

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 12-2/21 on December 28, 2021

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	Cytosar	cytarabine	powder lyophilized for solution for injection	100mg; glass vial	Corden Pharma Latina S.p.A, Via del Murillo, Km 2,800-04013 Sermoneta, Latina	Italy	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	20394 28.12.2021
2	Cytosar	cytarabine	powder lyophilized for solution for injection	500mg; glass vial	Corden Pharma Latina S.p.A, Via del Murillo, Km 2,800-04013 Sermoneta, Latina	Italy	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	20395 28.12.2021
3	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, TR-41480, Gebze-Kocaeli, Turkey- bulk manufacturer	Poland	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana,	Slovenia	PoM	20396 28.12.2021

4	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, TR-41480, Gebze-Kocaeli, Turkey- bulk manufacturer	Poland	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	20397 28.12.2021
5	Amlodipin	amlodipine (amlodipine besilate)	tablets	5mg; (30/3x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64a, Chapaev str., Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64a, Chapaev str., Borisov 222518, Minsk region	Belarus	PoM	20398 28.12.2021
6	Amlodipin	amlodipine (amlodipine besilate)	tablets	10mg; (30/3x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64a, Chapaev str., Borisov 222518, Minsk region	Belarus	PoM	20399 28.12.2021

7	Sermion	nicergoline	powder lyophilized for solution for injection	4mg; (4) glass vials, (4) solvent in ampoules 4ml	<p>Pfizer Manufacturing Belgium N.V., Rijksweg 12, B-2870 Puurs- powder secondary packager, batch releaser, Wyeth Farma S.A., Autovia del Norte A-1 Km 23 Desvio Algete, Km 1 28700 San Sebastian de los Reyes Madrid, Spain- powder bulk manufacturer, primary packager, quality control, Pfizer Manufacturing Belgium N.V., Rijksweg 12, B-2870 Puurs, Belgium- solvent bulk manufacturer</p>	Belgium	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	PoM	20400 28.12.2021
8	Tamiflu	oseltamivir (oseltamivir phosphate)	capsules hard	75mg; (10/1x10/) in blister	<p>F. Hoffmann-La Roche Ltd., Wurmisweg, CH-4303, Kaiseraugst- packager, quality (psysicochemical) control, batch releaser, Cenexi SAS, Rue Marcel et Jacques Gaucher, 52, Fontenay sous Bois, 94120, France- bulk manufacturer, F. Hoffmann La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Switzerland- quality (microbiological) control</p>	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070	Switzerland	PoM	20401 28.12.2021

9	Ducressa	dexamethasone (dexamethasone sodium phosphate), levofloxacin (levofloxacin hemihydrate)	drops eye	1mg/ml+5mg/ml; 5ml plastic vial-droper	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, Tubilux Pharma S.p.A., Via Costarica, 20/22, 00071 Pomezia/Rome, Italy- bulk manufacturer, packager, quality control	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	PoM	20402 28.12.2021
10	Otofix 40mg/g+10mg/g ear drops, solution	phenazone, lidocaine (lidocaine hydrochloride)	drops ear (solution)	40mg/g+10mg/g; glass bottle 15ml and dropper applicator	Sopharma JSC, Industrial zone Sandanski 2800	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	20403 28.12.2021
11	Euthyrox	levothyroxine (levothyroxine sodium)	tablets	25mcg; (100/4x25/) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	PoM	20404 28.12.2021
12	Euthyrox	levothyroxine (levothyroxine sodium)	tablets	50mcg; (100/4x25/) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	PoM	20405 28.12.2021
13	Euthyrox	levothyroxine (levothyroxine sodium)	tablets	75mcg; (100/4x25/) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	PoM	20406 28.12.2021

14	Euthyrox	levothyroxine (levothyroxine sodium)	tablets	100mcg; (100/4x25/) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	PoM	20407 28.12.2021
15	Euthyrox	levothyroxine (levothyroxine sodium)	tablets	125mcg; (100/4x25/) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	PoM	20408 28.12.2021
16	Euthyrox	levothyroxine (levothyroxine sodium)	tablets	150mcg; (100/4x25/) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	PoM	20409 28.12.2021
17	Avelox	moxifloxacin	tablets coated	400mg; (5/1x5/) in blister	Bayer Healthcare Manufacturing S.r.l., Via delle Groane, 126 20024, Garbagnate Milanese	Italy	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen,	Germany	PoM	20410 28.12.2021
18	Pergoveris	follitropin alfa, lutropin alfa	powder lyophilized for solution for s/c injection	150IU+75IU; (1) glass vial and (1) solvent in vial 1ml, (3) glass vials and (3) solvent in vials 1ml, (10) glass vials and (10) solvent in vials 1ml	Merck Serono S.A., Succursale d` Aubonne, Zone Industrielle de l` Ouriettaz, 1170 Aubonne	Switzerland	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	20411 28.12.2021

19	Mydocalm-Richter	tolperisone (tolperisone hydrochloride), lidocaine (lidocaine hydrochloride)	solution for i/m injection	100mg/ml+2,5mg/ml; (5/1x5/) ampoules 1ml in plastic tray	GEDEON RICHTER- RUS JSC, Lesnaya st. 40., Shuvoe settl., Yegoriyevsky district, Moscow region, 140342- secondary packager, quality control, batch releaser, Gedeon Richter Plc, Gyomroi st. 19-21, 1103 Budapest, Hungary- bulk manufacturer, primary packager	Russia	GEDEON RICHTER- RUS JSC, Lesnaya st. 40., Shuvoe settl., Yegoriyevsky district, Moscow region, 140342	Russia	PoM	20412 28.12.2021
20	Norditropin NordiFlex	somatropin	solution for s/c injection	6mg/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 Vaerloseevej 30, Vaerlosee, 3500, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	20413 28.12.2021
21	Famotidine	famotidine	powder lyophilized for solution for injection	20mg; (5) glass vials and (5) solvent in ampoules 5ml	FSOE "Kursk Biofactory", 305004, Kursk region, Kursk, Razina street, building 5	Russia	"B-PHARM" LLC, 143026, Moscow region, Odintsovo, d.p. Novoivanovskoye, Agrokhimikov str. 2A	Russia	PoM	20414 28.12.2021
22	Pulmicort 0,25mg/ml	budesonide	nebuliser suspension	0,25mg/ml; (20/4x5/) plastic container in pack 2ml	AstraZeneca AB, SE-151 85, Sodertalje	Sweden	AstraZeneca AB, SE-151 85, Sodertalje	Sweden	PoM	20415 28.12.2021

23	Pulmicort 0,5mg/ml	budesonide	nebuliser suspension	0,5mg/ml; (20/4x5/) plastic container in pack 2ml	AstraZeneca AB, SE-151 85, Sodertalje	Sweden	AstraZeneca AB, SE-151 85, Sodertalje	Sweden	PoM	20416 28.12.2021
24	Dexketoprofen	dexketoprofen (dexketoprofen trometamol)	solution for injection/infusion	25mg/ml; (5/1x5/) ampoules 2ml in blister, (10/2x5/) ampoules 2ml in blister	FSOE "Kursk Biofactory", 305004, Kursk region, Kursk, Razina street, building 5	Russia	"B-PHARM" LLC, 143026, Moscow region, Odintsovo, d.p. Novoivanovskoye, Agrokhimikov str. 2A	Russia	PoM	20417 28.12.2021
25	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, Calwer Str. 7, 71034 Boblingen	Germany	PoM	20418 28.12.2021
26	Captopril	captopril	tablets	50mg; (30/3x10/) 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 222518, Minsk region	Belarus	PoM	20419 28.12.2021

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 12-2/21 on December 28, 2021

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	Canephron N	centauri herba, levistici radix, rosmarini folia	drops oral	6mg/g+6mg/g+6mg/g; glass container-dropper 100ml	Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt	Germany	Bionorica SE, Kerschensteinerstr . 11-15, 92318 Neumarkt	Germany	PoM	20376 28.12.2021
2	Sinupret	gentiane radix, primulae flos, rumicis herba, sambuci flos, verbenae herba	drops oral	2mg/g+6mg/g+6mg/g+6 mg/g+6mg/g; 100ml glass container-dropper	Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt	Germany	Bionorica SE, Kerschensteinerstr . 11-15, 92318 Neumarkt	Germany	PoM	20377 28.12.2021
3	Valmox	levofloxacin (levofloxacin hemihydrate)	tablets film- coated	500mg; (10/1x10/) in blister	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi- packager, quality control, batch releaser, INNOVA CAPTAB, 81-B, EPIP, Phase-I, Jharmajri, Baddi, Distt. Solan [H.P.], India- bulk manufacturer	Georgia	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi	Georgia	PoM	20378 28.12.2021
4	Noofen	gamma-amino-beta- phenylbutyric acid hydrochloride	capsules	250mg; (20/2x10/) in blister	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	Olainfarm JSC, 5 Rupnicu Str., Olaime, LV-2114	Latvia	PoM	20379 28.12.2021

5	Noofen	gamma-amino-beta-phenylbutyric acid hydrochloride	capsules	500mg; (24/4x6/) in blister	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	PoM	20380 28.12.2021
6	Avexon-Rational	ceftriaxone (ceftriaxone sodium)	powder for solution for i/m and i/v injection	1000mg; (1) glass vial, (50) glass vials	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	20381 28.12.2021
7	Enterofuryl	nifuroxazide	suspension oral	200mg/5ml; 90ml suspension in 125ml glass bottle and plastic measuring spoon (2,5ml/5ml)	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	PoM	20382 28.12.2021
8	Fluimucil-antibiotic IT	thiamphenicol (thiamphenicol glycinate acetylcysteinate)	powder lyophilized for solution for i/m injection and inhalation	500mg; (3) glass vials and (3) solvent in ampoules 4ml	Zambon S.P.A., Via della Chimica, 9, Vicenza, 36100	Italy	Zambon S.P.A., Via Lillo del Duca, 10, Bresso, 20091	Italy	PoM	20383 28.12.2021

9	Amoxicillin	amoxicillin	granules for oral suspension	250mg/5ml; 40g granules in 100ml glass bottle and measuring spoon 5ml	Hemofarm A.D. 26300, Vrsac, Beogradskii put bb- batch releaser, Hemofarm A.D., Vrsac, 26224, Dubovac, str. Cara Lazara bb, Serbia- bulk manufacturer, packager, quality control	Serbia	Hemofarm A.D. 26300, Vrsac, Beogradskii put bb	Serbia	PoM	20384 28.12.2021
10	Niperten	bisoprolol (bisoprolol fumarate)	tablets film-coated	2,5mg; (30/2x15/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, KRKA, tovarna zdravil, d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	20385 28.12.2021
11	Niperten	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (30/2x15/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, KRKA, tovarna zdravil, d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	20386 28.12.2021

12	Niperten	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg; (30/2x15/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, KRKA, tovarna zdravil, d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	20387 28.12.2021
13	Timalin	polypeptides of thymus	powder lyophilized for solution for i/m injection	10mg; (5) glass vials; (10) glass vials	Samson-Med LLC, Moscow highway, 13, Saint Petersburg, 196158	Russia	Samson-Med LLC, Moscow highway, 13, Saint Petersburg, 196158	Russia	PoM	20388 28.12.2021
14	Hydrochlorothiazide	hydrochlorothiazide	tablets	25mg; (100/4x25/) in blister	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	20389 28.12.2021
15	Gelofusine	gelatin succinylated, sodium chloride	solution for infusion	40mg/ml+7,01mg/ml; (10) plastic bottles 500ml	B.Braun Medical AG, Route de Sorge, 9 CH-1023 Crissier	Switzerland	B.Braun Melsungen AG, Carl-Braun-Strasse 1, 34212 Melsungen	Germany	PoM	20390 28.12.2021

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N N 12-2/21 on December 28, 2021

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	Aquadetrim plus	vitamin A, vitamin D3	drops oral	20000IU/ml+10000IU/ml; 10ml glass bottle-dropper	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	17654/1/1 28.12.2021
2	Galvus	vildagliptin	tablets	50mg; (28/2x14/) in blister, (56/4x14/) in blister	Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19791/1/1 28.12.2021

3	Controloc	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant film-coated	40mg; (14/1x14/) in blister, (28/2x14/) in blister	Takeda GmbH, Lehnitz str. 70-98, 16515 Oranienburg	Germany	Takeda GmbH, Byk-Gulden str. 2, D-78467, Konstanz	Germany	PoM	18685/2/1 28.12.2021
4	Vsiqq	Brolucizumab	solution for intraocular injection	120mg/ml; glass vial and filter needle	Novartis Pharma Stein AG Technical Operations Schweiz, Stein Steriles, Schaffhauserstrasse, Stein AG, 4332	Switzerland	Novartis Overseas Investments AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19953/1/1 28.12.2021
5	Fentavera	fentanyl	patch transdermal	50mcg/h; (5) patches	Acino AG, Am Windfeld 35, 83714 Miesbach- batch releaser, Luye Pharma AG, Am Windfeld 27 and 35, 83714 Miesbach, Germany- bulk manufacturer, packager, quality control	Germany	Acino AG, Leopoldstrasse 115, 80804 Munich	Germany	PoM	18857/2/2 28.12.2021
6	Fentavera	fentanyl	patch transdermal	75mcg/h; (5) patches	Acino AG, Am Windfeld 35, 83714 Miesbach- batch releaser, Luye Pharma AG, Am Windfeld 27 and 35, 83714 Miesbach, Germany- bulk manufacturer, packager, quality control	Germany	Acino AG, Leopoldstrasse 115, 80804 Munich	Germany	PoM	18858/2/2 28.12.2021
7	Clopidogrel-Asteria	clopidogrel (clopidogrel bisulfate)	tablets film-coated	75mg; (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 15 Ermou str. 14564 Kifissia, Attica	Greece	PoM	18701/1/1 28.12.2021

8	Proculin	naphazoline (naphazoline hydrochloride)	drops eye (solution)	0,3mg/ml; 10ml plastic container	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje-batch releaser, Mefar Ilac Sanayii A.S., Ramazanoglu, Mah. Ensar-Cad. No:20, 34906 Kurtkoy-Pendik, Istanbul, Turkey-bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	OTC	17357/2/1 28.12.2021
9	Sodium chloride	sodium chloride	solution for injection	9mg/ml; (10/1x10/) ampoules 5ml label banderol, (10/1x10/) ampoules 5ml dividella, (10/1x10/) ampoules 5ml CAMA	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	PoM	16797/2/1 28.12.2021
10	Febrofid	ketoprofen (ketoprofen lysine)	gel for external use	25mg/g; 30g aluminium tube, 50g aluminium tube	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	19781/1/1 28.12.2021

11	Rissar	risperidone	tablets film-coated	1mg; (20/2x10/) 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	17405/2/1 28.12.2021
12	Rissar	risperidone	tablets film-coated	2mg; (20/2x10/) 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	17406/2/1 28.12.2021
13	Rissar	risperidone	tablets film-coated	3mg; (20/2x10/) 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	17407/2/1 28.12.2021
14	Emsibel	methylethylpiridinol hydrochloride	solution for i/v and i/m injection	30mg/ml; (5/1x5/) ampoules 5ml, (10/2x5/) ampoules 5ml	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30- quality control, batch releaser, Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30, N2, Belarus- bulk manufacturer, packager	Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	PoM	16815/1/1 28.12.2021
15	Valerian extract	valerian thick extract	tablets coated	20mg; (50/5x10/) in blister, (50/2x25/) in blister, (25) in blister, (10) in blister, (50) glass bottle, (50/1x50/) glass bottle	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	OTC	16563/1/1 28.12.2021

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-2/21 on December 28, 2021

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1	Verospiron	spironolactone	tablets	25mg; (20/1x20/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	19270/1 28.12.2021
2	Verospiron 50mg	spironolactone	capsules	50mg; (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	19075/1 28.12.2021
3	Strepsils	dichlorobenzyl alcohol, amylmetacresol	lozenges with honey and lemon flavour	1,2mg+0,6mg; (24/2x12/), (36/3x12/), in blister	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	OTC	19410/1 28.12.2021

4	Relief Advance	benzocaine	ointment rectal	200mg/g; 28.4g laminated tube and applicator	Famar S.A.,National Road Athens-Lamia, Km 49, 19011 Avlona	Greece	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	17203/2 28.12.2021
5	Timalin	polypeptides of thymus	powder lyophilized for solution for i/m injection	10mg; (5) glass vials; (10) glass vials	Samson-Med LLC, Moscow highway, 13, Saint Petersburg, 196158	Russia	Samson-Med LLC, Moscow highway, 13, Saint Petersburg, 196158	Russia	PoM	15833/2/4 28.12.2021
6	Canephron N	centauri herba, levistici radix, rosmarini folia	drops oral	6mg/g+6mg/g+6mg/g; glass container-dropper 100ml	Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt	Germany	Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt	Germany	PoM	14577/1 28.12.2021
7	Sinupret	gentian radix, primulae flos, rumicis herba, sambuci flos, verbenae herba	drops oral	2mg/g+6mg/g+6mg/g+6mg/g+6mg/g; glass container-dropper 100ml	Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt	Germany	Bionorica SE, Kerschensteinerstr. 11-15, 92318 Neumarkt	Germany	PoM	14568/1 28.12.2021
8	Sandimmun Neoral	ciclosporin	capsules soft	25mg; (50/10x5) in blister	Lek Pharmaceuticals d.d.,Trimlini 2D, Lendava, 9220 -batch releaser,packager, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany-bulk manufacturer	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	18340/1 28.12.2021

9	Sandimmun Neoral	ciclosporin	capsules soft	50mg; (50/10x5/) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220 -batch releaser, packager, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany- bulk manufacturer	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	18341/1 28.12.2021
10	Sandimmun Neoral	ciclosporin	capsules soft	100mg; (50/10x5/) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220 -batch releaser, packager, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany- bulk manufacturer	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	18342/1 28.12.2021
11	Detralex	diosmin, hesperidin	tablets film- coated	450mg+50mg; (30/2x15/), (36/3x12/) and (60/4x15/) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	OTC	17194/2 28.12.2021
12	Valmox	levofloxacin (levofloxacin hemihydrate)	tablets film- coated	500mg; (10/1x10/) in blister	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi-batch releaser, packager, M/s INNOVA CAPTAB, 81-B, EPIP, Phase-I, Jharmajri, Baddi, Distt. Solan [H.P.], India- bulk manufacturer	Georgia	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi	Georgia		16004/3 28.12.2021

13	Xalkori	crizotinib	capsules	200mg; (10/1x10/) in blister, (60/6x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstätte Freiburg, Mooswaldallee 1, 79090 Frieberg	Germany	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	PoM	18884/2 28.12.2021
14	Xalkori	crizotinib	capsules	250mg; (10/1x10/) in blister, (60/6x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstätte Freiburg, Mooswaldallee 1, 79090 Frieberg	Germany	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	PoM	18885/2 28.12.2021
15	Ocrevus	ocrelizumab	concentrate for solution for infusion	30mg/ml; 10ml glass vial	F. Hoffmann-La Roche Ltd. 4303 Kaiseraugst-secondary packager, batch releaser, Roche Diagnostics GmbH, Sandhofer Strasse 116, Mannheim, Baden Wurttemberg 68305, Germany-bulk manufacturer, primary packager	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	18365/3 28.12.2021
16	Clexane	enoxaparin (enoxaparin sodium)	solution for injection	20mg/0,2ml; (2) pre-filled syringe 0,2ml	SANOFI WINTHROP INDUSTRIE, MAISONS-ALFORT, 180 rue Jean Jaures, 94700	France	Sanofi-Aventis France, 82 avenue Raspail, 94250 Gentilly	France	PoM	17471/1 28.12.2021
17	Clexane	enoxaparin (enoxaparin sodium)	solution for injection	40mg/0,4ml; N10(5x2) pre-filled syringe 0,4ml	SANOFI WINTHROP INDUSTRIE, MAISONS-ALFORT, 180 rue Jean Jaures, 94700	France	Sanofi-Aventis France, 82 avenue Raspail, 94250 Gentilly	France	PoM	17470/2/1 28.12.2021

18	Clexane	enoxaparin (enoxaparin sodium)	solution for injection	60mg/0,6ml; (2) pre-filled syringe 0,6ml	SANOFI WINTHROP INDUSTRIE, MAISONS-ALFORT, 180 rue Jean Jaures, 94700	France	Sanofi-Aventis France, 82 avenue Raspail, 94250 Gentilly	France	PoM	17469/1 28.12.2021
19	GripptoFlu cold and flu	paracetamol, phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid	powder for oral solution with cranberry flavour	325mg+10mg+20mg+50mg; (10) sachet 13g	Marbiopharm JSC, 424006, the Republic of Mari El, Yoshkar-Ola, st. Karl Marx 121	Russia	Marbiopharm JSC, 424006, the Republic of Mari El, Yoshkar-Ola, st. Karl Marx 121	Russia	OTC	17123/1 28.12.2021
20	Cardiomagnyl	acetylsalicylic acid, magnesium hydroxide	tablets film-coated	75mg+15.2mg; (30) and (100) in glass container	Takeda GmbH, Lehnitzstrasse 70-98, Oranienburg 16515	Germany	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	17292/3/1 28.12.2021
21	Cardiomagnyl	acetylsalicylic acid, magnesium hydroxide	tablets film-coated	150mg+30,39mg; (30) and (100) in glass container	Takeda GmbH, Lehnitzstrasse 70-98, Oranienburg 16515	Germany	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	17291/3/1 28.12.2021
22	Prestance 5mg/5mg	perindopril (perindopril arginine), amlodipine (amlodipine besilate)	tablets	5mg+5mg; (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co Wicklow	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	17894/3 28.12.2021
23	Prestance 5mg/10mg	perindopril (perindopril arginine), amlodipine (amlodipine besilate)	tablets	5mg+10mg; (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co Wicklow	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	17895/3 28.12.2021

24	Prestance 10mg/5mg	perindopril (perindopril arginine), amlodipine (amlodipine besilate)	tablets	10mg+5mg; (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co Wicklow	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	17897/3 28.12.2021
25	Prestance 10mg/10mg	perindopril (perindopril arginine), amlodipine (amlodipine besilate)	tablets	10mg+10mg; (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co Wicklow	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	17896/3 28.12.2021
26	Amoxicillin	amoxicillin	granules for oral suspension	250mg/5ml; 40g granules in 100ml glass bottle and measuring spoon 5ml	Hemofarm A.D. 26300, Vrsac, Beogradskii put bb-batch releaser, Hemofarm A.D., Vrsac, 26224, Dubovac, str. Cara Lazara bb, Serbia-bulk manufacturere, packager	Serbia	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	PoM	16171/3 28.12.2021
27	Dexdor	dexmedetomidine (dexmedetomidine hydrochloride)	concentrate for solution for infusion	100mcg/ml (5) ampoules 2ml, (25) ampoules 2ml	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	PoM	19463/2 28.12.2021
28	Enterofuryl	nifuroxazide	suspension oral	200mg/5ml; 90ml suspension in 125ml glass bottle and plastic measuring spoon (2.5ml/5ml)	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	PoM	16380/4 28.12.2021

29	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	20016/1 28.12.2021
30	Otirelax	phenazone, lidocaine (lidocaine hydrochloride)	drops ear	40mg/g+10mg/g; 15ml plastic bottle-dropper	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A	Romania	OTC	16452/1 28.12.2021
31	Gemcitabin Ebewe	gemcitabine (gemcitabine hydrochloride)	concentrate for solution for i/v infusion	10mg/ml; (1) glass vial 20ml	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	16054/1 28.12.2021
32	Gemcitabin Ebewe	gemcitabine (gemcitabine hydrochloride)	concentrate for solution for i/v infusion	10mg/ml; (1) glass vial 100ml	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	16055/1 28.12.2021

33	Bridion	sugammadex (sugammadex sodium)	solution for i/v injection	100mg/ml; (10) glass vial 2ml	N.V. Organon, Kloosterstraat 6, 5349 AB Oss- batch releaser, secondary packager, Patheon Manufacturing Services LLC, 5900 Martin Luther King Jr. Higway, Greenville, North Carolina 27834, USA- bulk manufacturer, primary packager	the Netherlands	Merck Sharp & Dohme IDEA GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	17793/3/1 28.12.2021
34	Bridion	sugammadex (sugammadex sodium)	solution for i/v injection	100mg/ml; (10) glass vials 2ml	N.V. Organon, Kloosterstraat 6, 5349 AB Oss- secondary packager, quality control, batch releaser, Patheon Manufacturing Services LLC, 5900 Martin Luther King Jr. Higway, Greenville, North Carolina 27834, USA- bulk manufacturer, primary packager	the Netherlands	Merck Sharp & Dohme IDEA GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	19993/1 28.12.2021
35	Bridion	sugammadex (sugammadex sodium)	solution for i/v injection	100mg/ml; (10) glass vials 2ml	N.V. Organon, Kloosterstraat 6, 5349 AB Oss	the Netherlands	Merck Sharp & Dohme IDEA GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	20224/1 28.12.2021
36	Simva-Denk 20	simvastatin	tablets film-coated	20mg; (30/3x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	16224/3 28.12.2021

37	Enterofuryl	nifuroxazide	capsules	100mg; (30/3x10/) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	PoM	16943/2 28.12.2021
38	Enterofuryl	nifuroxazide	capsules	200mg; (16/2x8/) in blister	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	PoM	16944/2 28.12.2021
39	Minidiab	glipizide	tablets	5mg (30/2x15/) in blister	Pfizer Italia S.r.l. Localita Marino del Tronto, 63100 Ascoli Piceno	Italy	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York, 10017	USA	PoM	19547/2 28.12.2021
40	Nurofen Forte	ibuprofen	tablets coated	400mg; (12/1x12/) 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	18614/3 28.12.2021

41	Avexon-Rational	ceftriaxone (ceftriaxone sodium)	powder for solution for i/m and i/v injection	1000mg; glass vial (1), (50)	Aversi-Rational Ltd, Chirnakhuli str. 14, 0198 Tbilisi-secondary packager, batch releaser (bulk manufacturer, primary packager-Reyoung Pharmaceutical Co. Ltd., No 6 Erlangshan Road, Yiyuan County, Shandong Province, China)	Georgia	Aversi-Rational Ltd, Chirnakhuli str. 14, 0198 Tbilisi	Georgia	PoM	15797/3/1 28.12.2021
42	Voltaren	diclofenac (diclofenac sodium)	solution for injection	25mg/ml; (5) ampoules 3ml	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18640/7 28.12.2021
43	Voltaren Retard	diclofenac (diclofenac sodium)	tablets prolonged-release	75mg; (20/2x10/) in blister	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata (NA)	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	16589/2 28.12.2021
44	Voltaren Retard	diclofenac (diclofenac sodium)	tablets prolonged-release	75mg; (20/2x10/) in blister	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	20294/1 28.12.2021

45	Thyrozol	thiamazole	tablets film-coated	5mg; (50/5x10/) in blister, (50/2x25/) in blister	Merck KGaA, Frankfurter Strasse 250, A18, A31, A32, D2, D3, D11, D12, D15, D39, N79, N80, N90, PH5, PH16, PH23, PH28, PH31, PH33, PH50, PH51, PH52, PH80, 64293 Darmstadt	Germany	Merck KGaA Frankfurter Strasse 250, 64 293 Darmstadt	Germany	PoM	18411/1 28.12.2021
46	Thyrozol	thiamazole	tablets film-coated	10mg; (50/5x10/) in blister, (50/2x25/) in blister	Merck KGaA, Frankfurter Strasse 250, A18, A31, A32, D2, D3, D11, D12, D15, D39, N79, N80, N90, PH5, PH16, PH23, PH28, PH31, PH33, PH50, PH51, PH52, PH80, 64293 Darmstadt	Germany	Merck KGaA Frankfurter Strasse 250, 64 293 Darmstadt	Germany	PoM	18412/1 28.12.2021
47	Vasilip	simvastatin	tablets film-coated	10mg; (28/4x7/) 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	16948/1 28.12.2021
48	Vasilip	simvastatin	tablets film-coated	20mg; (28/4x7/) 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	16947/1 28.12.2021
49	Tasigna	nilotinib (nilotinib hydrochloride monohydrate)	capsules hard	200mg; (28/7x4) in blister; (28/2x14) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18112/3 28.12.2021

50	Glurenorm	gliquidone	tablets	30mg; (60/6x10/) in blister	Boehringer Ingelheim Ellas A.E., 5th km, Paiania-Markopoulo, 194 00 Koropi	Greece	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein	Germany	PoM	17772/3 28.12.2021
51	Sandimmun Neoral	ciclosporin	capsules soft	25mg; (50/10x5/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein-batch releaser, packager, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany bulk manufacturer	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	16540/2 28.12.2021
52	Sandimmun Neoral	ciclosporin	capsules soft	50mg; (50/10x5/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein-batch releaser, packager, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany bulk manufacturer	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	16539/2 28.12.2021

53	Sandimmun Neoral	ciclosporin	capsules soft	100mg; (50/10x5/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein-batch releaser, packager, Catalent Germany Eberbach GmbH, Gammelsbacher Str. 2, 69412 Eberbach, Germany bulk manufacturer	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	16541/2 28.12.2021
54	Tasigna	nilotinib (nilotinib hydrochloride monohydrate)	capsules hard	150mg; (28/7x4/) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland- bulk manufacturer, quality control	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19871/1 28.12.2021
55	Tasigna	nilotinib (nilotinib hydrochloride monohydrate)	capsules hard	200mg; (28/7x4) in blister, (28/2x14) in blister	Lek Pharmaceuticals d.d., Trimlini 2D, Lendava, 9220- packager, batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland- bulk manufacturer, quality control	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19872/1 28.12.2021
56	Oxivin-DF	oxymetazoline (oxymetazoline hydrochloride)	spray nasal	0,5mg/ml; 10ml plastic vial with pump dispenser	Dosfarm LLP, 050034, Almaty city, Chaplygin str.3	Kazakhstan	Dosfarm LLP, 050034, Almaty city, Chaplygin str.3	Kazakhstan	OTC	17056/1 28.12.2021

57	Betaderm	betamethasone (betamethasone dipropionate), gentamicin (gentamicin sulfate)	ointment for external use	0,5mg/g+1mg/g; aluminium tube 15g	Pharmaceutical Works Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	PoM	20025/1 28.12.2021
58	Fluimucil-antibiotic IT	thiamphenicol (thiamphenicol glycinate acetylcysteinate)	powder lyophilized for solution for i/m injection and inhalation	500mg; (3) glass vial and (3) solvent in ampoules 4ml	Zambon S.P.A., Via della Chimica, 9, Vicenza, 36100	Italy	Zambon S.P.A., Via Lillo del Duca, 10, Bresso, 20091	Italy	PoM	15922/3 28.12.2021
59	Revolade	eltrombopag (eltrombopag olamine)	tablets film-coated	25mg; (28/4x7/) in blister	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos-batch releaser, packager, Glaxo Operations UK Ltd, Priory Street, Ware, Hertfordshire, SG12 0DJ, UK- bulk manufacturer	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	16618/3 28.12.2021
60	Revolade	eltrombopag (eltrombopag olamine)	tablets film-coated	50mg; (28/4x7/) in blister	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos-batch releaser, packager, Glaxo Wellcome Operations, Priory Street, Ware, Hertfordshire, SG12 0DJ, UK- bulk manufacturer	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	17502/2 28.12.2021

61	Hepathrombin H	heparin sodium, prednisolone (prednisolone acetate), polidocanol	suppositories rectal	120IU+1,675mg+30mg; (10/2x5/)	Hemofarm A.D., 26300 Vrsac, Beogradskii put bb-batch releaser, Hemofarm A.D. Vrsac, branch plant Sabac, 15000, Sabac, Hajduk Veljkova str. No: bb, Serbia-bulk manufacturer, packager	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradskii put bb	Serbia	OTC	16372/1 28.12.2021
62	Myfortic	mycophenolic acid (mycophenolate sodium)	tablets gastro-resistant	180mg; (120/12x10/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	18043/4 28.12.2021
63	Myfortic	mycophenolic acid (mycophenolate sodium)	tablets gastro-resistant	180mg; (120/12x10/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	16977/5 28.12.2021
64	Myfortic	mycophenolic acid (mycophenolate sodium)	tablets gastro-resistant	180mg; (120/12x10/) 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	19445/3 28.12.2021

65	Exforge	amlodipine (amlodipine besilate), valsartan	tablets film-coated	5mg+160mg; (14/1x14/) in blister, (28/2x14/) in blister	Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19885/2 28.12.2021
66	Exforge	amlodipine (amlodipine besilate), valsartan	tablets film-coated	10mg+160mg; (14/1x14/) in blister, (28/2x14/) in blister	Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	19886/2 28.12.2021
67	Piracetam	piracetam	solution for i/m and i/v injection	200mg/ml; (10) ampoules 5ml CAMA, (10) ampoules 5ml label banderol, (10) ampoules 5ml dividella	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	PoM	16088/3/2 28.12.2021
68	Cardilopin	amlodipine (amlodipine besilate)	tablets	2,5mg; (30/3x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	17006/1 28.12.2021
69	Cardilopin	amlodipine (amlodipine besilate)	tablets	5mg; (30/3x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	17005/1 28.12.2021

70	Cardilopin	amlodipine (amlodipine besilate)	tablets	10mg; (30/3x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	17004/1 28.12.2021
71	Paracetamol Sopharma 500mg tablets	paracetamol	tablets	500mg; (10/1x10/) and (20/2x10/) blisters	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	18119/2 28.12.2021
72	Neyrotex	ethylmethylhydroxypyridine succinate	solution for i/m and i/v injection	50mg/ml; (10/2x5/) and (50/10x5) ampoules 2ml in blister	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region- quality control, batch releaser, "Sotex"PharmFirm" CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, Russia- bulk manufacturer, packager	Russia	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad district, Moscow Region, 141345	Russia	PoM	16482/2/1 28.12.2021

73	Neyrotex	ethylmethylhydroxypyridine succinate	solution for i/m and i/v injection	50mg/ml; (5) ampoules 5ml in blister	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad urban district, Moscow Region-quality control, batch releaser, "Sotex"PharmFirm" CJSC, Bld. 10, village Belikovo, Sergiev Posad urban district, Moscow Region, Russia- bulk manufacturer, packager	Russia	SotexPharmFirm" CJSC, Bld. 11, village Belikovo, Sergiev Posad district, Moscow Region, 141345	Russia	PoM	16481/2/1 28.12.2021
74	Anaprilin	propranolol (propranolol hydrochloride)	tablets	40mg; (50/5x10/) 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	16599/2 28.12.2021
75	Mycosyst	fluconazole	capsules	150mg; (1) in blister, (2) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	19324/1 28.12.2021
76	IMMUNOMAX BIO	peptidoglycan	powder lyophilized for solution for i/m injection	200IU; (3) glass vial	IMMAPHARMA LLC, 18/11, st. Gamaleya, Moscow, 123098	Russia	Avexima OJSC, 31A/1, Leningradsky pr., Moscow, 125284	Russia	PoM	16073/3/1 28.12.2021

77	Fevarin	fluvoxamine (fluvoxamine maleate)	tablets film-coated	50mg; (15/1x15/) in blister	Mylan Laboratories SAS, Route de Belleville, Lieudit Maillard, 01400 Chatillon sur Chalaronne	France	Abbott Healthcare Products B.V., C.J. van Houtenlaan 36, 1381 CP Weesp	the Netherlands	PoM	18477/3 28.12.2021
78	Fevarin	fluvoxamine (fluvoxamine maleate)	tablets film-coated	100mg; (15/1x15/) in blister	Mylan Laboratories SAS, Route de Belleville, Lieudit Maillard, 01400 Chatillon sur Chalaronne	France	Abbott Healthcare Products B.V., C.J. van Houtenlaan 36, 1381 CP Weesp	the Netherlands	PoM	18478/3 28.12.2021
79	Fluimucil-antibiotic IT	tiamphenicol (tiamphenicol glycinate acetylcysteinate)	powder lyophilized for solution for i/m injection and inhalation	500mg; (3) glass vial and (3) solvent in ampoules 4ml	Zambon S.P.A., Via della Chimica, 9, Vicenza, 36100	Italy	Zambon S.P.A., Via Lillo del Duca, 10, Bresso, 20091	Italy	PoM	15922/4 28.12.2021