

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 10-1/20 on October 15, 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	Kestine	ebastine	tablets film-coated	10mg; (5/1x5/) in blister, (10/1x10/) in blister	Industrias Farmaceuticas Almirall S.A., Ctra. Nacional II, Km. 593, 08740 Sant Andreu de la Barca, Barcelona	Spain	Almirall, S.A., Ronda General Mitre, 151, 08022 Barcelona	Spain	R	19442 15.10.2020
2	Erynit Tatpharm	pentaerithryl tetranitrate	tablets	10mg; (50/5x10/) in blister	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	R	19444 15.10.2020
3	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	R	19445 15.10.2020

LIST

of the medicines recommended for the registration (new packaging) by the Center according to the meeting decision N 10-1/20 on October 15, 2020

President \_\_\_\_\_ E. Amroya

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	Meteospasmyl	alverine (alverine citrate), simethicone	capsules	60mg+300mg; (20/2x10/) in blister, (30/3x10/) in blister	Laboratoires MAYOLY SPINDLER, 6 avenue de l'Europe, 78400 Chatou-packager, quality control (physicochemical), batch releaser, Laboratoires GALENIQUES VERNIN, 20 rue Louis-Charles Vernin, 77190 Dammarie-Les-Lys, France- bulk manufacturer, quality control (microbiological)	France	Laboratoires MAYOLY SPINDLER, 6 avenue de l'Europe, 78400 Chatou	France	OTC	14991/2 15.10.2020

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 10-1/20 on October 15, 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	Trimecor MR	trimetazidine (trimetazidine dihydrochloride)	tablets film-coated modified-release	35mg; (30/3x10/) in blister, (60/6x10/) in blister	GM Pharmaceuticals Ltd, 65, Phonichala str., 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, 65, Phonichala str., 0165 Tbilisi	Georgia	R	19435 15.10.2020
2	Fluimucil	acetylcysteine	tablets effervescent	600mg; (10/5x2/) in blister	Zambon Switzerland Ltd., Via Industria 13, CH-6814, Cadempino	Switzerland	Zambon S.P.A., Via Lillo Del Duca, 10, Bresso, 20091	Italy	OTC	19436 15.10.2020
3	Cevikap	ascorbic acid	drops oral	100mg/ml; glass bottle-dropper 10ml, glass bottle-dropper 30ml	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, quality control	Poland	Medana Pharma S.A., 98-200 Sieradz, W. Lokietka 10	Poland	OTC	19437 15.10.2020

4	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	19438 15.10.2020
5	Albunorm Octapharma 5%	albumin human	solution for i/v infusion	50mg/ml; 100ml glass bottle, 250ml glass bottle, 500ml glass bottle	Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A-1100 Vienna	Austria	Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A-1100 Vienna	Austria	R	19439 15.10.2020
6	Codelac Neo	butamirate (butamirate citrate)	tablets modified-release film-coated	50mg; (10/1x10/) in blister	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	OTCPharm PJSC, 123317, Moscow, Testovskaya str., 10	Russia	OTC	19440 15.10.2020
7	Albunorm Octapharma 20%	albumin human	solution for i/v infusion	200mg/ml; 50ml glass bottle, 100ml glass bottle	Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A-1100 Vienna	Austria	Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A-1100 Vienna	Austria	R	19441 15.10.2020

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 10-1/20 on October 15, 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	Argosulfan	silver sulfathiazole	cream for external use	20mg/g; 15g aluminium tube, 40g 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	16114/1/1 15.10.2020
2	Fluoxetine Lannacher	fluoxetine (fluoxetine hydrochloride)	capsules	20mg; (20/2x10/) 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	18526/2/1 15.10.2020

**LIST**

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision 10-1/20 on October 15, 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	Ferrum Lek	iron (III)-hydroxide dextran complex	solution for i/m injection	50mg/ml; (5) ampoules 2ml, (50) ampoules 2ml	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	R	19069/1 15.10.2020
2	Rhophylac 300	immunoglobulin anti-D (Rh) human	solution for i/v and i/m injection	300mcg/2ml; pre-filled syringe 2ml and needle, in blister	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22-batch releaser, bulk manufacturer, CSL Behring GmbH, Emil-von-Behring-Strasse 76, 35041 Marburg, Germany- primary and secondary packager	Switzerland	CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22	Switzerland	R	15215/2 15.10.2020
3	Encifer	Iron sucrose complex	solution for i/v injection	20mg/ml; (5) ampoules 5ml	Emcure Pharmaceuticals Ltd., Plot NO. J-174, J-168, J-168/1, MIDC, Tarapur, Boisar, Thane 401506, Maharashtra State	India	Emcure Pharmaceuticals Ltd., T-184, M.I.D.C., Bhosari, Pune-411026, Maharashtra	India	R	15097/1 15.10.2020

4	Gabapentin	gabapentin	capsules	300mg; (30/3x10/) 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	16293/1 15.10.2020
5	Kalcinova	vitamin A, vitamin D3, vitamin B6, vitamin C, calcium, phosphorus	tablets	1000IU+100IU+0,4mg+15mg+100mg+77mg; (27/3x9/) 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	16784/1 15.10.2020
6	Coldrex MaxGrip	paracetamol, phenylephrine (phenylephrine hydrochloride), ascorbic acid	powder for oral solution with lemon flavour	1000mg+10mg+40mg; (10) sachets 6,427g	SmithKline Beecham S.A. Ctra. de Ajalvir, KM-2500-28806, Alcalá de Henares, Madrid	Spain	GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	OTC	18670/1 15.10.2020
7	CellCept	mycophenolate mofetil	capsules	250mg; (100/10x10/) in blister	F. Hoffmann-La Roche Ltd., 4303, Kaiseraugst-packager, batch releaser, Delpharm Milano S.R.L, Via Carnevale, 1, Segrate (MI), 20090, Italy-bulk manufacturer, quality control	Switzerland	F. Hoffmann-La Roche Ltd., Greenzacherstrasse, 124, CH-4070, Basel	Switzerland	R	18692/1 15.10.2020
8	Augmentin	amoxicillin trihydrate, clavulanic acid (potassium clavulanate)	powder for oral suspension with mixed fruit flavour	200mg/5ml+28,5mg/5 ml; 70ml glass bottle with measuring device	Glaxo Wellcome Production, ZI de la Peyenniere, 53100 Mayenne	France	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	18704/1 15.10.2020

9	Hydrocortison-Richter	hydrocortisone (hydrocortisone acetate), lidocaine (lidocaine hydrochloride)	suspension for injection	25mg/ml+5mg/ml; (1) glass vial 5ml	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	15063/1 15.10.2020
10	Multi-tabs Kid	vitamin A, vitamin D3, vitamin E, vitamin B1, vitamin B2, vitamin B6, vitamin B12, nicotinamide, pantothenic acid, folic acid hydrate, vitamin C, iron, zinc, copper, manganese, chromium, selen, iodine	tablets chewable raspberry-strawberry	400mcg+10mcg+5mg+0.7mg+0.8mg+0.9mg+1mcg+9mg+3mg+20mcg+40mg+10mg+5mg+1mg+1mg+20mcg+25mcg+70mcg; (30/3x10/) and (60/6x10/) in blister	Pfizer Consumer Manufacturing Italy S.R.L., Via Nettunense, 90, Aprilia, 04011	Italy	Pfizer Innovations LLC, Presnenskaya nab., building 10, Moscow, 123112	Russia	OTC	17376/2/2 15.10.2020
11	Septotele total	benzydamine (benzydamine hydrochloride), cetylpyridinium (cetylpyridinium chloride)	spray for local use	1,5mg/ml+5mg/ml; 30ml(250 dose) 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	15811/1 15.10.2020
12	Sumatriptan Canon	sumatriptan (sumatriptan succinate)	tablets film-coated	50mg; (2/1x2/) in blister	CJSC Canonpharma production, 105, Zarechnaya str. 141100 Moskow region, Schelkovo	Russia	CJSC Canonpharma production, 105, Zarechnaya str. 141100 Moskow region, Schelkovo	Russia	R	16220/2 15.10.2020
13	Sumatriptan Canon	sumatriptan (sumatriptan succinate)	tablets film-coated	100mg; (2/1x2/) in blister	CJSC Canonpharma production, 105, Zarechnaya str. 141100 Moskow region, Schelkovo	Russia	CJSC Canonpharma production, 105, Zarechnaya str. 141100 Moskow region, Schelkovo	Russia	R	16219/2 15.10.2020



14	Quamatel	famotidine	tablets film-coated	20mg; (28/2x14/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	18874/1 15.10.2020
15	Quamatel	famotidine	tablets film-coated	40mg; (14/1x14/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	18875/1 15.10.2020
16	Kestine	ebastine	tablets film-coated	20mg; (10/1x10/) in blister	Industrias Farmaceuticas Almirall S.A., Ctra. Nacional II, Km. 593, 08740 Sant Andreu de la Barca, Barcelona	Spain	Almirall, S.A., Ronda General Mitre, 151, 08022 Barcelona	Spain	R	16992/2 15.10.2020
17	Gliatilin	choline alfoscerate	solution for injection	250mg/ml; (3) ampoules 4ml	Italfarmaco S.p.A., Viale Fulvio Testi, 330 - 20126 Milan	Italy	Italfarmaco S.p.A., Viale Fulvio Testi, 330 - 20126 Milan	Italy	R	18346/1 15.10.2020
18	Palibone	risedronic acid (risedronate sodium)	tablets film-coated	35mg; (4/1x4/) in blister	Pharmathen S.A., Dervenakion 6, 15351 Pallini, Attiki	Greece	Pharmathen S.A., Dervenakion 6, 15351 Pallini, Attiki	Greece	R	18314/1 15.10.2020
19	Velaxin	venlafaxine (venlafaxine hydrochloride)	capsules prolonged-release	37,5mg; (28/2x14/) 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 st. 30-38	Hungary	R	17454/1 15.10.2020

20	Velaxin	venlafaxine (venlafaxine hydrochloride)	capsules prolonged-release	75mg; (28/2x14/) 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 st. 30-38	Hungary	R	17455/1 15.10.2020
21	Velaxin	venlafaxine (venlafaxine hydrochloride)	capsules prolonged-release	150mg; (28/2x14/) 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 st. 30-38	Hungary	R	17456/1 15.10.2020
22	Velaxin	venlafaxine (venlafaxine hydrochloride)	capsules prolonged-release	37,5mg; (28/2x14/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	R	17074/1 15.10.2020
23	Velaxin	venlafaxine (venlafaxine hydrochloride)	capsules prolonged-release	75mg; (28/2x14/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	R	17075/1 15.10.2020

24	Velaxin	venlafaxine (venlafaxine hydrochloride)	capsules prolonged-release	150mg; (28/2x14/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	R	17073/1 15.10.2020
25	Nevanac	nepafenac	drops eye (suspension)	1mg/ml; plastic bottle 5ml	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	15198/2 15.10.2020
26	Septolete total lemon and honey	benzydamine (benzydamine 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	17899/2 15.10.2020
27	Septolete 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	19216/1 15.10.2020
28	Neoton	phosphocreatine (phosphocreatine sodium)	powder for solution for infusion	1000mg; glass vial, solvent in glass vial 50ml, infusion system	Alfasigma S.p.A., Via Enrico Fermi, 1-65020, Alanno (Pescara)	Italy	Alfasigma S.p.A., Via Ragazzi del, 99, 5-40133 Bologna (BO)	Italy	R	17900/1 15.10.2020

29	Lorista	losartan (losartan potassium)	tablets film-coated	100mg; (28/2x14/) 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	16942/2 15.10.2020
30	Tobrex	tobramycin	drops eye (solution)	3mg/ml; 5ml plastic vial	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	18041/2 15.10.2020
31	Hexalyse	biclotymol, lysozyme (lysozyme hydrochloride), enoxolone	tablets orodispersible	5mg+5mg+5mg; (30/3x10/) blisters	Laboratoires Bouchara-Recordati, Parc Mecatronic 03410 Saint Victor	France	Laboratoires Bouchara-Recordati, Immeuble le Wilson, 70 avenue du General de Gaulle, 92800 Puteaux	France	OTC	14591/2 15.10.2020
32	Hexaspray	biclotymol	aerosol for local use	750mg/30g; 30g glass bottle with pump dispenser	Laboratoires Bouchara-Recordati, Parc Mecatronic 03410 Saint Victor	France	Laboratoires Bouchara-Recordati, Immeuble le Wilson, 70 avenue du General de Gaulle, 92800 Puteaux	France	OTC	14867/1 15.10.2020
33	Vurdon	diclofenac (diclofenac sodium)	tablets slow release film-coated	100mg; (10/1x10/) in blister	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorphosis, Attica	Greece	R	19235/1 15.10.2020



37	Albunorm Octapharma 20%	albumin human	solution for i/v infusion	200mg/ml; 50ml and 100ml glass bottle	Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A- 1100 Vienna	Austria	Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A- 1100 Vienna	Austria	R	14931/4 15.10.2020
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