

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 9-1/20 on September 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	Aspirin	acetylsalicylic acid	chewable tablets	81mg; (36) in plastic container	Allegiant Health 75 North Industry Court, Deer Park, New York (NY) 11729	USA	Allegiant Health 75 North Industry Court, Deer Park, New York (NY) 11729	USA	OTC	19389 15.09.2020
2	Celebrex	celecoxib	capsules	100mg; (20/2x10/) 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	R	19390 15.09.2020

3	Celebrex	celecoxib	capsules	200mg; (20/2x10/) 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	R	19391 15.09.2020
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LIST

of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 9-1/20 on September 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	Numeta G13%E Preterm	alanine, arginine, aspartic acid, cysteine, glutamic acid, glycine, histidine, Isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, potassium acetate, calcium chloride dehydrate, magnesium acetate tetrahydrate, sodium glycerophosphate hydrated, glucose monohydrate, refined olive oil + refined soya bean oil	emulsion for infusion	0,75g+0,78g+0,56g+0,18g+0,93g+0,37g+0,35g+0,62g+0,93g+1,15g+0,22g+0,30g+0,39g+0,28g+0,37g+0,06g+0,35g+0,19g+0,07g+0,71g+0,61g+0,55g+0,10g+0,98g+44g+7,5g; (10) bags 300ml	Baxter SA., Boulevard Rene Branquart 80, Lessines, 7860	Belgium	Baxter Healthcare Ltd, Caxton Way, Thretford, Norfolk, IP24 3SE	UK	R	19411 15.09.2020

2	Numeta G16%E	alanine, arginine, aspartic acid, cysteine, glutamic acid, glycine, histidine, Isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, sodium chloride, potassium acetate, calcium chloride dehydrate, magnesium acetate tetrahydrate, sodium glycerophosphate hydrated, glucose monohydrate, refined olive oil + refined soya bean oil	emulsion for infusion	1,03g+1,08g+0,77g+0,24g+1,29g+0,51g+0,49g+0,86g+1,29g+1,59g+0,31g+0,41g+0,54g+0,39g+0,51g+0,08g+0,48g+0,26g+0,10g+0,98g+0,30g+1,12g+0,46g+0,33g+0,98g+85,25+15,5g; (6) bags 500ml	Baxter SA., Boulevard Rene Branquart 80, Lessines, 7860	Belgium	Baxter Healthcare Ltd, Caxton Way, Thretford, Norfolk, IP24 3SE	UK	R	19412 15.09.2020
3	Numeta G19%E	alanine, arginine, aspartic acid, cysteine, glutamic acid, glycine, histidine, Isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, sodium chloride, potassium acetate, calcium chloride dehydrate, magnesium acetate tetrahydrate, sodium glycerophosphate hydrated, glucose monohydrate, refined olive oil + refined soya bean oil	emulsion for infusion	1,83g+1,9g+1,37g+0,43g+2,29g+0,91g+0,87g+1,53g+2,29g+2,82g+0,55g+0,73g+0,96g+0,69g+0,91g+0,14g+0,85g+0,46g+0,18g+1,74g+1,79g+3,14g+0,56g+0,55g+2,21g+210,65+28,1g; (6) bags 1000ml	Baxter SA., Boulevard Rene Branquart 80, Lessines, 7860	Belgium	Baxter Healthcare Ltd, Caxton Way, Thretford, Norfolk, IP24 3SE	UK	R	19413 15.09.2020

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 9-1/20 on September 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	Solcoseryl	protein-free hemodialysate from calves blood	solution for i/v injection	42,5mg/ml; (25/5x5/) ampoules 2ml in blister	Legacy Pharmaceuticals Switzerland GmbH, Ruhrbergstrasse 21, 4127 Birsfelden	Switzerland	MEDA Pharmaceuticals Switzerland GmbH, Hegnaustrasse 60, 8602 Wangen-Bruttisellen	Switzerland	R	19394 15.09.2020
2	Solcoseryl	hemodialysate from calves blood protein-free	solution for i/v injection	42,5mg/ml; (5/1x5/) ampoules 5ml in blister	Legacy Pharmaceuticals Switzerland GmbH, Ruhrbergstrasse 21, 4127 Birsfelden	Switzerland	MEDA Pharmaceuticals Switzerland GmbH, Hegnaustrasse 60, 8602 Wangen-Bruttisellen	Switzerland	R	19395 15.09.2020
3	Metronidazole-Asteria	metronidazole	tablets	500mg; (30/3x10/) 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	19396 15.09.2020
4	Hemomycin	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3/) in blister	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	R	19397 15.09.2020

5	Hartil	ramipril	tablets	2,5mg; (14/2x7/) in blister, (28/4x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120-batch releaser, Actavis Ltd., BLB 015, BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19398 15.09.2020
6	Hartil	ramipril	tablets	5mg; (14/2x7/) in blister, (28/4x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120-batch releaser, Actavis Ltd., BLB 015, BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19399 15.09.2020
7	Hartil	ramipril	tablets	10mg; (14/2x7/) in blister, (28/4x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120-batch releaser, Actavis Ltd., BLB 015, BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta- bulk manufacturer, packager, quality control	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19400 15.09.2020
8	Allergosan	chloropyramine (chloropyramine hydrochloride)	cream for external use	10mg/g; aluminium tube 18g	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia- batch releaser, Sopharma JSC, Vrabevo vlg. 5660, district of Lovetch, Bulgaria- bulk manufacturer, packager, quality control	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	19401 15.09.2020

9	Allergosan	chloropyramine (chloropyramine hydrochloride)	ointment for external use	10mg/g; aluminium tube 18g	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia- batch releaser, Sopharma JSC, Vrabevo vlg. 5660, district of Lovetch, Bulgaria- bulk manufacturer, packager, quality control	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	19402 15.09.2020
10	Diclo-ton 75mg/3ml	diclofenac (diclofenac sodium)	solution for injection/infusion	25mg/ml; (5) ampoules 3ml	Medochemie Ltd. (Ampoule Injectable Facility) 48 Iapetou street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol	Cyprus	Medochemie Ltd.,1-10 Constantinoupolis street, 3011 Limassol	Cyprus	R	19403 15.09.2020
11	Intrafer-200 B12	iron, cyanocobalamin	solution for injection	200mg/ml+200mcg/ml; (1) glass bottle 100ml	Interchemie werken "De Adelaar" Eesti AS, Vanapere tee 14, Viimsi, Harju county- bulk manufacturer, primary packager, quality control (microbiological), batch releaser, Interchemie werken "De Adelaar" B.V., Metaalweg 8, 5804 CG Venray, the Netherlands- secondary packager, quality control (physical/chemical)	Estonia	Interchemie werken "De Adelaar" B.V., Metaalweg 8, 5804 CG Venray	the Netherlands	R	19404 15.09.2020

12	Limoxin-200LA	oxytetracycline (oxytetracycline dihydrate)	solution for injection	200mg/ml; (1) glass bottle 50ml, (1) glass bottle 100ml	Interchemie werken "De Adelaar" Eesti AS, Vanapere tee 14, Viimsi, Harju county- bulk manufacturer, primary packager, quality control (microbiological), batch releaser, Interchemie werken "De Adelaar" B.V., Metaalweg 8, 5804 CG Venray, the Netherlands- secondary packager, quality control (physical/chemical)	Estonia	Interchemie werken "De Adelaar" B.V., Metaalweg 8, 5804 CG Venray	the Netherlands	R	19405 15.09.2020
13	ACC 100	acetylcysteine	powder for oral solution	100mg; (20) sachets 3g	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben- batch releaser, Lindopharm GmbH, Neustrasse 82, D- 40721 Hilden, Germany- bulk manufacturer, packager, quality control (physicochemical), IMQ - Institut fur mikrobiologische Qualitatssicherung GmbH, Benninghofer Weg 2, Mettmann, 40822, Germany- quality control (microbiological)	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	19406 15.09.2020

14	ACC 200	acetylcysteine	powder for oral solution	200mg; (20) sachets 3g	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben- batch releaser, Lindopharm GmbH, Neustrasse 82, D-40721 Hilden, Germany- bulk manufacturer, packager, quality control (physicochemical), IMQ- Institut fur mikrobiologische Qualitatssicherung GmbH, Benninghofer Weg 2, Mettmann, 40822, Germany- quality control (microbiological)	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	19407 15.09.2020
15	Upsarin Upsa with vitamin C	acetylsalicylic acid, ascorbic acid	tablets effervescent	330mg+200mg; (10) in plastic container	UPSA SAS, 979, avenue des Pyrenees, 47520 Le Passage	France	UPSA SAS, 3, rue Joseph Monier- 92500 Rueil- Malmaison	France	OTC	19408 15.09.2020
16	Chondro-Ritz	chondroitin sulfate (chondroitin sulfate sodium), glucosamine (glucosamine sulfate)	capsules	200mg+250mg; (50/5x10/) in blister	GM Pharmaceuticals Ltd, 65, Qvemo Phonichala str., 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, 65, Qvemo Phonichala str., 0165 Tbilisi	Georgia	OTC	19409 15.09.2020
17	Strepsils	dichlorobenzyl alcohol, amylmetacresol	lozenges with honey and lemon flavour	1,2mg+0,6mg; (24/2x12/), (36/3x12/), in blister	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	OTC	19410 15.09.2020

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 9-1/20 on September 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	Doxycycline-Asteria	doxycycline (doxycycline hyclate)	capsules	100mg; (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	15173/1/1 15.09.2020
2	Ceftriaxone-Asteria Inj. 0,5g	ceftriaxone (ceftriaxone sodium)	powder for solution for i/m/ and i/v injection	500mg; (1) and (10) glass vial	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	16746/1/1 15.09.2020
3	Ceftriaxone-Asteria Inj. 1g	ceftriaxone (ceftriaxone sodium)	powder for solution for i/m and i/v injection	1000mg; (1) and (10) glass vial	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	16747/1/1 15.09.2020

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision 9-1/20 on September 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	Metrogyl	metronidazole	gel for external use	10mg/g; aluminium or laminated plastic tube 30g	Unique Pharmaceutical Laboratories, Plot N 304-308, G.I.D.C. Industrial Area, Panoli: 394 116, Gujarat State for	India	Unique Pharmaceutical Laboratories (a division of J. B. Chemicals & Pharmaceuticals Ltd.) Worli, Mumbai-400 030	India	R	14638/1 15.09.2020
2	Peristalid	lactulose	syrup	667mg/ml; glass bottle 200ml and measuring cup 20ml	Laboratorios Basi -Industria Farmaceutica, S.A., Parque Industrial Manuel Lourenco Ferreira, Lote 15, Mortagua, 3450-232	Portugal	GM Pharmaceuticals Ltd, 65, Phonichala, Tbilisi	Georgia	OTC	16061/1 15.09.2020
3	Humalog	insulin lispro	solution for injection	100IU/ml (3,5mg/ml); (5) cartridges 3ml	Lilly France S.A.S., Zone Industrielle, 2 rue du Colonel Lilly, 67640 Fegersheim	France	Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht	the Netherlands	R	15929/1 15.09.2020

4	Humalog Mix 50	insulin lispro solution and insulin lispro protamine suspension	suspension for injection	100U/ml (3,5mg/ml); (5) glass 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	18646/2 15.09.2020
5	Amoksiklav 2x625mg tablets	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	500mg+125mg; (10/2x5/) in blister, (14/2x7/) in blister	Lek Pharmaceuticals d.d. Perzonalni 47, 2391 Prevalje	Slovenia	Lek Pharmaceuticals d.d. Verovskova Str. 57, 1526 Ljubljana	Slovenia	R	18353/1 15.09.2020
6	Amoksiklav 2x1000mg tablets	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	875mg+125mg; (10/2x5/) in blister, (14/2x7/) in blister	Lek Pharmaceuticals d.d. Perzonalni 47, 2391 Prevalje	Slovenia	Lek Pharmaceuticals d.d. Verovskova Str. 57, 1526 Ljubljana	Slovenia	R	18354/1 15.09.2020
7	Amoksiklav 625mg film-coated tablets	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	500mg+125mg; (15/3x5) in blister	Lek d.d., Perzonalni 47, 2391 Prevalje- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Nacionalni laboratorij za zdravje, okolje in hrano (NLZOH)2, Prvomajska ulica 1, Maribor, 2000, Slovenia- quality control (microbial-non sterile)	Slovenia	Lek d.d., Verovskova str. 57, 1526 Ljubljana	Slovenia	R	19026/1 15.09.2020
8	Troypofol	propofol	emulsion for injection/ infusion	10mg/ml; 20ml glass vial	Troikaa Pharmaceuticals Ltd., C-1, Sara Industrial Estate, Selaqui, Dehradun-248197, Uttarakhand	India	Troikaa Pharmaceuticals Ltd., Commerce House-1, Satya Marg, Bodakdev, Ahmedabad-380054	India	R	16404/1 15.09.2020

9	Diclo-Denk 100 Retard	diclofenac (diclofenac sodium)	tablets prolonged-release	100mg; (10/1x10/) and (100/10x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	R	16078/2 15.09.2020
10	Nurofen for children	ibuprofen	suspension oral with orange flavour	100mg/5ml; 100ml,150ml and 200ml plastic container and measuring syringe	Reckitt Benckiser Healthcare India Private Limited, Khasra No. 701/534, Village Sandholi, Baddi-Nalagarh Road, District Solan, Baddi, Himachal Pradesh, IN-173 205	India	Reckitt Benckiser Healthcare International Ltd, Thane Road, Nottingham, NG90 2DB	UK	OTC	17842/1 15.09.2020
11	Phlogenzym	bromelain, trypsin, rutin	tablets gastro-resistant	450FIP-U+1440FIP-U(24mckat)+100mg; (40/2x20/) in blister, (100/5x20/) in blister, (200/10x20/) in blister, (800) in plastic container	Mucos Emulsions GmbH, Miraustrasse 17, D-13509 Berlin	Germany	Mucos Pharma GmbH & Co. KG, Miraustrasse 17, D-13509 Berlin	Germany	OTC	18978/2/1 15.09.2020
12	Strepsils with vitamin C	dichlorobenzyl alcohol, amylmetacresol, ascorbic acid	lozenges with orange flavour	1.2mg+0.6mg+100mg; (24/2x12/), 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	15036/3 15.09.2020

13	Wobenzym	pancreatin, trypsin, chymotrypsin, bromelain, papain, amylase, lipase, rutoside trihydrate	tablets gastro-resistant	300 prot.UA+360FIP-U+300FIP-U+225FIP-U+90FIP-U+50FIP-U+34FIP-U+50mg (40/2x20/) and (200/10x20/) in blister, (800) in plastic bottle	Mucos Emulsionsgesellschaft mbH, Miraustrasse 17, D-13509 Berlin	Germany	Mucos Pharma GmbH & Co. KG, Miraustrasse 17, D-13509 Berlin	Germany	OTC	17623/1 15.09.2020
14	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	18744/3 15.09.2020
15	Dopegyt	methyldopa (methyldopa sesquihydrate)	tablets	250mg; (50) in glass container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	R	15403/3 15.09.2020
16	Spasmovax	phloroglucinol	solution for i/m and i/v injection	10mg/ml; (10) ampoules 4ml	Doppel Farmaceutici S.r.l., Via Volturmo 48, Quinto De Stampi, 20089 Rozzano (MI)	Italy	SCHARPER S.p.A., Viale Ortles 12, 20139 Milan	Italy	R	16373/2 15.09.2020
17	Spasmovax ORO	phloroglucinol (phloroglucinol dihydrate), 1,3,5-trimethoxybenzene	tablets	80mg+80mg; (20/2x10/) in blister	Doppel Farmaceutici S.r.l., Via Volturmo 48, Quinto De` Stampi, 20089 Rozzano (MI)	Italy	SCHARPER S.p.A., Viale Ortles 12, 20139 Milan	Italy	R	17008/2 15.09.2020

18	Losar-Denk 25	losartan (losartan potassium)	tablets film-coated	25mg; (28/2x14/) blisters	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	18143/1 15.09.2020
19	Sulfocamphocaine-Darnitsa	sulfocamphoric acid, procaine base	solution for injection	49,6mg/ml+50,4mg/ml; (10/2x5/) ampoules 2ml, in blister	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kiev, Borispolskaya Str.,13	Ukraine	Darnitsa Pharmaceutical Firm PrJSC, 02093, Kiev, Borispolskaya Str.,13	Ukraine	R	15425/1 15.09.2020
20	Lucentis	ranibizumab	solution for injection	10mg/ml; (1) glass vial 0.23ml, (1) filter needle	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	R	16590/3 15.09.2020
21	Omeprazole	omeprazole	capsules	20mg; (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	15611/1 15.09.2020
22	Analgin	metamizole (metamizole sodium)	solution for i/v and i/m injection	500mg/ml; (10) ampoules 2ml	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	15450/1 15.09.2020

23	Rasilez HCT	aliskiren (aliskiren hemifumarate), hydrochlorothiazide	tablets film-coated	150mg+12,5mg; (14/1x14/) In blister, (28/2x14/) in blister	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata, (NA)	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	15943/1 15.09.2020
24	Rasilez HCT	aliskiren (aliskiren hemifumarate), hydrochlorothiazide	tablets film-coated	150mg+25mg; (14/1x14/) in blister, (28/2x14/) in blister	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata, (NA)	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	15940/1 15.09.2020
25	Rasilez HCT	aliskiren (aliskiren hemifumarate), hydrochlorothiazide	tablets film-coated	300mg+12,5mg; (14/1x14/) in blister, (28/2x14/) in blister	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata, (NA)	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	15942/1 15.09.2020
26	Rasilez HCT	aliskiren (aliskiren hemifumarate), hydrochlorothiazide	tablets film-coated	300mg+25mg; (14/1x14/) in blister, (28/2x14/) in blister	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata, (NA)	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	15941/1 15.09.2020
27	Strepsils	dichlorobenzyl alcohol, amylmetacresol	lozenges sugar free, with strawberry flavour	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	14817/4 15.09.2020

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 9-1/20 on September 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	Anti Gripp complex with lemon flavor	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	OTC	19414 15.09.2020
2	Anti Gripp complex 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	OTC	19415 15.09.2020