

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 8-1/20 on August 14, 2020

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	Mucaltin Tatpharm	althaea officinalis extract	tablets	50mg; (10) in strip	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	OTC	19362 14.08.2020
2	Roxera Plus	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets film-coated	10mg+10mg; (30/3x10/) in blister, (60/6x10/) in blister, (90/9x10/) 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	R	19363 14.08.2020
3	Telaxel	timolol (timolol maleate)	drops eye (solution)	5mg/ml; plastic vial 5ml	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	Pharmatech CJSC, 111 Raffi str., Yerevan, 0064	Republic of Armenia	R	19364 14.08.2020

4	Onbrez Breezhaler	indacaterol (indacaterol maleate)	powder for inhalation, capsules hard	150mcg; (30/3x10/) in blister and inhaler	Novartis Farmaceutica S.A., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona- bulk manufacturer, packager, quality control (physicochemical, microbiological), batch releaser, Pharmanalytica SA., Via Balestra, Locarno, 6600, Switzerland- quality control (physicochemical)	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	19365 14.08.2020
5	Onbrez Breezhaler	indacaterol (indacaterol maleate)	powder for inhalation, capsules hard	300mcg; (30/3x10/) in blister and inhaler	Novartis Farmaceutica S.A., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona- bulk manufacturer, packager, quality control (physicochemical, microbiological), batch releaser, Pharmanalytica SA., Via Balestra, Locarno, 6600, Switzerland- quality control (physicochemical)	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	19366 14.08.2020
6	Mobicam	meloxicam	tablets	7,5mg; (20/2x10/) in blister	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi- packager, quality control, batch releaser, REPLEK FARM Ltd. Skopje, 188 str. Kozle, 1000 Skopje, Republic of North Macedonia- bulk manufacturer	Georgia	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi	Georgia	R	19370 14.08.2020

7	Mobicam	meloxicam	tablets	15mg; (20/2x10/) in blister	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi- packager, quality control, batch releaser, REPLEK FARM Ltd. Skopje, 188 str. Kozle, 1000 Skopje, Republic of North Macedonia- bulk manufacturer	Georgia	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi	Georgia	R	19371 14.08.2020
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LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 8-1/20 on August 14, 2020

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	Xefocam Rapid	lornoxepam	tablets film-coated	8mg; (12/2x6/) in blister	Takeda GmbH, Betriebsstätte Oranienburg, Lehnitzstrasse 70-98, 16515 Oranienburg	Germany	Takeda Pharma A/S, Dybendal Alle 10, 2630 Taastrup	Denmark	R	19354 14.08.2020
2	Xefocam Rapid	lornoxepam	tablets film-coated	8mg; (12/2x6/) in blister	Takeda GmbH, Betriebsstätte Oranienburg, Lehnitzstrasse 70-98, 16515 Oranienburg- packager, quality control, batch releaser, Takeda Pharma A/S, Apotekerstien 9, 9500 Hobro, Denmark- bulk manufacturer	Germany	Takeda Pharma A/S, Dybendal Alle 10, 2630 Taastrup	Denmark	R	19355 14.08.2020
3	Yaz plus	pink tablet-drospirenone, ethinyl estradiol, levomefolate (levomefolate calcium); light orange tablet- levomefolate (levomefolate calcium)	tablets film-coated	pink tablet- 3mg+0,02mg+0,451mg; light orange tablet- 0,451mg; (28/24 pink tablet+4 light orange tablet/), in blister	Bayer Weimar GmbH & Co. KG, Dobereinerstrasse 20, 99427 Weimar	Germany	Bayer AG, Kaiser- Wilhelm-Allee 1, 51373 Leverkusen	Germany	R	19356 14.08.2020

4	Deep Relief	ibuprofen, levomenthol(menthol)	gel for external use	50mg/g+30mg/g; 15g aluminum tube, 50g aluminum tube, 100g aluminum tube	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	OTC	19357 14.08.2020
5	Furosemide	furosemide	tablets	40mg; (40/1x40/) in blister, (40/4x10/) 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	R	19358 14.08.2020
6	Trombopol Polpharma	acetylsalicylic acid	tablets gastro- resistant	75mg; (30/3x10/) in blister, (60/6x10/) in blister	Pharmaceutical Works Polpharma S.A., ul. Pelplinska 19, 83-200 Starogard Gdanski	Poland	Pharmaceutical Works Polpharma S.A., ul. Pelplinska 19, 83-200 Starogard Gdanski	Poland	OTC	19359 14.08.2020
7	Trombopol Polpharma	acetylsalicylic acid	tablets gastro- resistant	150mg; (30/3x10/) in blister, (60/6x10/) in blister	Pharmaceutical Works Polpharma S.A., ul. Pelplinska 19, 83-200 Starogard Gdanski	Poland	Pharmaceutical Works Polpharma S.A., ul. Pelplinska 19, 83-200 Starogard Gdanski	Poland	OTC	19360 14.08.2020
8	Meloxicam DC	meloxicam	solution for injection	10mg/ml; (3) ampoules 1,5ml	Zhangjiakou Kaiwei Pharmaceutical Co. Ltd., No 27, Lingyuan Road, Zhangjiakou, Heibei Province	China	Danhson-BG Co Ltd., Otez Paissij str. 26, Radomir 2400	Bulgaria	R	19361 14.08.2020

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 8-1/20 on August 14, 2020

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	Artrum	ketoprofen	gel for external use	25mg/g; 50g aluminium tube	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	R	14845/1/2 14.08.2020
2	Artrum	ketoprofen	gel for external use	50mg/g; 50g aluminium tube	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	R	14846/1/2 14.08.2020
3	Biprol	bisoprolol (bisoprolol fumarate)	tablets film-coated	2,5mg; (30/3x10/) in blister	Hemofarm LLC, 249032, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	R	16250/1/1 14.08.2020

4	Zoledronic acid	zoledronic acid	powder lyophilized for solution for infusion	4mg; (1) glass vial 10ml	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	R	15291/1/1 14.08.2020
5	Meropenem-Asteria	meropenem	powder for solution for i/v injection/ infusion	500mg; (1), (5), (10) glass vials	Hankook Korus Pharm Co., Ltd, 78 Daepungsandan-ro, Daeso-myeon, Eumseong-gun, Chungcheongbuk-do	Korea South	Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan	Republic of Armenia	R	15178/1/1 14.08.2020
6	Nifuroxazide	nifuroxazide	tablets film-coated	100mg; (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" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	R	15629/1/1 14.08.2020

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision 8-1/20 on August 14, 2020

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	Mexiprim	ethylmethylhydroxypyridine succinate	solution for i/m and i/v injection	50mg/ml; (10/2x5/) ampoules 2ml, blister	Scientific Technological Pharmaceutical Firm POLISAN LLC, lit. A, building 2, Salova st. 72, Saint Petersburg, 192102	Russia	Nizhpharm OJSC, 603950, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	R	14573/1 14.08.2020
2	Mexiprim	ethylmethylhydroxypyridine succinate	solution for i/m and i/v injection	50mg/ml; (5/1x5/) ampoules 5ml, blister	Scientific Technological Pharmaceutical Firm POLISAN LLC, lit. A, building 2, Salova st. 72, Saint Petersburg, 192102	Russia	Nizhpharm OJSC, 603950, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	R	14572/1 14.08.2020
3	Talliton	carvedilol	tablets	6,25mg; (14/2x7/) and (28/4x7/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	15018/2 14.08.2020

4	Talliton	carvedilol	tablets	12,5mg; (14/1x14/) and (28/2x14/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	15017/2 14.08.2020
5	Talliton	carvedilol	tablets	25mg; (14/1x14/) and (28/2x14/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	15016/2 14.08.2020
6	Ketonal	ketoprofen	suppositories rectal	100mg; (12/2x6/)	Sandoz Ilac Sanayi ve Ticaret A.S., Gebze Plastikciler Organize Sanayi Boelgesi Ataturk Bulvari 9, Cadde No.1, 41400, Kocaeli	Turkey	Lek d.d., Verovskova str. 57,1526 Ljubljana	Slovenia	R	18662/1 14.08.2020
7	Euphylline	aminophylline	tablets	150mg; (10/1x10/) in blister, (30/3x10/) in blister, (10) 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" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	R	15622/1 14.08.2020

8	Atenolol	atenolol	tablets	50mg; (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" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	R	15585/1 14.08.2020
9	Atenolol	atenolol	tablets	100mg; (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" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	R	15586/1 14.08.2020
10	Amaryl	glimepiride	tablets	3mg; (30/2x15/) in blister	SANOFI S.P.A., S.S. 17 km 22, 67019 Scoppito (AQ)	Italy	Sanofi-Aventis Deutschland GmbH, Bruningstrasse 50, D-65926 Frankfurt am Main	Germany	R	16924/1 14.08.2020
11	Trombopol Polpharma	acetylsalicylic acid	tablets gastro-resistant coated	75mg; (30/3x10/) in blister, (60/6x10/) in blister	Pharmaceutical Works Polpharma S.A., ul. Pelplinska19, 83-200 Starogard Gdanski	Poland	Pharmaceutical Works Polpharma S.A., ul. Pelplinska19, 83-200 Starogard Gdanski	Poland	OTC	15057/3 14.08.2020

12	Trombopol Polpharma	acetylsalicylic acid	tablets gastro-resistant coated	150mg; (30/3x10/) in blister, (60/6x10/) in blister	Pharmaceutical Works Polpharma S.A., ul. Pelplinska19, 83-200 Starogard Gdanski	Poland	Pharmaceutical Works Polpharma S.A., ul. Pelplinska19, 83-200 Starogard Gdanski	Poland	OTC	15058/3 14.08.2020
13	Chondro-Ritz	chondroitin (chondroitin sulfate), glucosamine (glucosamine sulfate)	capsules	200mg+250mg; (50/5x10/), in blister	GM Pharmaceuticals Ltd, PSP group 65, Qyemo Phonichala str., Tbilisi	Georgia	GM Pharmaceuticals Ltd, PSP group 65, Qyemo Phonichala str., Tbilisi	Georgia	OTC	15185/1 14.08.2020
14	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	R	16107/1 14.08.2020
15	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	R	16108/1 14.08.2020
16	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	R	16110/1 14.08.2020

17	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	R	16109/1 14.08.2020
18	Levomicetin-Darnitsa	chloramphenicol	tablets	500mg; (10) in blister	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13	Ukraine	R	17591/1 14.08.2020
19	Tetracaine	tetracaine (tetracaine hydrochloride)	drops eye	10mg/ml; (1) and (10) plastic vial-dropper 10ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	R	17050/2 14.08.2020
20	Zometa	zoledronic acid (zoledronic acid monohydrate)	solution for infusion	0,04mg/ml; glass vial 100ml	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein-secondary packager, quality control, batch releaser, Fresenius Kabi Austria GmbH, Hafnerstrasse 36, Graz, 8055, Austria-bulk manufacturer, primary packager	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	18836/2 14.08.2020
21	Zometa	zoledronic acid (zoledronic acid monohydrate)	solution for infusion	0,04mg/ml; 100ml glass vial	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	R	16491/1 14.08.2020

22	Rosulip Plus	rosuvastatin (rosuvastatin zinc), ezetimibe	capsules	10mg+10mg; (30/3x10/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, packager, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65, Hungary- bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30- 38	Hungary	R	15360/2 14.08.2020
23	Rosulip Plus	rosuvastatin (rosuvastatin zinc), ezetimibe	capsules	20mg+10mg; (30/3x10/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, packager, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65, Hungary- bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30- 38	Hungary	R	15361/2 14.08.2020
24	Rosulip Plus	rosuvastatin (rosuvastatin zinc), ezetimibe	capsules	40mg+10mg; (30/3x10/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, packager, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65, Hungary- bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30- 38	Hungary	R	15362/2 14.08.2020
25	Valused	valerian root dry extract, hop strobiles dry extract, passion flower dry extract	capsules soft	60mg+40mg+40mg; (30/2x15/) in blister	P.P.F. "Hasco-Lek" S.A., ul. Zmigrodzka 242 E, 51-131 Wroclaw	Poland	P.P.F. "Hasco-Lek" S.A., ul. Zmigrodzka 242 E, 51-131 Wroclaw	Poland	OTC	17093/2 14.08.2020

26	Mononine 500	human blood coagulation factor IX	powder and solvent for solution for injection or infusion	500IU; I pack (N1 glass vial with powder, N1 glass vial with solvent 5ml, N1 filter transfer device 20/20), II pack (N1 disposable syringe 10ml, N1 venipuncture set, N2 alcohol swabs, N1 non-sterile plaster)	CSL Behring GmbH, Emil-von-Behring-Strasse 76, 35041 Marburg-batch releaser, CSL Behring L.L.C., 1201 N Kinzie Ave, Bradley, Illinois (IL) 60915, USA-bulk manufacturer, packager	Germany	CSL Behring GmbH, Emil-von-Behring-Strasse 76, 35041 Marburg	Germany	R	15369/1 14.08.2020
27	Mononine 1000	human blood coagulation factor IX	powder and solvent for solution for injection or infusion	1000IU; - I pack (N1 glass vial with powder, N1 glass vial with solvent 10ml, N1 filter transfer device 20/20), II pack (N1 disposable syringe 10ml, N1 venipuncture set, N2 alcohol swabs, N1 non-sterile plaster)	CSL Behring GmbH, Emil-von-Behring-Strasse 76, 35041 Marburg-batch releaser, CSL Behring L.L.C., 1201 N Kinzie Ave, Bradley, Illinois (IL) 60915, USA-bulk manufacturer, packager	Germany	CSL Behring GmbH, Emil-von-Behring-Strasse 76, 35041 Marburg	Germany	R	15368/1 14.08.2020
28	Acyclovir Denk 5% Cream	aciclovir	cream for topical use	50mg/g; 7g aluminium tube	RubiePharm Arzneimittel GmbH, Bruder-Grimm-Str. 62, 36396 Steinau an der Strasse	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	15673/1 14.08.2020
29	Nifuromed	nifuroxazide	suspension oral with banana flavour	44mg/ml; glass bottle 100ml and measuring cup	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	Medical Horizon Ltd, Ararat province, Masis city, Masis station, Gortsaranain 22	Republic of Armenia	R	18111/1 14.08.2020

30	Lasolvan syrup 30mg/5ml	ambroxol (ambroxol hydrochloride)	syrup	30mg/5ml; 100ml glass bottle and measuring cup	Boehringer Ingelheim Espana S.A., Prat de la Riba, 50, 08174 Sant Cugat del Valles, Barcelona	Spain	Sanofi-Aventis Deutschland GmbH, Industriepark Hoechst, Bruningstrasse 50, D-65926 , Frankfurt am Main	Germany	OTC	16750/2 14.08.2020
31	Lasolvan syrup 15mg/5ml	ambroxol (ambroxol hydrochloride)	syrup	15mg/5ml; 100ml glass bottle and measuring cup	Boehringer Ingelheim Espana S.A., Prat de la Riba, 50, 08174 Sant Cugat del Valles, Barcelona	Spain	Sanofi-Aventis Deutschland GmbH, Industriepark Hoechst, Bruningstrasse 50, D-65926 , Frankfurt am Main	Germany	OTC	16749/2 14.08.2020
32	Rosulip	rosuvastatin (rosuvastatin zinc)	tablets film- coated	5mg; (14/2x7/), (28/4x7/), (56/8x7/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30- 38	Hungary	R	15461/1 14.08.2020
33	Rosulip	rosuvastatin (rosuvastatin zinc)	tablets film- coated	10mg; (14/2x7/), (28/4x7/), (56/8x7/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30- 38	Hungary	R	15462/1 14.08.2020

34	Rosulip	rosuvastatin (rosuvastatin zinc)	tablets film-coated	20mg; (14/2x7/), (28/4x7/), (56/8x7/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	15463/1 14.08.2020
35	Rosulip	rosuvastatin (rosuvastatin zinc)	tablets film-coated	40mg; (14/2x7/), (28/4x7/), (56/8x7/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	15464/1 14.08.2020
36	Rosulip	rosuvastatin (rosuvastatin zinc)	tablets film-coated	5mg; (14/2x7/), (28/4x7/), (56/8x7/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, packager, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65, Hungary-bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	R	15465/1 14.08.2020
37	Rosulip	rosuvastatin (rosuvastatin zinc)	tablets film-coated	10mg; (14/2x7/), (28/4x7/), (56/8x7/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, packager, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65, Hungary-bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	R	15466/1 14.08.2020

38	Rosulip	rosuvastatin (rosuvastatin zinc)	tablets film-coated	20mg; (14/2x7/), (28/4x7/), (56/8x7/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, packager, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65, Hungary-bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	R	15467/1 14.08.2020
39	Rosulip	rosuvastatin (rosuvastatin zinc)	tablets film-coated	40mg; (14/2x7/), (28/4x7/), (56/8x7/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, packager, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65, Hungary-bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	R	15468/1 14.08.2020
40	Prospan cough drops	hedera helix	drops oral	20mg/ml; 20ml glass vial-dropper	Engelhard Arzneimittel GmbH& Co. KG, Herzbergstrasse 3, 61138 Niederdorfelden	Germany	Engelhard Arzneimittel GmbH& Co. KG, Herzbergstrasse 3, 61138 Niederdorfelden	Germany	OTC	15680/1 14.08.2020
41	Dexarom	dexketoprofen (dexketoprofen trometamol)	solution for i/m and i/v injection	25mg/ml; (5/1x5/) ampoules 2ml, blister, (10/2x5/) ampoules 2ml, blisters	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	R	14622/1 14.08.2020

42	Metronidazole-Asteria	metronidazole	tablets	500mg; (30/3x10/) and (100/10x10/), in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-si, Chungcheongbuk-do	Korea South	GL Corporation, Woori Venture Tower #201, 70, Seonyu-ro, Yeongdeungpo-ku, Seoul	South Korea	R	14424/4 14.08.2020
43	Oxaliplatin	oxaliplatin	powder lyophilized for solution for infusion	50mg; (1) glass bottle or vial	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	R	15660/1 14.08.2020
44	Oxaliplatin	oxaliplatin	powder lyophilized for solution for infusion	100mg; (1) glass bottle or vial	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	R	15659/1 14.08.2020
45	Grandaxin	tofisopam	tablets	50mg; (20/2x10/) and (60/6x10/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65 -batch releaser, packager, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary-bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	R	16442/1 14.08.2020
46	Grandaxin	tofisopam	tablets	50mg; (20/2x10/) and (60/6x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	16443/1 14.08.2020

47	Parlazin	cetirizine (cetirizine dihydrochloride)	film-coated tablets	10mg; (10/1x10/) in blister, (30/3x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	OTC	15292/2 14.08.2020
48	Parlazin	cetirizine (cetirizine dihydrochloride)	film-coated tablets	10mg; (10/1x10/) in blister, (30/3x10/) in blister	Egis Pharmaceuticals PLC 9900, Kormend, Matyas kiraly u. 65-batch releaser, packager, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120-bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	OTC	15293/2 14.08.2020
49	Gadovist	gadobutrol	solution for injection	604.72mg/ml; (5) glass syringe 7.5ml	Bayer AG, Mullerstrasse 178, 13353, Berlin	Germany	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	R	18315/1 14.08.2020
50	Nimelid	nimesulide	granules for oral suspension	100mg; (10) and (30) sachets 2g	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	R	14921/1 14.08.2020
51	Diroton	lisinopril (lisinopril dihydrate)	tablets	5mg; (14/1x14/), (28/2x14/) and (56/4x14/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	16939/1 14.08.2020
52	Diroton	lisinopril (lisinopril dihydrate)	tablets	10mg; (14/1x14/), (28/2x14/) and (56/4x14/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	16940/1 14.08.2020

53	Diroton	lisinopril (lisinopril dihydrate)	tablets	20mg; (14/1x14/), (28/2x14/) and (56/4x14/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	16941/1 14.08.2020
54	Captopril Denk 25	captopril	tablets	25mg; (20/2x10/) and (100/10x10) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	17813/3 14.08.2020
55	Perufen	ibuprofen	suspension oral	20mg/ml; 100ml and 200ml glass vial and measuring device	Laboratorios Basi -Industria Farmaceutica, S.A., Parque Industrial Manuel Lourenco Ferreira, Lote 15, Mortagua, 3450-232	Portugal	GM Pharmaceuticals Ltd, 65, Phonicchala, Tbilisi	Georgia	OTC	16408/2 14.08.2020
56	Maviret	glecaprevir, pibrentasvir	tablets film-coated	100mg+40mg; (84(4x21(7x3)) in blister	AbbVie Deutschland GmbH & Co. KG, Knolstrasse, 67061 Ludwigshafen - batch releaser, packager, quality control, Fournier Laboratories Ireland Limited, Anngrove, Carrigtwohill, Co. Cork, Ireland- bulk manufacturer	Germany	AbbVie Biopharmaceuticals GmbH, Neuhofstrasse 23, 6341 Baar	Switzerland	R	18744/2 14.08.2020
57	Karvidil	carvedilol	tablets	6,25mg; (28/2x14/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	R	16240/1 14.08.2020

58	Karvidil	carvedilol	tablets	12,5mg; (28/2x14/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	R	16239/1 14.08.2020
59	Karvidil	carvedilol	tablets	25mg; (28/2x14/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	R	16238/1 14.08.2020
60	Valerianae tincture	valerianae extract	tincture	200mg/ml; glass vial 30ml	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	OTC	15530/1 14.08.2020
61	Aquadetrim Vitamin D3 Medana	colecalfiferol	drops oral	15000IU/ml; 10ml glass bottle	Medana Pharma S.A., 98-200 Sieradz, W. Lokietka 10- batch releaser, Medana Pharma S.A., str. Polskiej Organizacji Wojskowej 57, 98-200 Sieradz, Poland- bulk manufacturer, packager	Poland	Medana Pharma S.A., 98-200 Sieradz, W. Lokietka 10	Poland	R	16671/1 14.08.2020
62	Levomecol	chloramphenicol, 6-methyluracil	ointment	7,5mg/g+40mg/g aluminium tube 30g, aluminium tube 40g	SIC "Borshchahivskiy Chemical-Pharmaceutical Plant" PJSC, 17, Mira St, Kyiv, 03134	Ukraine	SIC "Borshchahivskiy Chemical-Pharmaceutical Plant" PJSC, 17, Mira St, Kyiv, 03134	Ukraine	OTC	18510/1 14.08.2020

63	Humalog Mix 25	insulin lispro solution and insulin lispro protamine suspension	suspension for injection	100U/ml (3,5mg/ml); (5) cartridges 3ml	Lilly France S.A.S., 2, rue du Colonel Lilly, 67640 Fegersheim	France	Eli Lilly Nederland B.V., Grootslag 1-5, NL-3991, RA Houten	the Netherlands	R	17366/1 14.08.2020
64	Somnol	zopiclone	tablets coated	7,5mg; (10/1x10/) and (20/2x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	R	16194/1 14.08.2020
65	Digoxin Grindeks	digoxin	tablets	0,25mg; (50/2x25/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	R	16249/1 14.08.2020
66	Terbinafine-Asteria	terbinafine (terbinafine hydrochloride)	cream for external use	10mg/g; 30g aluminium tube	Hankook Korus Pharm Co., Ltd, 30, Gangjeoro, Jecheon-Si, Chungcheongbuk-do-batch releaser, Dongkwang Pharm Co., Ltd, 115, Sandan-ro, Pyeongtaek-si, Gyeonggi-do, Korea South-bulk manufacturer, packager	Korea South	GL Corporation, Woori Venture Tower 201,70, Seonyu-ro, YoungDeungPo-Ku, Seoul	Korea South	OTC	14796/1 14.08.2020
67	Anauran	lidocaine (lidocaine hydrochloride), neomycin (neomycin sulfate), polymyxin B (polymyxin B sulfate)	drops ear	4g/100ml+0.5g(37500 0IU)/100ml+1000000IU/100ml; 25ml glass bottle	Zambon S.P.A., Via Della Chimica, 9, Vicenza, 36100	Italy	Zambon S.P.A., Via Lillo Del Duca, 10, Bresso, 20091	Italy	R	15496/1 14.08.2020

68	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	250mg+125mg; (20/2x10/) in blister	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	17635/2 14.08.2020
69	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	500mg+125mg; (14/2x7/) in blister	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	17633/2 14.08.2020
70	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	875mg+125mg; (14/2x7/) in blister	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	17634/2 14.08.2020
71	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	powder for oral suspension	125mg/5ml+31,25mg/5ml; 100ml glass bottle	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	17636/2 14.08.2020
72	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	powder for oral suspension with mixed fruit flavour	200mg/5ml+28,5mg/5ml; 70ml glass bottle with measuring device	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	17694/2 14.08.2020

73	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	powder for oral suspension	250mg/5ml+62,5mg/5 ml; 100ml glass bottle	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	17637/2 14.08.2020
74	Paraflu for adults	pheniramine (pheniramine maleate), paracetamol, vitamin C	powder for oral solution with lemon flavor	25mg+500mg+200mg; (10) sachets 13g	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	R	19112/1 14.08.2020
75	Paraflu for children	pheniramine (pheniramine maleate), paracetamol, vitamin C	powder for oral solution with raspberry flavor	10mg+280mg+100mg; (10) sachets 13g	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	R	19113/1 14.08.2020