

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 12-1/21 on December 10, 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	Propofol-Novo	propofol	emulsion for injection or infusion	10mg/ml; (5) vials 20ml	Firm "Novofarm-BiosynteZ" LLC, 11700, Zhytomyr region, town Novograd-Volynskyyi, Zhytomyrska street, building 38	Ukraine	Firm "Novofarm-BiosynteZ" LLC, 11700, Zhytomyr region, town Novograd-Volynskyyi, Zhytomyrska street, building 38	Ukraine	PoM	20344 10.12.2021
2	Propofol-Novo	propofol	emulsion for injection or infusion	10mg/ml; vial 50ml	Firm "Novofarm-BiosynteZ" LLC, 11700, Zhytomyr region, town Novograd-Volynskyyi, Zhytomyrska street, building 38	Ukraine	Firm "Novofarm-BiosynteZ" LLC, 11700, Zhytomyr region, town Novograd-Volynskyyi, Zhytomyrska street, building 38	Ukraine	PoM	20345 10.12.2021
3	KOXIKEA	etoricoxib	tablets film-coated	60mg; (28/4x7/) in blister	Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa	Greece	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	20346 10.12.2021

4	KOXIKEA	etoricoxib	tablets film-coated	90mg; (28/4x7/) in blister	Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa	Greece	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	20347 10.12.2021
5	KOXIKEA	etoricoxib	tablets film-coated	120mg; (7/1x7/) in blister	Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa	Greece	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	PoM	20348 10.12.2021
6	Vertigo	betahistine (betahistine dihydrochloride)	tablets	16mg; (30/3x10/) in blister	Medochemie Ltd (Factory AZ), 2 Michael Erakleous street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol-packager, quality control, batch releaser, Farmaceutisch Analytisch Laboratorium Duiven B.V., Dijkgraaf 30, RL, Duiven, Gelderland, 6921, the Netherlands- bulk manufacturer	Cyprus	Medochemie Ltd., 1-10 Constantinoupolos street, 3011 Limassol	Cyprus	PoM	20349 10.12.2021
7	Vertigo	betahistine (betahistine dihydrochloride)	tablets	24mg; (30/3x10/) in blister	Medochemie Ltd (Factory AZ), 2 Michael Erakleous street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol-packager, quality control, batch releaser, Farmaceutisch Analytisch Laboratorium Duiven B.V., Dijkgraaf 30, RL, Duiven, Gelderland, 6921, the Netherlands- bulk manufacturer	Cyprus	Medochemie Ltd., 1-10 Constantinoupolos street, 3011 Limassol	Cyprus	PoM	20350 10.12.2021

8	Polyoxidonium	azoximer bromide	suppositories rectal and vaginal	6mg; (10/2x5/)	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	OTC	20351 10.12.2021
9	Polyoxidonium	azoximer bromide	suppositories rectal and vaginal	12mg; (10/2x5/)	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	OTC	20352 10.12.2021
10	Zolacef 1g	cefazolin (cefazolin sodium)	powder for solution for injection or infusion	1000mg; (1) glass vial 10ml, (50) glass vials 10ml	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111- batch releaser, Reyoung Pharmaceutical Co. Ltd., No1 Ruiyang Road, Yiyuan County, Shandong Province, China- bulk manufacturer, packager, quality control	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM	20353 10.12.2021
11	Madopar	levodopa, benserazide (benserazide hydrochloride)	tablets	200mg+50mg; (100) in glass bottle	F. Hoffmann La Roche Ltd., Viaduktstrasse 33, 4051 Basel- batch releaser, DELPHARM MILANO S.R.L., VIA CARNEVALE, 1-20090 (MI), Italy- bulk manufacturer, packager, quality control	Switzerland	F. Hoffmann La Roche Ltd., Grenzacherstrasse 124 Basel, CH- 4070	Switzerland	PoM	20354 10.12.2021
12	Karnilev	levocarnitine	solution oral	1g/10ml; glass bottle 10ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Spey Medical Ltd, Lynton House 7-12 Tavistock square, WC1H 9LT, London	UK	PoM	20355 10.12.2021

13	Elevit Pronatal	vitamin A, vitamin D3, vitamin E, vitamin C, folic acid, vitamin B1, vitamin B2, vitamin B6, vitamin B12, nicotinamide, biotin, calcium pantothenate, calcium, magnesium, phosphor, ferrum, zinc, copper, manganese	tablets film-coated	3600IU+500IU+15mg+100mg+0,8mg+1,6mg+1,8mg+2,6mg+4mcg+19mg+200mcg+10mg+125mg+100mg+125mg+60mg+7,5mg+1mg+1mg; (30/3x10/) in blister, (100/5x20/) 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	JSC BAYER, 3rd Rybinskaya st., 18, build. 2, 107113 Moscow	Russia	OTC	20356 10.12.2021
14	Phosphogliv URSO	ursodeoxycholic acid, sodium glycyrrhizinate (glycyrrhizinic acid trisodium)	capsules	250mg+35mg; (50/5x10/) in blister	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	PoM	20358 10.12.2021
15	DIALAC Forte	simeticone	capsules soft gelatin	240mg; (20/1x20/) in blister	Laboratorios Alcala Farma, S.L., Avenida de Madrid, 82, 28802 Alcala de Henares- packager, quality control, batch releaser, Laboratorios Alcala Farma, C/ Nunneaton, 85, 19004 Guadalajara, Spain- bulk manufacturer	Spain	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	OTC	20359 10.12.2021

16	Cetrotide	cetrorelix (cetrorelix acetate)	powder lyophilized for solution for s/c injection	0,25mg; N7 glass vials with powder, N7 prefilled syringes with solvent 1ml, N14 needles, N14 alcohol swabs; N1 glass vials with powder, N1 prefilled syringes with solvent 1ml, N 2 needles, N 2 alcohol swabs	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt- batch releaser, FAREVA PAU 2, 50 chemin de Mazerolles, 64320 Idron, France- powder bulk manufacturer, primary packager, ABBOTT Biologicals B.V. Veerweg 12, 8121 AA Olst, the Netherlands- solvent bulk manufacturer, primary packager, quality control, FAREVA PAU 1, Avenue du Bearn, 64320 Idron, France- powder quality control, ABBOTT Biologicals B.V. Veerweg 12, 8121 AA Olst, the Netherlands- secondary packager	Germany	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	20360 10.12.2021
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LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 12-1/21 on December 10, 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	Abasaglar	insulin glargine	solution for injection	100U/ml; (5) cartridges 3ml	Lilly France S.A.S., Zone Industrielle, 2 rue du Colonel Lilly, 67640 Fegersheim	France	Eli Lilly Regional Operations GmbH., Koelblgasse 8-10, 1030, Vienna	Austria	PoM	20316 10.12.2021
2	Gexosept-Rn	chlorhexidine	suppositories vaginal	16mg; (10/2x5/)	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	OTC	20317 10.12.2021
3	Sertazol	sertaconazole (sertaconazole nitrate)	suppositories vaginal	300mg; (1)	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	20318 10.12.2021

4	Iodine 5% alcoholic solution	iodine	solution for external use	50mg/ml; 10ml glass bottle, 15ml glass bottle, 30ml glass bottle, 250ml glass bottle	Alfa-Pharm CJSC, Khrimyan Hayrik 62, Gyumri	Republic of Armenia	Alfa-Pharm CJSC, Khrimyan Hayrik 62, Gyumri	Republic of Armenia	OTC	20319 10.12.2021
5	Fluocinolone	fluocinolone acetonide	ointment for external use	0,25mg/g; 15g aluminium tube	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	20320 10.12.2021
6	Noliprel arginine	perindopril arginine, indapamide	tablets film-coated	2,5mg+0,625mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	20321 10.12.2021
7	Noliprel Forte arginine	perindopril arginine, indapamide	tablets film-coated	5mg+1,25mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	20322 10.12.2021
8	Ostalon	alendronic acid (alendronate sodium trihydrate)	tablets film-coated	70mg; (4/1x4/) in blister	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Poland Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	20323 10.12.2021

9	Orsoten	orlistat	capsules	120mg; (21/3x7/) in blister, (21/1x21/), in blister, (42/6x7/) in blister, (42/2x21/), in blister	Krka-RUS LLC, 50 Moskovskaya str., Istra, Moscow region 143500	Russia	Krka-RUS LLC, 50 Moskovskaya str., Istra, Moscow region 143500	Russia	PoM	20324 10.12.2021
10	Privigen	human normal immunoglobulin	solution for infusion	100mg/ml; 25ml glass vial	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	PoM	20325 10.12.2021
11	Privigen	human normal immunoglobulin	solution for infusion	100mg/ml; 50ml glass vial	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	PoM	20326 10.12.2021
12	Privigen	human normal immunoglobulin	solution for infusion	100mg/ml; 100ml glass vial	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	PoM	20327 10.12.2021
13	Privigen	human normal immunoglobulin	solution for infusion	100mg/ml; 200ml glass vial	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	PoM	20328 10.12.2021
14	Bravadin	ivabradine (ivabradine hydrobromide)	tablets film-coated	5mg; (28/2x14/) in blister	Krka-RUS LLC, 50 Moskovskaya str., Istra, Moscow region 143500	Russia	Krka-RUS LLC, 50 Moskovskaya str., Istra, Moscow region 143500	Russia	PoM	20329 10.12.2021



15	Bravadin	ivabradine (ivabradine hydrobromide)	tablets film-coated	7,5mg; (28/2x14/) in blister	Krka-RUS LLC, 50 Moskovskaya str., Istra, Moscow region 143500	Russia	Krka-RUS LLC, 50 Moskovskaya str., Istra, Moscow region 143500	Russia	PoM	20330 10.12.2021
16	Betastin	betahistine (betahistine dihydrochloride)	tablets	24mg; (20/2x10/) in blister, (30/3x10/) in blister, (100/10x10/) in blister	Pharmacare PLC, Ramallah, Betunia, Industrial Zone	Palestine	Pharmacare Int. Co./German Palestinian Joint Venture, Jerusalem, P.O. box 51621	Palestine	PoM	20331 10.12.2021
17	Loratadine	loratadine	tablets	10mg; (10/1x10/) 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	OTC	20332 10.12.2021
18	Metformin Denk 850	metformin (metformin hydrochloride)	tablets film-coated	850mg; (30/2x15/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor L+S AG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany-quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20333 10.12.2021

19	Metformin Denk 1000	metformin (metformin hydrochloride)	tablets film-coated	1000mg; (30/2x15/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor L+S AG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20334 10.12.2021
20	Singlon	montelukast (montelukast sodium)	tablets chewable	4mg; (28/4x7/) in blister	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- batch releaser, quality control, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	20335 10.12.2021
21	Singlon	montelukast (montelukast sodium)	tablets chewable	5mg; (28/4x7/) in blister	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- batch releaser, quality control, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	20336 10.12.2021

22	Singlon	montelukast (montelukast sodium)	tablets film-coated	10mg; (28/4x7/) in blister	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- batch releaser, quality control, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	20337 10.12.2021
23	Papaverine hydrochloride	papaverine (papaverine hydrochloride)	solution for injection	20mg/ml; (10) ampoules 2ml CAMA, (10) ampoules 2ml label banderol, (10) ampoules 2ml 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	20338 10.12.2021
24	Capotril	captopril	tablets	50mg; (24/2x12/) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	20339 10.12.2021
25	Berodual N	ipratropium bromide (ipratropium bromide monohydrate), fenoterol (fenoterol hydrobromide)	aerosol for inhalation, dosed	20mcg/dose+50mcg/dose; 10ml (200doses) aluminium container with measuring pump	Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, 55216 Ingelheim am Rhein	Germany	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein	Germany	PoM	20340 10.12.2021

26	Azithromycin	azithromycin	capsules	250mg; (6/1x6/) 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	20341 10.12.2021
27	Thiopental	thiopental (thiopental sodium)	powder lyophilized for solution for i/v injection	500mg; (40) glass vials	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	20342 10.12.2021
28	Thiopental	thiopental (thiopental sodium)	powder lyophilized for solution for i/v injection	1000mg; (40) glass vial	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	20343 10.12.2021

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N N 12-1/21 on December 10, 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	Biseptol	sulfamethoxazole, trimethoprim	tablets	400mg+80mg; (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	18264/2/2 10.12.2021
2	Polvertic	betahistine (betahistine dihydrochloride)	tablets	24mg (20/2x10/) in blister, (30/3x10/) in blister, (40/4x10/) in blister, (50/5x10/) in blister, (60/6x10/) in blister, (100/10x10/) in blister	Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 10 Wladyslawa Lokietka St. 98-200 Sieradz- batch releaser, Catalent Germany Schorndorf GmbH, Steinbeisstrasse 1und 2, 73614, Schorndorf, Germany- bulk manufacturer, Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 57 Polskiej Organizacji Wojskowej st. 98-200 Sieradz, Poland- packager, quality control	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	PoM	19491/1/1 10.12.2021

3	Aquadetrim Vitamin D3 Medana	coleciferol	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	16671/1/1 10.12.2021
4	Xefocam Rapid	lornoxicam	tablets film- coated	8mg; (12/2x6/) in blister	Takeda GmbH, Betriebsstatte Oranienburg, Lehnitzstrasse 70-98, 16515 Oranienburg	Germany	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	19354/1/1 10.12.2021
5	Bobotic	simethicone	drops oral	66,66mg/ml; 30ml 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	OTC	17849/1/1 10.12.2021

6	Mucosat-Belmed	chondroitin sulfate (chondroitin sulfate sodium)	solution for i/m injection	100mg/ml; (5/1x5/ and(10/2x5/) ampoules 2ml	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30- quality control, batch releaser, Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30, No2, Belarus- bulk manufacturer, packager	Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	PoM	17135/1/1 10.12.2021
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LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-1/21 on December 10, 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	Norvasc	amlodipine (amlodipine besilate)	tablets	5mg; (30/3x10/) blisters	R-Pharm Germany GmbH, Heinrich-Mack-Str. 35, 89257, Illertissen	Germany	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	PoM	18766/2 10.12.2021
2	Norvasc	amlodipine (amlodipine besilate)	tablets	10mg; (30/3x10/) in blister	R-Pharm Germany GmbH, Heinrich-Mack-Str. 35, 89257, Illertissen	Germany	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	PoM	18767/2 10.12.2021
3	Norvasc	amlodipine (amlodipine besilate)	tablets	5mg; (30/3x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Baden-Wuerttemberg, Mooswaldallee 1, 79090 Freiburg- packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	PoM	19129/2 10.12.2021



4	Norvasc	amlodipine (amlodipine besilate)	tablets	10mg; (30/3x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Baden-Wuerttemberg, Mooswaldallee 1, 79090 Frieburg- packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	PoM	19130/2 10.12.2021
5	Nuvaring	etonogestrel, ethinylestradiol	vaginal delivery system (vaginal ring)	11,7mg+2,7mg; (1) sachet	N.V. Organon, Kloosterstraat 6, 5349 AB Oss	Switzerland	Organon Central East GmbH, Weyrstrasse 20, 6006 Luzern	Switzerland	PoM	18919/4/1 10.12.2021
6	Rosulip Plus	rosuvastatin (rosuvastatin zinc), ezetimibe	capsules	5mg+10mg; (30/3x10/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, packager, bulk manufacturer (tablets manufacturer), Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65, Hungary- bulk manufacturer (capsulation)	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	18085/4 10.12.2021

7	Rosulip Plus	rosuvastatin (rosuvastatin zinc), ezetimibe	capsules	10mg+10mg; (30/3x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30- 38	Hungary	PoM	19673/2 10.12.2021
8	Rosulip Plus	rosuvastatin (rosuvastatin zinc), ezetimibe	capsules	20mg+10mg; (30/3x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30- 38	Hungary	PoM	19674/2 10.12.2021
9	Rosulip Plus	rosuvastatin (rosuvastatin zinc), ezetimibe	capsules	40mg+10mg; (30/3x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120- packager, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65, Hungary- bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30- 38	Hungary	PoM	19675/2 10.12.2021

10	Rosulip Plus	rosuvastatin (rosuvastatin zinc), ezetimibe	capsules	5mg+10mg; (30/3x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120-packager, batch releaser, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65, Hungary-bulk manufacturer, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	19700/2 10.12.2021
11	Docetaxel Ebewe	docetaxel	concentrate for solution for infusion	10mg/ml; glass vial 2ml	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	16267/2 10.12.2021
12	Docetaxel Ebewe	docetaxel	concentrate for solution for infusion	10mg/ml; glass vial 8ml	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	16268/2 10.12.2021
13	Cytotec	misoprostol	tablets	200mcg; (28/2x14/) in blister, (60/6x10/) in blister	Piramal Healthcare UK Limited, Whalton Road Morpeth, Northumberland, NE61 3YA	UK	Pfizer H.C.P. Corporation, 235, East 42nd str. New York 10017	USA	PoM	18849/2 10.12.2021

14	Movalis	meloxicam	solution for i/m injection	15mg/1,5ml; (3) ampoules 1,5ml	Boehringer Ingelheim Espana S.A., Prat de la Riba, 50, 08174 Sant Cugat del Valles, Barcelona	Spain	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein	Germany	PoM	17162/2 10.12.2021
15	SIMBRINZA	brinzolamide, brimonidine (brimonidine tartrate)	drops eye, suspension	10mg/ml+2mg/ml; 5ml plastic vial-dropper	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	16308/3/1 10.12.2021
16	Fluocinolone	fluocinolone acetonide	ointment for external use	0,25mg/g; 15g aluminium tube	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	16378/1 10.12.2021
17	Esomeprazol SANDOZ 20mg	esomeprazole (esomeprazole magnesium dihydrate)	tablets gastro-resistant	20mg; (14/2x7/) in blister, (28/4x7/) in blister	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	19961/1 10.12.2021
18	Esomeprazol SANDOZ 40mg	esomeprazole (esomeprazole magnesium dihydrate)	tablets gastro-resistant	40mg; (14/2x7/) in blister, (28/4x7/) in blister	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	19962/1 10.12.2021

19	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 PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	16718/2 10.12.2021
20	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	17980/2 10.12.2021
21	Glucovance	glibenclamide, metformin (metformin hydrochloride)	tablets film-coated	2,5mg+500mg; (30/2x15/) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400 Semoy	France	Merck Sante s.a.s., 37 rue Saint Romain- 69379 Lyon	France	PoM	19379/1 10.12.2021
22	Glucovance	glibenclamide, metformin (metformin hydrochloride)	tablets film-coated	5mg+500mg; (30/2x15/) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400 Semoy	France	Merck Sante s.a.s., 37 rue Saint Romain- 69379 Lyon	France	PoM	19380/1 10.12.2021
23	Trifas 5	torasemide	tablets	5mg; (30/3x10/) in blister	Berlin-Chemie A.G., Glienicker Weg 125 D-12489 Berlin-packager, batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, D-12347 Berlin, Germany-bulk manufacturer	Germany	Menarini International Operations Luxembourg S.A., 1, avenue de la Gare, 1611	Luxembourg	PoM	18580/1 10.12.2021

24	Trifas 10	torasemide	tablets	10mg; (30/3x10/) in blister	Berlin-Chemie A.G., Glienicker Weg 125 D-12489 Berlin-packager, batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, D-12347 Berlin, Germany-bulk manufacturer	Germany	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, 1611	Luxembourg	PoM	18581/1 10.12.2021
25	Campto	irinotecan (irinotecan hydrochloride trihydrate)	concentrate for solution for infusion	20mg/ml vial; plastic vial 2ml	Pfizer (Perth) Pty Limited, 15 Brodie Hall Drive Technology Park Bentley WA 6102	Australia	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	18308/3 10.12.2021
26	Orsoten	orlistat	capsules	120mg; (21/3x7/) in blister, (21/1x21/), in blister, (42/6x7/) in blister, (42/2x21/), in blister	Krka-RUS LLC, 50 Moskovskaya str., Istra, Moscow region 143500	Russia	Krka-RUS LLC, 50 Moskovskaya str., Istra, Moscow region 143500	Russia	PoM	15579/2/2 10.12.2021
27	Biseptol	sulfamethoxazole, trimethoprim	tablets	100mg+20mg; (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	18263/2/1 10.12.2021
28	Troxerutin Sopharma 300mg capsules hard	troxerutin	capsules hard	300mg; (50/5x10/) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	16467/1 10.12.2021

29	Insulatard	insulin human (recombinant DNA)	suspension for injection	100IU/ml; glass vial 10ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd - batch releaser, bulk manufacturer, primary packager, Novo Nordisk A/S, Hallas Alle, DK-4400 Kalundborg, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	18617/3 10.12.2021
30	Insulatard Penfill	insulin human	suspension for injection	100IU/ml; (5) glass cartridges 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	18296/3 10.12.2021
31	Insulatard	insulin human (recombinant DNA)	suspension for injection	100IU/ml; (1) glass vial 10ml	Novo Nordisk Production SAS, 45 avenue d`Orleans, F-28000, Chartres	France	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	17160/4 10.12.2021
32	Vitamin B complex	thiamine (thiamine nitrate), riboflavin, pyridoxine (pyridoxine hydrochloride), nicotinamide	film-coated tablets	5mg+1mg+4mg+50mg ; (20/1x20/) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	16917/1 10.12.2021

33	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	19445/2 10.12.2021
34	Carsil 22,5mg coated tablets	silymarin	tablets coated	22,5mg; (80/8x10/) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	16728/1 10.12.2021
35	Recormon	epoetin beta	solution for i/v and s/c injection	2000IU/0,3ml; (6) pre-filled syringes 0,3ml and (6) needles	Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim	Germany	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	PoM	18566/2 10.12.2021
36	Ketonal Extra 25mg granules for oral solution	ketoprofen (ketoprofen lysine)	granules for oral solution	25mg; (15) sachets, (30) sachets,	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana-batch releaser, Fine Foods & Pharmaceuticals N.T.M. S.p.A., Via Grignano, 43, 24041, Brembate (BG), Italy-bulk manufacturer, packager, quality control	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	18773/1 10.12.2021



37	Ketonal Extra Plus 50mg granules for oral solution	ketoprofen (ketoprofen lysine)	granules for oral solution	50mg; (12) bipartite sachets	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana-batch releaser, Fine Foods & Pharmaceuticals N.T.M. S.p.A., Via Grignano, 43, 24041, Brembate (BG), Italy-bulk manufacturer, packager, quality control	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	18583/3/1 10.12.2021
38	Concor	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg (30/3x10/) in blister, (30/1x30/) in blister, (50/5x10/) in blister, (50/2x25/) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, 35 Valovaya Street, Moscow 115054	Russia	PoM	18384/2/2 10.12.2021
39	Concor	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg (30/3x10/) in blister, (30/1x30/) in blister, (50/5x10/) in blister, (50/2x25/) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, 35 Valovaya Street, Moscow 115054	Russia	PoM	18385/2/2 10.12.2021
40	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	19885/1 10.12.2021
41	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	19886/1 10.12.2021

42	Bisoprolol 2,5mg film-coated tablets	bisoprolol (bisoprolol fumarate)	tablets film-coated	2,5mg; (30/2x15/) in blister	Lek S.A.,16 Podlipie Str., 95-010 Strykow	Poland	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	16754/3 10.12.2021
43	Bisoprolol 5mg film-coated tablets	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (100/4x25/) in blister	Lek S.A., ul. Domaniewska 50C, Warszawa, 02-672-batch releaser, Lek S.A.,16 Podlipie Str., 95-010 Strykow, Poland-bulk manufacturer, packager,	Poland	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	16755/3 10.12.2021
44	Bisoprolol 10mg film-coated tablets	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg; (100/4x25/) in blister	Lek S.A.,16 Podlipie Str., 95-010 Strykow	Poland	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	PoM	16756/3 10.12.2021
45	Antiflu Kids	paracetamol, ascorbic acid, chlorpheniramine (chlorpheniramine maleate)	powder for oral solution with raspberry flavour	160mg+50mg+1mg; (5) sachets	Contract Pharmacal Corporation, 135 Adams avenue, Hauppauge, New York 11788- packager, quality control, batch releaser, Contract Pharmacal Corporation, 150 Commerce Drive Hauppauge, New York 11788, USA- bulk manufacturer	USA	JSC BAYER, 3rd Rybinskaya St., 18, build. 2, 107113 Moscow	Russia	OTC	20056/1 10.12.2021

46	Enap	enalaprilat	solution for injection	1,25mg/ml; (5) ampoules 1ml, 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	16949/1 10.12.2021
47	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	5mg; (56/4x14/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18505/7 10.12.2021
48	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	15mg; (56/4x14/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18506/7 10.12.2021
49	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	20mg; (56/4x14/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18507/6 10.12.2021
50	Simva-Denk 40	simvastatin	tablets film-coated	40mg; (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	16225/1 10.12.2021
51	Relium	diazepam	tablets film-coated	5mg; (20/1x20/) in blister	Tarchomin Pharmaceutical Works "Polfa" S.A., 2.A. Fleminga str., 03-176 Warsaw	Poland	Tarchomin Pharmaceutical Works "Polfa" S.A., 2.A. Fleminga str., 03-176 Warsaw	Poland	PoM	19678/2 10.12.2021

52	Capotril	captopril	tablets	25mg; (24/1x24/) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	18455/1 10.12.2021
53	Capotril 50mg	captopril	tablets	50mg; (24/2x12/) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	PoM	15868/1 10.12.2021
54	Papaverine hydrochloride	papaverine (papaverine hydrochloride)	solution for injection	20mg/ml; (10) ampoules 2ml CAMA, (10) ampoules 2ml label banderol, (10) ampoules 2ml dividella	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	PoM	16033/2/1 10.12.2021
55	Sirdalud	tizanidine (tizanidine hydrochloride)	tablets	2mg; (30/3x10/) in blister	Novartis Saglik, Gida ve Tarim Urunleri San.Ve Tic. A.S., Yenisehir Mahallesi, Ihlara Vadisi Sokak,N2. Pendik,Istambul TR 34912	Turkey	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	16582/3/1 10.12.2021

56	Sirdalud	tizanidine (tizanidine hydrochloride)	tablets	4mg; (30/3x10/) in blister	Novartis Saglik, Gida ve Tarim Urunleri San.Ve Tic. A.S., Yenisehir Mahallesi, Ihlara Vadisi Sokak,N2. Pendik,Istambul TR 34912	Turkey	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	16583/3/1 10.12.2021
57	Propofol-Lipuro	propofol	emulsion for i/v injection	10mg/ml; (5) ampoules 20ml	B.Braun Melsungen AG, Mistelweg 2, Berlin, 12357	Germany	B.Braun Melsungen AG, Carl-Braun-Strasse 1,34212 Melsungen	Germany	PoM	19086/1 10.12.2021
58	Propofol-Lipuro	propofol	emulsion for i/v injection	10mg/ml; (10) glass vials 50ml	B.Braun Melsungen AG, Carl-Braun-Strasse 1, Melsungen, Hessen, 34212	Germany	B.Braun Melsungen AG, Carl-Braun-Strasse 1,34212 Melsungen	Germany	PoM	19087/1 10.12.2021
59	Rovastat	rosuvastatin (rosuvastatin calcium)	tablets film-coated	5mg; (28/4x7/) 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	17301/2/1 10.12.2021
60	Rovastat	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (28/4x7/) 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	17302/2/1 10.12.2021

61	Rovastat	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (28/4x7/) 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	17303/2/1 10.12.2021
62	Rovastat	rosuvastatin (rosuvastatin calcium)	tablets film-coated	40mg; (28/4x7/) 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	17304/2/1 10.12.2021
63	Motilium	domperidone	tablets film-coated	10mg; (10/1x10/) in blister, (30/1x30/) in blister	Janssen-Cilag, Domaine de Maigremont, 27100 Val De Reuil	France	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	PoM	19041/1 10.12.2021
64	Salbutamol Sopharma	salbutamol (salbutamol sulfate)	syrup	2mg/5ml; 125ml glass or plastic bottle and measuring cup	Sopharma JSC, Vrabevo vlg. 5660, district of Lovetch	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	17132/1 10.12.2021
65	Metformin Denk 850	metformin (metformin hydrochloride)	tablets film-coated	850mg; (30/2x15/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	16229/3 10.12.2021

66	Metformin Denk 1000	metformin (metformin hydrochloride)	tablets film-coated	1000mg; (30/2x15/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	16230/6 10.12.2021
67	Septotele total	benzydamine (benzydamine hydrochloride), cetylpyridinium (cetylpyridinium chloride)	spray for topical use	1,5mg/ml+5mg/ml; plastic container with pump dispenser 30ml (250 dose)	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	19838/1 10.12.2021
68	Septotele total eucalyptus	benzydamine (benzydamine hydrochloride), cetylpyridinium chloride	pastilles	3mg+1mg (8/1x8/), (16/2x8/), (24/3x8/) and (32/4x8/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto-quality control, batch releaser, KRKA d.d., Novo mesto, Ulica Rada Pusenjaka 10, Ljutomer, 9240, Slovenia-bulk manufacturer, packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	19958/1 10.12.2021
69	Septotele total lemon and honey	benzydamine (benzyadamine hydrochloride), cetylpyridinium chloride	lozenges	3mg+1mg; 16(2x8) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto - batch releaser, KRKA d.d., Novo mesto, Ulica Rada Pusenjaka 10, Ljutomer, 9240, Slovenia-bulk manufacturer, packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	17899/3/1 10.12.2021

70	Septotele total lemon and elderflower	benzydamine (benzydamine hydrochloride), cetylpyridinium chloride	lozenges	3mg+1mg; (8/1x8/), (16/2x8/), (24/3x8/), (32/4x8/) and (40/5x8/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto - batch releaser, KRKA d.d., Novo mesto, Ulica Rada Pusenjaka 10, Ljutomer, 9240, Slovenia-bulk manufacturer, packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	17900/2 10.12.2021
71	Gexosept-Rn	chlorhexidine	suppositories vaginal	16mg; (10/2x5/)	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	OTC	15713/2/1 10.12.2021
72	Triovit	beta-carotene, alpha-tocopherol acetate, ascorbic acid, selen	capsules	10mg+40mg+100mg+50mcg; (30/3x10/) 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	OTC	17027/2 10.12.2021
73	Azithromycin	azithromycin	capsules	250mg; (6/1x6/) in blister	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	16217/2 10.12.2021



74	Jadenu	deferasirox	tablets film-coated	180mg; (30/3x10/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr-packager, batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland-bulk manufacturer	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18370/3 10.12.2021
75	Jadenu	deferasirox	tablets film-coated	360mg; (30/3x10/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr-packager, batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein, Switzerland-bulk manufacturer	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18371/3 10.12.2021
76	Strepsils	dichlorobenzyl alcohol, amylmetacresol	lozenges with strawberry flavour, sugar free	1,2mg+0,6mg; (16/2x8/) 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	19427/1 10.12.2021
77	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	17496/3/1 10.12.2021

78	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	16976/3/1 10.12.2021
79	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	19866/1 10.12.2021
80	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)	Slovenia	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	19867/1 10.12.2021

81	Bravadin	ivabradine (ivabradine hydrobromide)	tablets film-coated	5mg; (28/2x14/) in blister	Krka-RUS LLC, 50 Moskovskaya str., Istra, Moscow region 143500	Russia	Krka-RUS LLC, 50 Moskovskaya str., Istra, Moscow region 143500	Russia	PoM	15986/1 10.12.2021
82	Bravadin	ivabradine (ivabradine hydrobromide)	tablets film-coated	7,5mg; (28/2x14/) in blister	Krka-RUS LLC, 50 Moskovskaya str., Istra, Moscow region 143500	Russia	Krka-RUS LLC, 50 Moskovskaya str., Istra, Moscow region 143501	Russia	PoM	15985/1 10.12.2021
83	Thiopental	thiopental (thiopental sodium)	powder lyophilized for solution for i/v injection	500mg; (40) glass vial	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	16034/1 10.12.2021
84	Thiopental	thiopental (thiopental sodium)	powder lyophilized for solution for i/v injection	1000mg; (40) glass vial	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	16035/1 10.12.2021
85	Ermucin	erdosteine	granules for oral suspension	225mg; (10) sachets 4,425mg	Fine Foods & Pharmaceuticals N.T.M. S.p.A., Via Grignano, 43, 24041, Brembate (BG)	Italy	UAB "MRA", Totoriu str. 20-9, LT-01121 Vilnius	Republic of Lithuania	PoM	18075/2 10.12.2021

86	Ermucin	erdosteine	capsules hard	300mg; (10/1x10/) and (20/2x10/) in blister	Edmond Pharma S.r.l., Strada Statale dei Giovi 131-20037 Paderno Dugnano (MI)- batch releaser, bulk manufacturer, Lamp San Prospero S.p.A., Via della Pace, 25/A-41030 San Prospero (MO), Italy-packager	Italy	UAB "MRA", Totoriu str. 20-9, LT-01121 Vilnius	Republic of Lithuania	PoM	18076/2 10.12.2021
87	ERMUCIN	erdosteine	powder for oral suspension	175mg/5ml; glass vial 50g and measuring cap	ZETA FARMACEUTICI S.P.A, VIA GALVANI, 10-36066, SANDRIGO (VI)	Italy	UAB "MRA" Totoriu str. 20-9, LT-01121 Vilnius	Lithuania	PoM	19980/1 10.12.2021
88	Desket	dexketoprofen (dexketoprofen trometamol)	solution for injection	25mg/ml; (10/2x5/) ampoules 2ml in blister	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	PoM	20058/1 10.12.2021