

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 9-2/20 on September 29, 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	Senadeksin	sennosides A	tablets	70mg; (20/2x10/) in blister, (140/14x10/) in blister	VIFITEH CJSC, Obolensk v., Obolenskoye shose, build. 20, Serpukhov district, Moscow region- bulk manufacturer, packager, quality control (physicochemical), batch releaser, VIFITEH CJSC, Obolensk v., Obolenskoye shose, build. 16/1, Serpukhov district, Moscow region, Russia- quality control (microbiological)	Russia	VIFITEH CJSC, SCRAM, Obolensk v., Serpukhov district, Moscow region, 142279	Russia	OTC	19416 29.09.2020
2	Gripoflex 500	paracetamol, pheniramine (pheniramine maleate), ascorbic acid	powder for oral solution	500mg+25mg+200mg; (5) laminated sachets 5g	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	R	19417 29.09.2020

3	Zulbex	rabeprazole (rabeprazole sodium)	tablets gastro-resistant	10mg; (28/2x14/) in blister, (56/4x14/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- packager, quality control, batch releaser, KRKA, tovarna zdravil, d.d., Novomeska cesta 22, Sentjernej 8310, Slovenia- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	19418 29.09.2020
4	Zulbex	rabeprazole (rabeprazole sodium)	tablets gastro-resistant	20mg; (28/2x14/) in blister, (56/4x14/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- packager, quality control, batch releaser, KRKA, tovarna zdravil, d.d., Novomeska cesta 22, Sentjernej 8310, Slovenia- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	19419 29.09.2020
5	Roxera Plus	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets film-coated	20mg+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	19420 29.09.2020

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 9-2/20 on September 29, 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	On.setron-Denk 4mg ODT	ondansetron	tablets orodispersible	4mg; (6/1x6/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning- bulk manufacturer, packager, quality control (physico-chemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany-quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	19421 29.09.2020
2	Artrum	ketoprofen	solution for i/v and i/m injection	50mg/ml; (10/2x5/ ampoules 2ml, in blister	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	R	19422 29.09.2020
3	Valsacor	valsartan	tablets film- coated	80mg; (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	R	19423 29.09.2020

4	Valsacor	valsartan	tablets film-coated	160mg; (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	R	19424 29.09.2020
5	Complivit Calcium D3	coleciferol, calcium (calcium carbonate)	tablets chewable with orange flavour	0,005mg+500mg; (30) in plastic container, (100) in plastic container	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	JSC "OTCPharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	19425 29.09.2020
6	Dimex	diphenhydramine (diphenhydramine hydrochloride), ammonium chloride	syrup	1.992mg/ml+19.92mg/ml; 125ml plastic bottle and measuring cup	Sopharma JSC, Vrabevo vlg. 5660, district of Lovetch	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	19426 29.09.2020
7	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 29.09.2020
8	Tarka	trandolapril, verapamil (verapamil hydrochloride)	tablets modified-release film-coated	2mg+180mg; (28/2x14/) in blister	AbbVie Deutschland GmbH & Co. KG, Knollstrasse, 67061 Ludwigshafen	Germany	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	R	19428 29.09.2020

9	Tarka	trandolapril, verapamil (verapamil hydrochloride)	tablets modified- release film- coated	4mg+240mg; (28/2x14/) in blister	AbbVie Deutschland GmbH & Co. KG, Knollstrasse, 67061 Ludwigshafen	Germany	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	R	19429 29.09.2020
10	Pedeks	permethrin	solution for external use	5mg/g; 60ml glass bottle	LMP Ltd., 1, Vietalvas street, Riga, LV-1009- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Grindeks JSC, Krustpils street 53, Riga, LV- 1057, Latvia- quality control (microbiological)	Latvia	LMP Ltd., 1, Vietalvas street, Riga, LV-1009	Latvia	OTC	19430 29.09.2020
11	Talliton	carvedilol	tablets	6,25mg; (14/2x7/) in blister, (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	19431 29.09.2020
12	Talliton	carvedilol	tablets	12,5mg; (14/1x14/) in blister, (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	19432 29.09.2020
13	Talliton	carvedilol	tablets	25mg; (14/1x14/) in blister, (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	19433 29.09.2020

14	Vitamin C-Asteria	ascorbic acid	tablets	500mg; (100/10x10/) in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-Si, Chungcheongbuk-do	Korea South	Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan	Republic of Armenia	OTC	19434 29.09.2020
----	-------------------	---------------	---------	--------------------------------	---	-------------	---	---------------------	-----	------------------

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 9-2/20 on September 29, 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	Salbutamol	salbutamol (salbutamol sulfate)	tablets	2mg; (30/2x15/) in blister	Warsaw Pharmaceutical Works "Polfa" S.A., Karolkowa 22/24 str., 01-207 Warsaw- batch releaser, Pharmaceutical Works Polpharma S.A., ul. Metalowca 2, Nowa Deba, 39-460, Poland - bulk manufacturer, packager, quality control	Poland	Warsaw Pharmaceutical Works "Polfa" S.A., Karolkowa 22/24 str., 01-207 Warsaw	Poland	R	19169/1/1 29.09.2020
2	Salbutamol	salbutamol (salbutamol sulfate)	tablets	4mg; (25/1x25/) in blister	Warsaw Pharmaceutical Works "Polfa" S.A., Karolkowa 22/24 str., 01-207 Warsaw- batch releaser, Pharmaceutical Works Polpharma S.A., ul. Metalowca 2, Nowa Deba, 39-460, Poland - bulk manufacturer, packager, quality control	Poland	Warsaw Pharmaceutical Works "Polfa" S.A., Karolkowa 22/24 str., 01-207 Warsaw	Poland	R	19170/1/1 29.09.2020

3	Rabeprazole-Asteria	rabeprazole (rabeprazole sodium)	tablets film-coated	20mg; (10/1x10/), in blister and (100/10x10/), in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-si, Chungcheongbuk-do	Korea South	Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan	Republic of Armenia	R	15170/1/1 29.09.2020
4	Ceftriaxone-Asteria Inj. 1g	ceftriaxone (ceftriaxone sodium)	powder for solution for i/m injection	1000mg; (1) glass vial and 3,5ml solvent in ampoule	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	18679/1/1 29.09.2020
5	Antigrippin with vitamin C	paracetamol, chlorphenamine (chlorphenamine maleate), ascorbic acid	tablets effervescent	500mg+10mg+200mg; (30/5x6/), in strip	Natur Produkt Pharma Sp. z o.o., ul. Podstoczysko 30, 07-300 Ostrow Mazowiecka	Poland	Bausch Health LLC., Shabolovka st. 31, building 5, 115162, Moscow	Russia	OTC	14955/1/2 29.09.2020
6	Antigrippin with vitamin C	paracetamol, chlorphenamine (chlorphenamine maleate), ascorbic acid	tablets effervescent	250mg+3mg+50mg; (30/5x6/), in strip	Natur Produkt Pharma Sp. z o.o., ul. Podstoczysko 30, 07-300 Ostrow Mazowiecka	Poland	Bausch Health LLC., Shabolovka st. 31, building 5, 115162, Moscow	Russia	OTC	14954/1/2 29.09.2020
7	Cilozek	cilostazol	tablets	100mg; (30/3x10/), in blister	Adamed Pharma S.A., 5 Marszalka J. Pilsudskiego Str., 95-200 Pabianice	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza St., 05-152 Czosnow	Poland	R	15379/1/1 29.09.2020
8	Anti-Angin Formula	chlorhexidine (chlorhexidine diacetate), tetracaine (tetracaine hydrochloride), ascorbic acid	lozenges	2mg+0,2mg+50mg; (20/2x10/) in blister	Herkel B.V., Nobelweg 6,3899 BN Zeewold	the Netherlands	Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	R	16369/1/1 29.09.2020

9	Zavicefta	ceftazidime (ceftazidime pentahydrate), avibactam (avibactam sodium)	powder for solution for infusion	2g+0.5g; (10) glass vial 20ml	ACS DOBFAR SpA, Via Alesandro Fleming, 2, Verona, 37135	Italy	Pfizer Ireland Pharmaceuticals Operations Support Group Ringaskiddy, County Cork	Ireland	R	18293/1/1 29.09.2020
10	Carbalex 200mg	carbamazepine	tablets	200mg; (50/5x10/) in blister, (100/10x10/) in blister	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach -batch releaser, G.L. Pharma GmbH, Industriestrasse 1, 8502 Lannach, Austria -bulk manufacturer, packager	Austria	Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	R	15754/1/1 29.09.2020
11	Carbalex 300mg retard	carbamazepine	tablets prolonged-release	300mg; (50/5x10/) in blister, (100/10x10/) in blister	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach -batch releaser, G.L. Pharma GmbH, Industriestrasse 1, 8502 Lannach, Austria -bulk manufacturer, packager	Austria	Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	R	15755/1/1 29.09.2020
12	Carbalex 600mg retard	carbamazepine	tablets prolonged-release	600mg; (50/5x10/) in blister, (100/10x10/) in blister	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach -batch releaser, G.L. Pharma GmbH, Industriestrasse 1, 8502 Lannach, Austria -bulk manufacturer, packager	Austria	Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	R	15756/1/1 29.09.2020

13	Letiram	levetiracetam	tablets film-coated	250mg; (30/3x10/), in blister and (60/6x10/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa, Greece-bulk manufacturer, packager	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	15308/2/1 29.09.2020
14	Letiram	levetiracetam	tablets film-coated	500mg; (30/3x10/), in blister and (60/6x10/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa, Greece-bulk manufacturer, packager	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	15307/2/1 29.09.2020
15	Letiram	levetiracetam	tablets film-coated	750mg; (30/3x10/), in blister and (60/6x10/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa, Greece-bulk manufacturer, packager	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	15309/2/1 29.09.2020
16	Letiram	levetiracetam	tablets film-coated	1000mg; (30/3x10/), in blister and (60/6x10/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, Rontis Hellas S.A., P.O. Box 3012, Larisa Industrial Area, 41004 Larisa, Greece-bulk manufacturer, packager	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	15310/2/1 29.09.2020

17	Clovate	clobetasol (clobetasol propionate)	ointment for external use	0,5mg/g; 25g aluminium tube	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	BauschHealth LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	R	14927/1/1 29.09.2020
18	Clovate	clobetasol (clobetasol propionate)	cream for external use	0,5mg/g; 25g aluminium tube	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	R	14928/1/1 29.09.2020
19	Laticort	hydrocortisone (hydrocortisone 17-n-butyrate)	solution for external use	1mg/ml; 20ml plastic vial	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	OTC	16113/1/2 29.09.2020
20	Laticort	hydrocortisone (hydrocortisone 17-n-butyrate)	ointment for external use	1mg/g; 15g aluminium tube	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	Bausch Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	OTC	16112/1/2 29.09.2020
21	Diclofenac-Asteria	diclofenac (diclofenac sodium)	tablets	50mg; (20/2x10/) and (100/10x10/), in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-si, Chungcheongbuk-do	Korea South	Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan	Republic of Armenia	R	15172/1/1 29.09.2020

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision 9-2/20 on September 29, 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	Co-Amlessa	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate), indapamide	tablets	2mg+5mg+0,625mg; (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	R	15854/2 29.09.2020
2	Co-Amlessa	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate), indapamide	tablets	4mg+5mg+1,25mg; (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	R	15855/2 29.09.2020
3	Co-Amlessa	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate), indapamide	tablets	4mg+10mg+1,25mg; (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	R	15856/1 29.09.2020
4	Co-Amlessa	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate), indapamide	tablets	8mg+5mg+2,5mg; (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	R	15857/2 29.09.2020

5	Co-Amlessa	perindopril (perindopril tert-butylamine), amlodipine (amlodipine besilate), indapamide	tablets	8mg+10mg+2,5mg; (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	R	15858/2 29.09.2020
6	BeneFix 250IU	nonacog alfa	powder and solvent for solution for injection	250IU; glass vial and solvent in pre-filled syringe 5ml, vial adapter, sterile infusion set, (2) alcohol swabs, plaster, gauze pad	Wyeth Farma S.A., Autovia del Norte A-1 Km 23 Desvio Algete, Km 1 28700 San Sebastian de los Reyes Madrid-bulk manufacturer, packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Eisenbahnstrasse 2-4 88085 Langenargen, Germany-solvent manufacturer	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	R	18620/2 29.09.2020
7	BeneFix 500IU	nonacog alfa	powder and solvent for solution for injection	500IU; glass vial and solvent in pre-filled syringe 5ml, vial adapter, sterile infusion set, (2) alcohol swabs, plaster, gauze pad	Wyeth Farma S.A., Autovia del Norte A-1 Km 23 Desvio Algete, Km 1 28700 San Sebastian de los Reyes Madrid-bulk manufacturer, packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Eisenbahnstrasse 2-4 88085 Langenargen, Germany-solvent manufacturer	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	R	18621/2 29.09.2020

8	BeneFix 1000IU	nonacog alfa	powder and solvent for solution for injection	1000IU; glass vial and solvent in pre-filled syringe 5ml, vial adapter, sterile infusion set, (2) alcohol swabs, plaster, gauze pad	Wyeth Farma S.A., Autovia del Norte A-1 Km 23 Desvio Algete, Km 1 28700 San Sebastian de los Reyes Madrid-bulk manufacturer, packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Eisenbahnstrasse 2-4 88085 Langenargen, Germany-solvent manufacturer	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	R	18622/2 29.09.2020
9	BeneFix 2000IU	nonacog alfa	powder and solvent for solution for injection	2000IU; glass vial and solvent in pre-filled syringe 5ml, vial adapter, sterile infusion set, (2) alcohol swabs, plaster, gauze pad	Wyeth Farma S.A., Autovia del Norte A-1 Km 23 Desvio Algete, Km 1 28700 San Sebastian de los Reyes Madrid-bulk manufacturer, packager, batch releaser, Vetter Pharma-Fertigung GmbH & Co. KG, Eisenbahnstrasse 2-4 88085 Langenargen, Germany-solvent manufacturer	Spain	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	R	18623/2 29.09.2020
10	Septanazal for adults	xylometazoline (xylometazoline hydrochloride), dexpanthenol	spray nasal	1mg/ml+50mg/ml; 10ml (100 doses) plastic container with pump dispenser	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	14759/1 29.09.2020
11	Septanazal for children	xylometazoline (xylometazoline hydrochloride), dexpanthenol	spray nasal	0,5mg/ml+50mg/ml; 10ml (100 doses) plastic container with pump dispenser	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	14760/1 29.09.2020

12	Decaris	levamisole (levamisole hydrochloride)	tablets	50mg; (2/1x2/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest-batch releaser, S.C. Gedeon Richter Romania S.A., 99-105 Guza Voda str.,Targu-Mures, Romania-bulk manufacturer, packager, quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	18810/1 29.09.2020
13	Decaris	levamisole (levamisole hydrochloride)	tablets	150mg; (1) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest-batch releaser, S.C. Gedeon Richter Romania S.A., 99-105 Guza Voda str.,Targu-Mures, Romania-bulk manufacturer, packager, quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	18811/1 29.09.2020
14	Niperten	bisoprolol (bisoprolol fumarate)	tablets film-coated	2,5mg; (30/2x15/) 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	16716/3/1 29.09.2020
15	Niperten	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (30/2x15/) 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	16714/3/1 29.09.2020
16	Niperten	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg; (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	R	16715/2 29.09.2020

17	Co-Vamloset	amlodipine (amlodipine besilate), valsartan, hydrochlorothiazide	tablets film-coated	5mg+160mg+12,5mg; (30/3x10/) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	R	18911/2/1 29.09.2020
18	Co-Vamloset	amlodipine (amlodipine besilate), valsartan, hydrochlorothiazide	tablets film-coated	10mg+160mg+12,5mg ; (30/3x10/) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	R	18912/2/1 29.09.2020
19	Co-Vamloset	amlodipine (amlodipine besilate), valsartan, hydrochlorothiazide	tablets film-coated	10mg+160mg+25mg; (30/3x10/) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region,143500	Russia	R	18913/2/1 29.09.2020
20	Xarelto	rivaroxaban	tablets film-coated	10mg; (30/3x10/) in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368, Leverkusen	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	R	17616/2 29.09.2020
21	Complivit Calcium D3	colecalfiferol, calcium	tablets chewable with orange flavour	0,005mg+500mg; (30) and (100) in plastic container	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	OTCPharm PJSC, 123317, Moscow, Testovskaya str., 10	Russia	OTC	13808/2 29.09.2020
22	Lodigrel	clopidogrel (clopidogrel hydrosulfate)	tablets film-coated	75mg; (14/2x7/) in blister, (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	18408/1 29.09.2020

23	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	R	15922/1 29.09.2020
24	Fluimucil	acetylcysteine	granules for oral solution	200mg; (20) and (60) sachet 1g	Zambon Switzerland Ltd., Via Industria 13, CH-6814, Cadempino	Switzerland	Zambon S.P.A., Via Lillo Del Duca, 10, Bresso, 20091	Italy	OTC	16216/1 29.09.2020
25	Duotrav	timolol (timolol maleate), travoprost	drops eye (solution)	5mg/ml+40mcg/ml; (1) 2,5ml plastic vial with measuring dropper	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	18027/2 29.09.2020
26	Survanta	beractant (phospholipids)	suspension intratracheal	25mg/ml; glass vial 4ml	AbbVie Inc., 1401 Sheridan Road, North Chicago, Illinois 60064	USA	AbbVie Biopharmaceuticals GmbH, Neuhofstrasse 23, 6341 Baar	Switzerland	R	16931/1 29.09.2020
27	Ceraxon	citicoline (citicoline sodium)	solution oral	100mg/ml; glass bottle 30ml and measuring syringe, (6) sachets 10ml, (10) sachets 10ml (30) sachets 10ml	Ferrer Internacional, S.A., Joan Buscalla, 1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer Internacional, S.A., Joan Gran Via Carlos III, 94 08028, Barcelona	Spain	R	18223/2 29.09.2020
28	Artrum	ketoprofen	solution for i/v and i/m injection	50mg/ml; (10/2x5/) ampoules 2ml, in blister	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	R	14843/3

29	Grammidin with anesthetic neo	gramicidin S (gramicidin S dihydrochloride), oxybuprocaine (oxybuprocaine hydrochloride), cetylpyridinium chloride (cetylpyridinium chloride monohydrate)	tablets to be sucked	3mg+0.2mg+1mg; (18/2x9/) in blister	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	15769/3 29.09.2020
30	Strepsils Express	dichlorobenzyl alcohol, amylmetacresol, lidocaine	lozenges	1,2mg+0.6mg+10mg; (24/2x12/), (24/3x8), 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	15040/5 29.09.2020
31	Nicorandil 10mg Tablets	nicorandil	tablets	10mg; (60/6x10/), in blister	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB - batch releaser, Dexcel Ltd., 1 Dexcel Street, Or-Akiva 30600, Israel-bulk manufacturer, packager	UK	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB	UK	R	15390/1 29.09.2020
32	Nicorandil 20mg Tablets	nicorandil	tablets	20mg; (60/6x10/), in blister	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB - batch releaser, Dexcel Ltd., 1 Dexcel Street, Or-Akiva 30600, Israel-bulk manufacturer, packager	UK	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB	UK	R	15389/1 29.09.2020

33	Azarga	timolol (timolol maleate), brinzolamide	drops eye (suspension)	5mg/ml+10mg/ml; 5ml vial	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	17919/2 29.09.2020
34	Vitamin C-Asteria	ascorbic acid	tablets	500mg; (100/10x10/ in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-Si, Chungcheongbuk-do	Korea South	Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan	Republic of Armenia	OTC	14868/2/1 29.09.2020
35	Valsacor	valsartan	tablets film- coated	80mg; (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	R	14916/2 29.09.2020
36	Valsacor	valsartan	tablets film- coated	160mg; (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	R	14917/2 29.09.2020
37	Nolpaza	pantoprazole (pantoprazole sodium)	powder for solution for injection	40mg; (1) glass vial, (5) glass vial, (10) glass vial	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- secondary packager, quality control, batch releaser, VALDEPHARM Parc Industriel d'Incarville, Parc de la Fringale - CS 10606, VAL DE REUIL, 27106, France- bulk manufacturer, primary packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	19313/1 29.09.2020
38	Bromocriptin- Richter	bromocriptine (bromocriptine mesilate)	tablets	2,5mg; (30) glass bottle	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	18812/1 29.09.2020

39	Lomexin	fenticonazole (fenticonazole nitrate)	cream for vaginal and external use	20mg/g; 30g aluminium tube, 78g aluminium tube and dispenser	Recordati Industria Chimica e Farmaceutica S.p.A., Via Civitali, 1-20148 Milano	Italy	Recordati Ireland Ltd., Raheens East, Ringaskiddy, Co Cork	Ireland	R	14858/4 29.09.2020
40	Diprosalic	betamethasone (betamethasone dipropionate), salicylic acid	ointment	0,5mg/g+30mg/g; 30g aluminium tube	Schering-Plough Labo N.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Schering-Plough Central East AG, Weyrstrasse 20, P.O. Box CH-6000 Lucerne 6	Switzerland	R	18088/2 29.09.2020
41	Celestoderm-V with Garamycin	betamethasone (betamethasone valerate), gentamicin (gentamicin sulfate)	ointment	1mg/g+1mg/g; 30g aluminium tube	Schering-Plough Labo N.V., Industriepark 30 B-2220, Heist-op-den-Berg	Belgium	Schering-Plough Central East AG, Weyrstrasse 20, P.O. Box CH-6000 Lucerne 6	Switzerland	R	18752/2 29.09.2020
42	Celestoderm-V	betamethasone (betamethasone 17-valerate)	ointment	1mg/g; aluminium tube 30g	Schering-Plough Labo N.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Schering-Plough Central East AG, Weyrstrasse 20, CH-6000 Lucerne 6	Switzerland	R	18483/1 29.09.2020
43	Dacarbazine medac	dacarbazine (dacarbazine citrate)	powder for solution for injection or infusion	200mg; (10) glass vial	Medac GmbH, Theaterstrasse 6, 22880 Wedel- secondary packager, quality control, batch releaser, Oncotec Pharma Production GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany- bulk manufacturer, primary packager	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	R	18974/1 29.09.2020

44	Celestoderm-V with Garamycin	betamethasone (betamethasone valerate), gentamicin (gentamicin sulfate)	ointment	1mg/g+1mg/g; 30g aluminium tube	Schering-Plough Labo N.V., Industriepark 30 B-2220, Heist-op-den-Berg	Belgium	Schering-Plough Central East AG, Weyrstrasse 20, P.O. Box CH-6000 Lucerne 6	Switzerland	R	18752/3 29.09.2020
45	Celestoderm-V cream with Garamycin	betamethasone (betamethasone 17-valerate), gentamicin (gentamicin sulfate)	cream	1mg/g+1mg/g; aluminium tube 30g	Schering-Plough Labo N.V., Industriepark 30 B-2220, Heist-op-den-Berg	Belgium	Schering-Plough Central East AG, Weyrstrasse 20, CH-6000 Lucerne 6	Switzerland	R	18373/2 29.09.2020
46	Trimecor MR	trimetazidine (trimetazidine dihydrochloride)	tablets film-coated modified-release	35mg; (30/3x10/) in blister, (60/6x10/), in blister	GM Pharmaceuticals Ltd, PSP group 65, Qvemo Phonichala str., Tbilisi	Georgia	GM Pharmaceuticals Ltd, PSP group 65, Qvemo Phonichala str., Tbilisi	Georgia	R	15220/1 29.09.2020
47	Azibiot	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3/), 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	14892/3 29.09.2020
48	Azibiot	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3/) 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	19347/1 29.09.2020
49	Pedeks	permethrin	solution for external use	5mg/g; 60ml glass bottle	LMP Ltd., 1, Vietalvas street, Riga, LV-1009	Latvia	LMP Ltd., 1, Vietalvas street, Riga, LV-1009	Latvia	OTC	15169/3 29.09.2020

50	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	R	16718/1 29.09.2020
51	Strepsils Intensive	flurbiprofen	lozenges with honey and lemon flavour	8,75mg; (24/3x8/) 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	15037/2 29.09.2020