

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 05-2/22 on May 30, 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	Letrozole	letrozole	tablets film-coated	2,5mg; (30/3x10/) in blister	Pharmacare Premium Ltd, HHF003 Hal-Far Industrial Estate Hal-Far, Birzebbugia, BBG3000	Malta	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	30.05.2022
2	Aectura Breezhaler	indacaterol (indacaterol maleate), mometasone fuorat	inhalation powder, capsules hard	150mcg+320mcg; (30/3x10/) in blister and inhaler	Siegfried 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), 1.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	30.05.2022

3	Primacef	cefepime (cefepime hydrochloride)	powder for solution for injection	1000mg; (1) glass vial, (50) glass vial	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi- secondary packager, quality control, batch releaser, Reyoung Pharmaceutical Co. Ltd., No1 Ruiyang Road, Yiyuan County, Shandong Province, China- bulk manufacturer, primary packager	Georgia	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi	Georgia	PoM	30.05.2022
4	Triumeq	dolutegravir (dolutegravir sodium), abacavir (abacavir sulfate), lamivudine	tablets film-coated	50mg+600mg+300mg; (30) in plastic container	Glaxo Wellcome S.A., Avenida Extremadura, 3, 09400 Aranda de Duero, Burgos- packager, batch releaser, Glaxo Operations UK Ltd, Priory Street, Ware, SG12 0DJ, UK- bulk manufacturer, quality control	Spain	ViiV Healthcare BV, Van Asch van Wijckstraat 55H, Amersfoort 3811 LP	the Netherlands	PoM	30.05.2022
5	Polyoxidonium	azoximer bromide	solution for injection and for topical use	6mg/ml; (1) pre-filled syringe 1ml and (1) needle and (5) pre-filled syringe 1ml and (5) needles	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	PoM	30.05.2022
6	Polyoxidonium	azoximer bromide	solution for injection and for topical use	6mg/ml; (5) glass vials 1ml	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	PoM	30.05.2022

7	Valdocef	cefadroxil(cefadroxi monohydrate)	capsules hard	500mg; (16/2x8/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- quality control, batch releaser, Alkaloid AD Skopje, Blvd. Partizanski odredi 98A, 1000 Skopje, Republic of North Macedonia- bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	30.05.2022
8	Exoderil	naftifine hydrochloride	solution for external use	10mg/g; 10 l glass bottle, 20 ml glass bottle	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- batch releaser, Globopharm Pharmazeutische Produktions-und Handels GmbH., Breitenfurter Strasse 251, 1230 Wien, Austria- bulk manufacturer, packager, quality control	Slovenia	Sandoz GmbH, Biochemiestrassen 10, A-6250 Kundl	Austria	PoM	30.05.2022
9	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	30.05.2022

10	Amorolfine Laquer	amorolfine (amorolfine hydrochloride)	medicated nail laquer	50mg/ml; 2,5ml glass vial, (10) spatulas, (30) nail files, (30) cleansing swabs	Chanelle Medical, Dublin Road, Loughrea, Co Galway, H62 FH90	Ireland	ARGO-PHARM LLC, 13/9 Sundukyan str., 0012 Yerevan	Republic of Armenia	PoM	30.05.2022
11	Influcid A	aconitum trit.D3, gelsemium trit.D3, ipecacuanha trit.D3, phosphorus trit.D5, bryonia trit. D2, eupatorium perfoliatum trit.D1	tablets	25mg+25mg+25mg+25mg+25mg+25mg; (40/2x20/) in blister	Dr. Gustav Klein GmbH & Co. KG, Steinenfeld 3, 77736 Zell am Harmersbach- bulk manufacturer, packager, quality control (physicochemical), batch releaser, GBA Pharma GmbH, Ernst-Abbe-Str. 40, Ulm, Baden-Wuerttemberg, 89079, Germany- quality control (microbiological)	Germany	Alpen Pharma GmbH, Steinenfeld 3 Zell am Harmersbach, 77736	Germany	OTC	30.05.2022

12	Infanrix Hexa	diphtheria toxoid, tetanus toxoid, pertussis toxoid, filamentous haemagglutinin, pertactin, hepatitis B surface antigen, type 1 (Mahoney) 40 D antigen, type 2 (MEF-1) 8D antigen, type 3 (Saukett) 32D antigen, haemophilus influenzae type b polysaccharide (conjugated to tetanus toxoid)	powder and suspension for suspension for injection	30IU/0,5ml+0IU/0,5ml+25mcg/0,5ml+25mcg/0,5ml+8mcg/0,5ml+10mcg /0,5ml+units/0,5ml+units/0,5ml+10mcg /0,5ml; glass vial 0,5ml, pre-filled syringe and (2) needles	GlaxoSmithKline Biologicals s.a., Rue de l' Institut, 89 B-1330 Rixensart- batch releaser, GlaxoSmithKline Biologicals SA, Rue des Aulnois, 637 59230 Saint-Amand-Les-Eaux, France- bulk manufacturer, packager, quality control(microbiological), 1. GlaxoSmithKline Biologicals s.a., Rue de l' Institut, 89 B-1330 Rixensart, Belgium 2.GlaxoSmithkline Biologicals SA, Parc de la Noire Epine Rue Fleming, 20, Wavre, B-1300, Belgium- quality control (physicochemical)	Belgium	GlaxoSmithKline Biologicals s.a., Rue de l' Institut, 89 B-1330 Rixensart	Belgium	PoM	30.05.2022
13	Polyoxidonium	azoximer bromide	solution for injection	3mg/ml; (1) syringe 1ml and (1) needle, (1) syringe 2ml and (1) needle, (5) glass vials 1ml and (1) needle, (5) glass vials 2ml (1) needle	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	PoM	30.05.2022
14	Polyoxidonium	azoximer bromide	solution for injection and for topical use	3mg/ml; (5) glass vials 1m; (5) glass vials 2ml	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	NPO Petrovax Pharm LLC, 1 Sosnovaya str., Pokrov village, Podolsk, Moscow region, 142143	Russia	PoM	30.05.2022

15	Grammidin for kids	gramicidin S (gramicidin S dihydrochloride), cetylpyridinium chloride (cetylpyridinium chloride monohydrate)	spray for topical use	0.03mg+0.1mg; aluminum bottle 112 dose with dosing device	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2- secondary packager, quality control, batch release, Delpharm Bladel B.V., Industrieweg 1, 5531 AD Bladel, the Netherlands bulk manufacturer, primary packager	Russia	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	30.05.2022
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LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 05-2/22 on May 30, 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	Fortrans	macrogol (macrogol 4000), sodium sulfate anhydrous, sodium hydrogen carbonate, sodium chloride, potassium chloride	powder for oral solution	64g+5.7g+1.68g+1.46g+0.75g ; (4) sachets 73,69g	Beaufour Ipsen Industrie, rue Ethe Virton, 28100 Dreux	France	Ipsen Consumer Healthcare, 65 quai Georges Gorse, 92100 Boulogne-Billancourt	France	OTC	30.05.2022
2	Omnadren 250	testosterone (testosterone propionate), testosterone (testosterone phenylpropionate), testosterone (testosterone isocaproate), testosterone (testosterone decanoate)	oily solution for i/m injection	30mg/ml+60mg/ml+60mg/ml+100mg/ml; (5) ampoules 1ml	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	30.05.2022
3	Ketotifen Sopharma	ketotifen (ketotifen hydrofumarate)	tablets	1mg; (30/3x10/) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	30.05.2022

4	Ciprofloxacin	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	250mg; (10/1x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	PoM	30.05.2022
5	Ciprofloxacin	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	500mg; (10/1x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	PoM	30.05.2022
6	Tamsol	tamsulosin (tamsulosin hydrochloride)	capsules modified-release	0,4mg; (10/1x10/) in blister, (30/3x10/) in blister	Gedeon Richter Plc., Gyomroi ut 19-21, Budapest, 1103- quality control(microbiological), batch releaser, Gedeon Richter Romania S.A., Guza Voda str. 99-105, Targu-Mures, 540306, Romania- bulk manufacturer, packager, quality control(physicochemical)	Hungary	Gedeon Richter Plc., Gyomroi ut 19-21, Budapest, 1103	Hungary	PoM	30.05.2022

7	Nixar	bilastin	tablets	20mg; (10/1x10/) in blister, (20/2x10/) in blister, (30/3x10/) in blister, (50/5x10/) in blister	A.Menarini Manufacturing Logistics and Services S.r.l., Via Campo Di Pile, 67100 L` Aquila- bulk manufacturer, packager, batch releaser, A. Menarini Manufacturing Logistics and Services S.r.l., Via Sette Santi, 3 50131 Firenze, Italy- quality control	Italy	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, 1611	Luxembourg	PoM	30.05.2022
8	Naklofen	diclofenac (diclofenac sodium)	solution for injection	75mg/3ml; (5/1x5/) ampoules 3ml in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, batch releaser, 1.KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto, Slovenia, 2.KRKA d.d., Novo mesto, Povahova ulica 5, 8501 Novo Mesto, Slovenia- quality control	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta	Slovenia	PoM	30.05.2022
9	Mezym forte 10000	pancreatin (lipase, amylase, protease)	tablets gastro-resistant	10000U+not less than 7500U+not less than 375U; (10/1x10/) in blister, (20/2x10/) in blister	Berlin-Chemie A.G.,Glienicker Weg 125, D-12489 Berlin- packager, quality control, batch releaser, Berlin-Chemie A.G., Tempelhofer Weg 83, D-12347 Berlin,Germany- bulk manufacturer	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	OTC	30.05.2022

10	Troypofol	propofol	emulsion for injection/infusion	10mg/ml; 20ml glass vial	Troikaa Pharmaceuticals Ltd., C-1, Sara Industrial Estate, Selaqui, Dehradun-248197, Uttarakhand	India	Troikaa Pharmaceuticals Ltd., Commerce House-1, Satya Marg, Bodakdev, Ahmedabad-380054	India	PoM	30.05.2022
11	Aspirin Cardio	acetylsalicylic acid	tablets gastro-resistant	100mg; (28/2x14/) in blister	Bayer Bitterfeld GmbH, Ortsteil Greppin Salegaster Chaussee 1, 06803 Bitterfeld-Wolfenpackager, quality control, batch releaser, Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen, Germany- bulk manufacturer	Germany	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	30.05.2022
12	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	30.05.2022
13	Otirelax	phenazone, lidocaine (lidocaine hydrochloride)	drops ear	40mg/g+10mg/g; 15ml plastic bottle-dropper	Rompharm Company SRL, Str. Eroilor, Nr. 1A, city Otopeni, Ilfov, 075100, Bld. Rompharm 1, Rompharm 2	Romania	Rompharm Company SRL, Str. Eroilor, Nr. 1A, city Otopeni, Ilfov, 075100	Romania	PoM	30.05.2022

14	Ortophen	diclofenac (diclofenac sodium)	tablets gastro-resistant	25mg; (30/3x10/) in blister	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PoM	30.05.2022
15	Ciprofloxacin	ciprofloxacin (ciprofloxacin hydrochloride)	drops eye	3mg/ml; 5ml plastic vial-dropper	S.C. Rompharm Company S.R.L., Str. Eroilor Nr.1A, Bld. Rompharm 1, Rompharm 2, city Otopeni, Ilfov, 075100	Romania	S.C. Rompharm Company S.R.L., Str. Eroilor Nr.1A, Bld. Rompharm 1, Rompharm 2, city Otopeni, Ilfov, 075100	Romania	PoM	30.05.2022
16	Tobrom	tobramycin	drops eye	3mg/ml; 5ml plastic bottle-dropper	Rompharm Company SRL, Str. Eroilor, Nr. 1A, city Otopeni, Ilfov, 075100, Bld. Rompharm 1, Rompharm 2	Romania	Rompharm Company SRL, Str. Eroilor, Nr. 1A, city Otopeni, Ilfov, 075100	Romania	PoM	30.05.2022
17	Magnelis B6	magnesium (magnesium lactate), pyridoxine (pyridoxine hydrochloride)	tablets coated	48mg+5mg; (90) in plastic container, (50/5x10/) in blister	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	JSC "OTCPharm", Testovskaya street, room II, flr.12, h.10, off. 29, Moscow 123112	Russia	OTC	30.05.2022

18	Kadcyla	trastuzumab emtansine	powder for concentrate for solution for infusion	160mg; glass vial 20ml	F. Hoffmann-La Roche Ltd. 4303 Kaiseraugst	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	30.05.2022
19	Kadcyla	trastuzumab emtansine	powder for concentrate for solution for infusion	100mg; glass vial 15ml	F. Hoffmann-La Roche Ltd. 4303 Kaiseraugst	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	30.05.2022

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 05-2/22 on May 30, 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	Bisoprolol	bisoprolol (bisoprolol fumarate)	tablets film-coated	2,5mg; (30/3x10/) in blister, (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	18066/1/1
2	Bisoprolol	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (30/3x10/) in blister, (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	18067/1/1

3	Bisoprolol	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg; (30/3x10/) in blister, (60/6x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64a, No4, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	PoM	18068/1/1
4	Amlodipine 5mg tablets	amlodipine (amlodipine besilate)	tablets	5mg; (30/3x10/) in blister	Lek S.A.,16 Podlipie Str., 95-010 Strykow- packager, quality control, batch releaser, Sandoz Grup Saglik Ueruenleri Ilaclari San. ve A.S., Gebze Organized Industrial Region Ihsan Dede, Cadde No. 900 Sokak, 41400, Gebze-Kocaeli, Turkey- bulk manufacturer	Poland	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	20396/1/1
5	Amlodipine 10mg tablets	amlodipine (amlodipine besilate)	tablets	10mg; (100/10x10/) in blister	Lek S.A.,16 Podlipie Str., 95-010 Strykow- packager, quality control, batch releaser, Sandoz Grup Saglik Ueruenleri Ilaclari San. ve A.S., Gebze Organized Industrial Region Ihsan Dede, Cadde No. 900 Sokak, 41400, Gebze-Kocaeli, Turkey- bulk manufacturer	Poland	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	20397/1/1

6	Hemoxiparine	enoxaparin (enoxaparin sodium)	solution for injection	2000 anti-Xa IU/0,2ml; (10/5x2/) glass syringes in blister	Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region, 141345- quality control, batch releaser, "Sotex"PharmFirm" CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, 141345, Russia- bulk manufacturer, primary packager, "Sotex"PharmFirm" CJSC, Bld. 12, village Belikovo, Sergiev Posad urban district, Moscow Region, 141345, Russia- secondary packager	Russia	Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	PoM	19896/1/1
7	Hemoxiparine	enoxaparin (enoxaparin sodium)	solution for injection	4000 anti-Xa IU/0,4ml; (10/5x2/) glass syringes in blister	Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region, 141345- quality control, batch releaser, "Sotex"PharmFirm" CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, 141345, Russia- bulk manufacturer, primary packager, "Sotex"PharmFirm" CJSC, Bld. 12, village Belikovo, Sergiev Posad urban district, Moscow Region, 141345, Russia- secondary packager	Russia	Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	PoM	19896/1/1

8	Hemoxiparine	enoxaparin (enoxaparin sodium)	solution for injection	6000 anti-Xa IU/0,6ml; (10/5x2/) glass syringes in blister	Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region, 141345- quality control, batch releaser, "Sotex"PharmFirm" CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, 141345, Russia- bulk manufacturer, primary packager, "Sotex"PharmFirm" CJSC, Bld. 12, village Belikovo, Sergiev Posad urban district, Moscow Region, 141345, Russia- secondary packager	Russia	Sotex"PharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad, Moscow Region, 141345	Russia	PoM	19898/1/1
9	Theraflex Chondrocream Forte	chondroitin sulfate, meloxicam	cream for external use	50mg/g+10mg/g; 30g aluminium tube, 100g aluminium tube	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	17771/2/2
10	Milgamma protekt	benfotiamine	tablets film-coated	300mg; (30/3x10/) 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 Boeblingen	Germany	OTC	19658/3/1

11	Milgamma	thiamine (thiamine hydrochloride), pyridoxine (pyridoxine hydrochloride), cyanocobalamin, lidocaine(lidocaine hydrochloride)	solution for i/m injection	100mg/2ml+100mg/2ml +1mg/2ml+20mg/2ml; (5) ampoules 2ml	Solupharm Pharmazeutische Erzeugnisse GmbH, Industriestrasse 3, D-34212 Melsungen	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen	Germany	PoM	17024/1/1
12	Magnerot	magnesium orotate (magnesium orotate dihydrate)	tablets	500mg; (20/2x10/) in blister, (50/5x10/) 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 Boeblingen	Germany	OTC	17669/2/1
13	Gabagamma	gabapentin	capsules hard	300mg; (20/2x10/) and (50/5x10/), in blister	Medis International a.s., Prumyslova 961/16, Bolatice, 74723- packager, batch releaser, Dragenopharm Apotheker Puschl GmbH, Gollstrasse 1, 84529 Tittmoning, Germany-bulk manufacturer, quality control (physicochemical), Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany-quality control (microbiological)	Czech Republic	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen	Germany	PoM	19925/1/1

14	Gabagamma	gabapentin	capsules hard	400mg; (20/2x10/) and (50/5x10/), in blister	<p>Medis International a.s., Prumyslova 961/16, Bolatice, 74723- batch releaser, packager, Dragenopharm Apotheker Puschl GmbH, Gollstrasse 1, 84529 Tittmoning, Germany-bulk manufacturer, quality control (physicochemical), Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany-quality control (microbiological)</p>	Czech Republic	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen	Germany	PoM	19926/1/1
15	Nanotropil novo	fonturacetam	tablets	100mg; (10/1x10/) in blister, (30/3x10/) in blister	<p>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)</p>	Russia	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo city, Fabrichnaya St., 2	Russia	PoM	20086/1/1

16	Ultravist 370	iopromide	solution for injection	769mg/ml (370mg iodine/ml); (10) glass vial 100ml	Bayer AG, Mullerstrasse 178, 13353, Berlin for Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen, Germany	Germany	Bayer AG, Mullerstrasse 178, 13353, Berlin for Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen, Germany	Germany	PoM	17051/3/3
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LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 05-2/22 on May 30, 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	Fortrans	macrogol (macrogol 4000), sodium sulfate anhydrous, sodium hydrogen carbonate, sodium chloride, potassium chloride	powder for oral solution	64g+5.7g+1.68g+1.46g +0.75g ; (4) sachets 73,69g	Beaufour Ipsen Industrie, rue Ethe Virton, 28100 Dreux	France	Ipsen Consumer Healthcare, 65 quai Georges Gorse, 92100 Boulogne-Billancourt	France	OTC	16307/1
2	Pabi-Dexamethason	dexamethasone	tablets	500mcg; (20/1x20/) in blister	Adamed Pharma S.A., 5 Marszalka Jozefa Pilsudskiego Str., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza St., 05-152 Czosnow	Poland	PoM	16444/1

3	Isoflurane	isoflurane	liquid for inhalation	100%; 250ml glass bottle	Piramal Pharma Limited, Sy.No.7-70, 70/1 & 70/2, Digwal Village, Kohir Mandal, Sangareddy District - 502 321, Telangana	India	Piramal Pharma Limited, Piramal Ananta, Agastya Corporate Park, Opposite Fire Brigade, Kamani Junction, LBS Marg, Kurla (West), Mumbai-400070, Maharashtra	India	PoM	16781/1
4	Caffetin Lady	ibuprofen (ibuprofen lysinate)	tablets film-coated	200mg; (10/1x10/) 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	OTC	20583/1
5	Naklofen	diclofenac (diclofenac sodium)	solution for injection	75mg/3ml; (5) ampoules 3ml	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	16675/3
6	Mezym forte 10000	pancreatin (lipase, amylase, protease)	tablets gastro-resistant	not less than 10000U+not less than 7500U+not less than-375U; (10/1x10/) and (20/2x10/) in blister	Berlin-Chemie A.G.,Glienicker Weg 125, D-12489 Berlin-batch releaser, packager, Berlin-Chemie A.G., Tempelhofer Weg 83, D-12347 Berlin,Germany-bulk manufacturer	Germany	Berlin-Chemie A.G., Glienicker Weg 125, 12489 Berlin	Germany	OTC	16665/4

7	Mezym forte 10000	pancreatin (lipase, amylase, protease)	tablets gastro-resistant	not less than 10000U+not less than 7500U+not less than 375U; (10/1x10/) in blister, (20/2x10/) in blister	Berlin-Chemie A.G.,Glienicker Weg 125, 12489 Berlin- batch releaser, Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden, Germany- bulk manufacturer, packager, quality control	Germany	Berlin-Chemie A.G.,Glienicker Weg 125, 12489 Berlin	Germany	OTC	20080/2
8	Magnelis B6	magnesium (magnesium lactate), pyridoxine (pyridoxine hydrochloride)	tablets film-coated	48mg+5mg; (90), in plastic container, (50/5x10/) in blister	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28 f	Russia	JSC "OTCPharm", Testovskaya street, room II, flr.12, h.10, off. 29, Moscow 123112	Russia	OTC	15199/2
9	Clotrimazole	clotrimazole	cream for external use	10mg/g; aluminium tube 20g	GlaxoSmithKline Pharmaceuticals S.A.,189 Grunwaldzka street, 60-322 Poznan	Poland	GlaxoSmithKline Pharmaceuticals S.A.,189 Grunwaldzka street, 60-322 Poznan	Poland	OTC	19746/3
10	Maviret	glecaprevir, pibrentasvir	tablets film-coated	100mg+40mg; (84(4x21(7x3)) in blister	AbbVie Deutschland GmbH & Co. KG, Knolstrasse, 67061 Ludwigshafen- batch releaser, packager, quality control, Fournier Laboratories Ireland Limited, Anngrove, Carrigtwohill, Co. Cork, Ireland- bulk manufacturer	Germany	AbbVie Biopharmaceuticals GmbH, Alte Steinhauserstrasse 14, 6330 Cham	Switzerland	PoM	18744/6/2

11	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	20669/1
12	Trimecor MR	trimetazidine (trimetazidine dihydrochloride)	tablets film-coated modified-release	35mg; (30/3x10/) in blister, (60/6x10/) in blister	GM Pharmaceuticals Ltd, 65, Phonichala str., 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, 65, Phonichala str., 0165 Tbilisi	Georgia	PoM	19435/2
13	Cordix	clopidogrel	tablets film-coated	75mg; 28(2x14) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice- batch releaser, Adamed Pharma S.A., 33, Szkolna St., 95-054 Ksawerow, Poland- bulk manufacturer, packager	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza St., 05-152 Czosnow	Poland	PoM	17058/2/2

14	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	19260/3/1
15	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	19261/3/1

16	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, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	18830/5/1
17	Velaxin	venlafaxine (venlafaxine hydrochloride)	capsules prolonged-release	150mg; (28/2x14/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30- 38	Hungary	PoM	17073/3
18	Velaxin	venlafaxine (venlafaxine hydrochloride)	capsules prolonged-release	37,5mg; (28/2x14/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30- 38	Hungary	PoM	17074/3
19	Velaxin	venlafaxine (venlafaxine hydrochloride)	capsules prolonged-release	75mg; (28/2x14/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30- 38	Hungary	PoM	17075/3

20	Velaxin	venlafaxine (venlafaxine hydrochloride)	capsules prolonged-release	37,5mg; (28/2x14/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	19841/1
21	Velaxin	venlafaxine (venlafaxine hydrochloride)	capsules prolonged-release	75mg; (28/2x14/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	19842/1
22	Velaxin	venlafaxine (venlafaxine hydrochloride)	capsules prolonged-release	150mg; (28/2x14/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	19843/1
23	GalvusMet	vildagliptin, metformin (metformin hydrochloride)	tablets film-coated	50mg+850mg; (30/3x10/) in blister, (60/6x10/) in blister	Novartis Saglik, Gida Ve Tarim Urunleri San.Ve Tic. A.S., Yenisehir Mahallesi, Ihlara Vadisi Sokak,No 2, Pendik,Istanbul 34912-packager, batch releaser, Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd., 10 Tuas Bay Lane, 637461, Singapore- bulk manufacturer, quality control	Turkey	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19535/3

24	GalvusMet	vildagliptin, metformin (metformin hydrochloride)	tablets film-coated	50mg+1000mg; (60/6x10/) in blister	Novartis Saglik, Gida Ve Tarim Urunleri San.Ve Tic. A.S., Yenisehir Mahallesi, Ihlara Vadisi Sokak, No 2, Pendik, Istanbul 34912- packager, batch releaser, Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd., 10 Tuas Bay Lane, 637461, Singapore- bulk manufacturer, quality control	Turkey	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19536/3
25	GalvusMet	vildagliptin, metformin (metformin hydrochloride)	tablets film-coated	50mg+850mg; (30/3x10/) in blister, (60/6x10/) in blister	Novartis Saglik, Gida Ve Tarim Urunleri San.Ve Tic. A.S., Yenisehir Mahallesi, Ihlara Vadisi Sokak, No 2, Pendik, Istanbul 34912- packager, batch releaser, Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr Baden Wurttemberg, Germany- bulk manufacturer, quality control (physicochemical), Novartis Pharma Stein AG Novartis Technical Operations Schweiz, Stein Solids, Schaffhauserstrasse, 4332 Stein AG, Switzerland- quality control (microbiological)	Turkey	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19537/3

26	GalvusMet	vildagliptin, metformin (metformin hydrochloride)	tablets film-coated	50mg+1000mg; (30/3x10/) in blister, (60/6x10/) in blister	Novartis Saglik, Gida Ve Tarim Urunleri San.Ve Tic. A.S., Yenisehir Mahallesi, Ihlara Vadisi Sokak,No 2, Pendik,Istanbul 34912-packager, batch releaser, Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr Baden Wurttemberg, Germany-bulk manufacturer, quality control (physicochemical), Novartis Pharma Stein AG Novartis Technical Operations Schweiz, Stein Solids, Schaffhauserstrasse, 4332 Stein AG, Switzerland-quality control (microbiological)	Turkey	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19538/3
27	Bronchobos	carbocisteine	capsules	375mg; (30/3x10/) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	OTC	19990/2
28	Broncholytin	glaucine (glaucine hydrobromide), ephedrine (ephedrine hydrochloride)	syrup	5,75mg/5ml+4,6mg/5 ml; 125ml 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	17232/2

29	Ketorolac	ketorolac (ketorolac tromethamine)	solution for i/m injection	30mg/ml; (10) ampoules 1ml, (10) ampoules 1ml label banderol, (10) ampoules 1ml dividella	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	17324/2/1
30	MemantinAST	memantine (memantine hydrochloride)	tablets film-coated	10mg; (28/4x7/) in blister	ONE PHARMA INDUSTRIAL PHARMACEUTICAL COMPANY SOCIETE ANONYME, 60th km N.N.R. Athinon-Lamias, Sximatari Voiotias, 32009	Greece	VIAN S.A., 2, Ag. Nektariou str., 15344 Gerakas, Pallini Attiki	Greece	PoM	20527/1
31	MemantinAST	memantine (memantine hydrochloride)	oral solution	5mg/0.5ml; glass vial 50ml with plastic cap and dosing pump	ONE PHARMA INDUSTRIAL PHARMACEUTICAL COMPANY SOCIETE ANONYME, 60th km N.N.R. Athinon-Lamias, Sximatari Voiotias, 32009	Greece	VIAN S.A., 2, Ag. Nektariou str., 15344 Gerakas, Pallini Attiki	Greece	PoM	20529/1
32	Otirelax	phenazone, lidocaine (lidocaine hydrochloride)	drops ear	40mg/g+10mg/g; 15ml plastic bottle-dropper	Rompharm Company SRL, Str. Eroilor, Nr. 1A, city Otopeni, Ilfov, 075100, Bld. Rompharm 1, Rompharm 2	Romania	Rompharm Company SRL, Str. Eroilor, Nr. 1A, city Otopeni, Ilfov, 075100	Romania	OTC	16452/2

33	Grammidin with anesthetic	gramicidin S (gramicidin S dihydrochloride), oxybuprocaine (oxybuprocaine hydrochloride), cetylpyridinium chloride	spray dosed	0,06mg/dose+0,15mg/dose+0,1mg/dose; aluminium bottle (112 dose) with pump dispenser	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2- secondary packager, quality control, batch releaser, Delpharm Bladel B.V., Industrieweg 1, 5531 AD Bladel, the Netherlands bulk manufacturer, primary packager	Russia	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	20046/2
34	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	875mg+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	17634/6
35	Flavamed effervescent tablets	ambroxol (ambroxol hydrochloride)	tablets effervescent	60mg; (10) aluminium or plastic container	Berlin-Chemie A.G.,Glienicker Weg 125, D-12489 Berlin- batch releaser, Hermes Pharma GmbH, Hans-Urmiler Ring 52, 82515 Wolfratshausen, Germany- bulk manufacturer, packager, quality control	Germany	Berlin-Chemie A.G.,Glienicker Weg 125, D-12489 Berlin	Germany	OTC	19323/2/1

36	Glivec	imatinib (imatinib mesylate)	tablets film-coated	100mg; (60/6x10/) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr, Germany-bulk manufacturer, quality control (physicochemical), Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland- quality control (microbiological)	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	19866/2
37	Glivec	imatinib (imatinib mesylate)	tablets film-coated	400mg; (30/3x10/) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr, Germany-bulk manufacturer, quality control (physicochemical), Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland- quality control (microbiological) for	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	19867/2
38	Glivec	imatinib (imatinib mesylate)	tablets film-coated	100mg; (60/6x10/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	17496/4/1

39	Glivec	imatinib (imatinib mesylate)	tablets film-coated	400mg; (30/3x10/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	16976/4/1
40	Troypofol	propofol	emulsion for injection/infusion	10mg/ml; 20ml glass vial	Troikaa Pharmaceuticals Ltd., C-1, Sara Industrial Estate, Selaqui, Dehradun-248197, Uttarakhand	India	Troikaa Pharmaceuticals Ltd., Commerce House-1, Satya Marg, Bodakdev, Ahmedabad-380054	India	PoM	16404/2
41	Visipaque	iodixanol	solution for injection	320mg iodine/ml; (10) plastic vials 100ml	GE Healthcare Ireland Limited, IDA Business Park, Carrigtwohill, Cork, T45 AV60	Ireland	GE Healthcare AS, P.O. Box 4220, Nydalen, 0401 Oslo	Norway	PoM	19108/2/1
42	Visipaque	iodixanol	solution for injection	320mg iodine/ml; (10) plastic vials 50ml	GE Healthcare Ireland Limited, IDA Business Park, Carrigtwohill, Cork, T45 AV60	Ireland	GE Healthcare AS, P.O. Box 4220, Nydalen, 0401 Oslo	Norway	PoM	19107/2/1
43	Lordestin	desloratadine (desloratadine hemisulfate)	tablets film-coated	5mg; (10/1x10/) in blister, (30/3x10/) in blister	Gedeon Richter-RUS JSC, Lesnaya st. 40, Shuvoye, Moscow region, Yegoriyevsky district, 140342	Russia	Gedeon Richter-RUS JSC, Lesnaya st. 40, Shuvoye, Moscow region, Yegoriyevsky district, 140342	Russia	PoM	16718/3

44	Ciprofloxacin	ciprofloxacin (ciprofloxacin hydrochloride)	drops eye	3mg/ml; 5ml plastic vial-dropper	S.C. Rompharm Company S.R.L., Str. Eroilor Nr.1A, Bld. Rompharm 1, Rompharm 2, city Otopeni, Ilfov, 075100	Romania	S.C. Rompharm Company S.R.L., Str. Eroilor Nr.1A, Bld. Rompharm 1, Rompharm 2, city Otopeni, Ilfov, 075100	Romania	PoM	16032/3
45	Tobrom	tobramycin	drops eye	3mg/ml; 5ml plastic bottle-dropper	Rompharm Company SRL, Str. Eroilor, Nr. 1A, city Otopeni, Ilfov, 075100, Bld. Rompharm 1, Rompharm 2	Romania	Rompharm Company SRL, Str. Eroilor, Nr. 1A, city Otopeni, Ilfov, 075100	Romania	PoM	16389/1
46	Depantol	dexpanthenol, chlorhexidine (chlorhexidine bigluconate)	suppositories vaginal	100mg+16mg; (10/2x5/)	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	18209/3
47	Analgin	metamizole (metamizole sodium)	tablets	500mg; (10/1x10/) and (20/2x10/) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	16841/3
48	Alfagin	panax ginseng, eleutherococcus senticosus, medicago sativa, emblica officinalis, trigonella foenum-graecum	capsules	50mg+200mg+500mg +800mg+500mg; (20) in plastic container, (60) in plastic container	Herbion Pakistan Pvt. Ltd., 30/28, Korangi Industrial area, Karachi-74900	Pakistan	Herbion Pakistan Pvt. Ltd., 30/28, Korangi Industrial area, Karachi-74900	Pakistan	OTC	15242/2

49	Topiramate Canon	topiramate	tablets film-coated	25mg; (28/4x7/) in blister	CJSC Canonpharma production, 105B bldg., 11, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, 141100- quality control, batch releaser, CJSC Canonpharma production, 105, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, 141100, Russia- bulk manufacturer, primary and secondary packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	PoM	16438/2/1
50	Topiramate Canon	topiramate	tablets film-coated	100mg; (28/4x7/) in blister	CJSC Canonpharma production, 105B bldg., 11, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, 141100- quality control, batch releaser, CJSC Canonpharma production, 105, Zarechnaya st., Schelkovo city, Schelkovo urban district, Moscow region, 141100, Russia- bulk manufacturer, primary and secondary packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	PoM	16439/2/1

51	Omnadren 250	testosterone (testosterone propionate), testosterone (testosterone phenylpropionate), testosterone (testosterone isocaproate), testosterone (testosterone decanoate)	solution for i/m injection, oily	30mg/ml+60mg/ml+60mg/ml+100mg/ml; (5) ampoules 1ml	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	16031/2/1
52	Traumeel	achillea millefolium MT, aconitum napellus D1, arnica montana D3, atropa belladonna D1, bellis perennis MT, calendula officinalis MT, echinacea MT, echinacea purpurea MT, hamamelis virginiana MT, hepar sulfuris D6, hypericum perforatum D6, matricaria recutita MT, mercurius solubilis Hahnemanni D6, symphytum officinale D4	ointment	0,9mg/g+0,5mg/g+15mg/g+0,5mg/g+1mg/g+4,5mg/g+1,5mg/g+1,5mg/g+4,5mg/g+0,25mg/g+0,9mg/g+1,5mg/g+0,4mg/g+1mg/g; 50g aluminium tube	Biologische Heilmittel Heel GmbH, Dr.-Reckeweg-Strasse 2-4, 76532 Baden-Baden	Germany	Biologische Heilmittel Heel GmbH, Dr.-Reckeweg-Strasse 2-4, 76532 Baden-Baden	Germany	OTC	19610/2/1
53	Miropriston	mifepristone	tablets	200mg; (3/1x3/) in blister	Obninsk Chemical Pharmaceutical Company CJSC, Kaluga region, Obninsk, Kiev highway, bld. 103, bld. 107	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	16423/1
54	Ketotifen Sopharma	ketotifen (ketotifen hydrofumarate)	tablets	1mg; (30/3x10/) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	16644/3 30.05.2022