbiological)	UK	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire , NN11 8PB	UK	PoM	19639/3 29.04.2022
7	Xalatan	latanoprost	drops eye	50mcg/ml; 2,5ml plastic container	Pfizer Manufacturing Belgium N.V., Rijksweg 12, B-2870 Puurs	Belgium	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	PoM	17980/3 29.04.2022
8	Clostilbegyt	clomifene (clomifene citrate)	tablets	50mg; (10) in glass vials	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	20262/1 29.04.2022
9	Arixtra	fondaparinux (fondaparinux sodium)	solution for injection	5mg/ml; (10/2x5/) pre-filled syringes 0.5ml in blister	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	19118/4 29.04.2022

10	Fastum gel	ketoprofen	gel	25mg/g; aluminum tube 30g, aluminum tube 50g, aluminum tube 100g	A. Menarini Manufacturing Logistics and Services S.r.l., Via Sette Santi, 3 50131 Firenze	Italy	A. Menarini Industrie Farmaceutiche Riunite S.r.l., Via Sette Santi, 3 50131 Firenze	Italy	PoM	19388/1 29.04.2022
11	Tramadol	tramadol (tramadol hydrochloride)	solution for injection	100mg/2ml; (5) ampoules 2ml	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	16624/1 29.04.2022
12	Diprosalic	betamethasone (betamethasone dipropionate), salicylic acid	lotion	0,5mg/g+20mg/g; 30ml plastic container-dropper	Cenexi HSC, 2 Rue Louis Pasteur, 14200 Herouville Saint- Clair	France	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	18902/3/1 29.04.2022
13	Aquadetrim Vitamin D3 Medana	colecalfiferol	drops oral	15000IU/ml; 10ml glass bottle	Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 10 Wladyslawa Lokietka St. 98-200 Sieradz -batch releaser, Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 57 Polskiej Organizacji Wojskowej st. 98-200 Sieradz, Poland- bulk manufacturer, packager, quality control	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	PoM	16671/2/1 29.04.2022

14	Alte	marshmallow root extract	syrup	2.36g/5ml; glass or plastic bottle 125g and measuring cup	Pharmaceutical Manufacturing Enterprise GEMI, 05-480 Karczew, Mickiewicza 36 str.	Poland	Pharmaceutical Manufacturing Enterprise GEMI, 05-480 Karczew, Mickiewicza 36 str.	Poland	OTC	14588/1 29.04.2022
15	Moviprep	sachet A-macrogol (macrogol 3350), sodium sulfate, sodium chloride, potassium chloride; sachet B-ascorbic acid, sodium ascorbate	powder for oral solution	sachet A-100g+7.5g+2.691g+1.015g; sachet B-4.7g+5.9g; (4/(2) sachetA(111.896g) + (2) sachetB(10.6g)/)	Norgine Limited, New Road, Tir-Y-Berth, Hengoed, Mid Glamorgan, CF82 8SJ- bulk manufacturer, packager, quality control (physicochemical), batch releaser, READING SCIENTIFIC SERVICES LIMITED, READING SCIENCE CENTRE, WHITEKNIGHTS CAMPUS, PEPPER LANE, READING, RG6 6LA, UK- quality control (microbiological)	UK	Norgine B.V., Antonio Vivaldistraat 150, 1083HP Amsterdam	the Netherlands	OTC	19299/3 29.04.2022
16	Acnamino MR 100mg Capsules	minocycline (minocycline hydrochloride)	capsules hard	100mg; (56/8x7/) in blister	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB - batch releaser, Dexcel Ltd., 1 Dexcel Street, Or-Akiva 3060000, Israel-bulk manufacturer, packager	UK	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB	UK	PoM	18024/3 29.04.2022

17	Rennie	calcium carbonate, magnesium carbonate	tablets chewable with orange flavour	680mg+80mg; (24/2x12/) in blister	Delpharm Gaillard, 33, rue de l`industrie, 74240 Gaillard	France	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	16736/1 29.04.2022
18	Ariprazol	aripiprazole	tablets	10mg; (30/3x10/) in blister, (60/6x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	18388/3/1 29.04.2022
19	Ariprazol	aripiprazole	tablets	15mg; (30/3x10/) in blister, (60/6x10/ in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	PoM	18389/3/1 29.04.2022
20	Vit-B-Denk	thiamine (thiamine hydrochloride)(vitaminB1), pyridoxine (pyridoxine hydrochloride)(vitaminB6)	tablets film- coated	100mg+200mg; (20/2x10/) 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	16231/3 29.04.2022
21	Fluimucil	acetylcysteine	solution for i/m and i/v injection and inhalation	100mg/ml; (5) ampoules 3ml	Zambon S.P.A., Via della Chimica, 9, Vicenza, 36100	Italy	Zambon S.P.A., Via Lillo del Duca, 10, Bresso, 20091	Italy	PoM	15794/3/1 29.04.2022
22	Pentatrop	cyclopentolate (cyclopentolate hydrochloride)	drops eye	10mg/ml; (1) and (10) plastic vial-dropper 5ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	PoM	16845/1 29.04.2022

23	Clotri-Denk100 Vaginal	clotrimazole	tablets vaginal	100mg; (6/1x6/) in blister	Artesan Pharma GmbH & Co. KG, Wendlandstrasse 1, 29439 Luechow	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	17985/1 29.04.2022
24	Sophalor	desloratadine	solution oral	0,5mg/ml; 120ml glass or plastic bottle and measuring cup	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia-batch releaser, Sopharma JSC, Vrabevo vlg. 5660, district of Lovetch, Bulgaria-bulk manufacturer, packager	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	17770/2 29.04.2022
25	ACC 200	acetylcysteine	tablets effervescent	200mg; (20) in plastic container	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben-batch releaser, Hermes Pharma Ges.m.b.H, Schwimmschulweg 1a, Wolfsberg, 9400, Austria- bulk manufacturer, packager, quality control	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	18716/6/1 29.04.2022

26	ACC Extra	acetylcysteine	tablets effervescent	600mg; (10/5x2/) in aluminium laminated sachets, (20/10x2/) in aluminium laminated sachets	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben-batch releaser, Hermes Arzneimittel GmbH, Hans-Urmiler Ring 52, Wolfratshausen, Germany-bulk manufacturer, packager	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	OTC	18240/4 29.04.2022
27	ACC Long	acetylcysteine	tablets effervescent	600mg; (10) in plastic container	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben-batch releaser, Hermes Pharma GmbH, Hans-Urmiler-Ring 52, 82515 Wolfratshausen, Germany -bulk manufacturer, packager, quality control	Germany	Sandoz Pharmaceuticals d.d. Verevskova 57, Ljubljana	Slovenia	OTC	18925/5/1 29.04.2022
28	Vitaprost	prostate extract	suppositories rectal	10mg; (10/2x5/)	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	20129/1 29.04.2022
29	Rocephin	ceftriaxone (ceftriaxone sodium)	powder for solution for injection	1000mg; (143/1x143/) glass vial	F.Hoffmann-La Roche Ltd. Wurmisweg, CH-4303 Kaiseraugst	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124 Basel, CH-4070	Switzerland	PoM	16640/2 29.04.2022

30	Cholisal	choline salicylate, cetalkonium chloride	gel dental	87,1mg/g+0,1mg/g; 10g 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	16274/2/1 29.04.2022
31	Risperidone	risperidone	tablets coated	2mg; (30/3x10/) blisters	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	16872/1 29.04.2022
32	Tramadol	tramadol (tramadol hydrochloride)	capsules	50mg; (20/2x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	16552/2 29.04.2022
33	Trulicity	dulaglutide	solution for injection	0,75mg/0.5ml; (4) pre- filled glass pen 0.5ml	Eli Lilly and Company, Indianapolis, IN 46285	USA	Eli Lilly and Company, Indianapolis, IN 46285	USA	PoM	17836/4 29.04.2022
34	Trulicity	dulaglutide	solution for injection	1,5mg/0.5ml; (4) pre- filled glass pen 0.5ml	Eli Lilly and Company, Indianapolis, IN 46285	USA	Eli Lilly and Company, Indianapolis, IN 46285	USA	PoM	17837/4 29.04.2022

35	IMMUNOMAX BIO	peptidoglycan	powder lyophilized for solution for i/m injection	200IU; (3) glass vial	IMMAPHARMA LLC, 18/11, st. Gamaleya, Moscow, 123098- batch releaser, bulk manufacturer, packager, quality control (physicochemical), Avexima Sibir LLC, 7, st. Hercen, Kemerovskaya region, Kuzbass, Anjero- Sudjensk, 652473, Russia- quality control (microbiological)	Russia	Avexima OJSC, 31A/1, Leningradsky pr., Moscow, 125284	Russia	PoM	16073/3/1 29.04.2022
36	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	20246/1 29.04.2022
37	Brimica Genuair	aclidinium (aclidinium bromide), formoterol fumarate dihydrate	powder for inhalation	340mcg/dose+12mcg/ dose; (1) inhaler with 60 unit doses, (3) inhalers with 180(3x60) unit doses	Industrias Farmaceuticas Almirall S.A., Ctra. Nacional II, Km. 593, 08740 Sant Andreu de la Barca, Barcelona	Spain	Berlin-Chemie AG (Menarini Group), Glienicke Weg 125, 12489 Berlin	Germany	PoM	19870/2/1 29.04.2022

38	Aspirin Cardio	acetylsalicylic acid	tablets gastro-resistant	100mg; (28/2x14/) in blister	Bayer Bitterfeld GmbH, Ortsteil Greppin, Salegaster Chaussee 1, 06803 Bitterfeld-Wolfen- batch releaser, packager, Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen, Germany - bulk manufacturer	Germany	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	17014/4/1 29.04.2022
39	Otrepin-Arpi	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; 15ml plastic bottle with pump dispenser	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	16846/1 29.04.2022
40	Nitromint	nitroglycerin	spray sublingual dosed	0,4mg/dose; 10g (180 doses) aluminium container and 10g (180 doses) COC container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	17585/3 29.04.2022
41	Norcolut	norethisterone	tablets	5mg; (20/2x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	19344 /1 29.04.2022

42	Calcemin Advance	calcium, vitamin D3, magnesium, zinc, copper, manganese, boron	tablets film-coated	500mg+200IU+40mg+7,5mg+1mg+1,8mg+250mcg; (30) in plastic container, (60) in plastic container, (120) in plastic container	Contract Pharmacal Corporation, 135 Adams avenue, Hauppauge, New York 11788- packager, quality control, batch releaser, Contract Pharmacal Corporation, 150 and 160 Commerce Drive Hauppauge, New York 11788, USA- bulk manufacturer	USA	JSC BAYER, 3rd Rybinskaya st., 18, build. 2, 107113 Moscow	Russia	OTC	20229/2 29.04.2022
43	Lysobact Complete Spray	lysozyme (lysozyme hydrochloride), cetylpyridinium chloride, lidocaine (lidocaine hydrochloride)	spray	20mg/ml+1,5mg/ml+0,5mg/ml; 30ml glass bottle with spraying pump and spray applicator	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	17938/3 29.04.2022
44	Spasmovax ORO	phloroglucinol (phloroglucinol dihydrate), 1,3,5-trimethoxybenzene	tablets	80mg+80mg; (20/2x10/) in blister	Doppel Farmaceutici S.r.l., Via Volturmo 48, Quinto De` Stampi, 20089 Rozzano (MI)	Italy	SCHARPER S.p.A., Viale Ortles 12, 20139 Milan	Italy	PoM	17008/4 29.04.2022
45	Flosteron	betamethasone (betamethasone dipropionate), betamethasone (betamethasone sodium phosphate)	suspension for injection	5mg/ml+2mg/ml; (5) 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	16523/4 29.04.2022

46	Sumatriptan Canon	sumatriptan (sumatriptan succinate)	tablets film-coated	50mg; (2/1x2/) in blister	CJSC Canonpharma production, Moscow region, Schelkovo urban district, Schelkovo city, Zarechnaya st, 105B bldg, 11- quality control, batch releaser, CJSC Canonpharma production, Moscow region, Schelkovo urban district, Schelkovo city, Zarechnaya st., 105, 105B bldg, 12, Russia- bulk manufacturer, packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	PoM	16220/3 29.04.2022
47	Sumatriptan Canon	sumatriptan (sumatriptan succinate)	tablets film-coated	100mg; (2/1x2/) in blister	CJSC Canonpharma production, Moscow region, Schelkovo urban district, Schelkovo city, Zarechnaya st, 105B bldg, 11- quality control, batch releaser, CJSC Canonpharma production, Moscow region, Schelkovo urban district, Schelkovo city, Zarechnaya st., 105, 105B bldg, 12, Russia- bulk manufacturer, packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	PoM	16219/3 29.04.2022
48	Herpevir	aciclovir	ointment	25mg/g; 5g and 15g aluminium tube	Kievmedpreparat PJSC, 03115, Kyiv, Peremogy avenue, 120	Ukraine	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	OTC	16386/1 29.04.2022