

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 12-2/19 on December 25, 2019

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	Xarelto	rivaroxaban	tablets film-coated	2,5mg; (56/4x14/) in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen, Germany	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	R	19035 25.12.2019
2	Hexpanthen	dexpantenol, chlorhexidine (chlorhexidine bigluconate)	suppositories vaginal	100mg+16mg; (10/2x5/)	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	OTC	19036 25.12.2019
3	Sedistress	dry extract of passiflora, ethyl ester of alpha-bromisovaleric acid	tablets	300mg+10.2mg, (30/3x10/) in blister, (60/3x60/)in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	OTC	19037 25.12.2019
4	Salbutamol	salbutamol (salbutamol sulfate)	suspension, pressurised inhalation	100mcg/dose; aluminium container with inhaler (200 doses)	Glaxo Wellcome Production, Zone Industrielle N 2, 23 Rue Lavoisier, 27000 Evreux	France	Laboratoire GlaxoSmithKline, 100, route de Versailles, 78163 Marly-Le-Roi cedex	France	R	19038 25.12.2019

5	Pyraminol 800mg film-coated tablets	piracetam	tablets film-coated	800mg; (20/2x10/) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia-quality control, batch releaser, Sopharma JSC, 3 Traiko Stanoev Str., Sofia 1797, Bulgaria- bulk manufacturer, packager	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	R	19039 25.12.2019
6	Fluimucil	acetylcysteine	solution oral	20mg/ml; glass bottle 100ml	Zambon S.P.A., Via della Chimica, 9, Vicenza, 36100	Italy	Zambon S.P.A., Via Lillo del Duca, 10, Bresso, 20091	Italy	OTC	19040 25.12.2019
7	Motilium	domperidone	tablets film-coated	10mg; (10/1x10/) in blister, (30/1x30/) in blister	Janssen-Cilag, Domaine de Maigremont, 27100 Val De Reuil	France	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	R	19041 25.12.2019
8	Integrilin	eptifibatide	solution for infusion	0,75mg/ml; (1) glass vial 100ml	Glaxo Operations UK Ltd., Harmire Road Barnard Castle Co Durham, DL12 8DT	UK	GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24	Ireland	R	19043 25.12.2019
9	Integrilin	eptifibatide	solution for infusion	2mg/ml; (1) glass vial 10ml	Glaxo Operations UK Ltd., Harmire Road Barnard Castle Co Durham, DL12 8DT	UK	GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24	Ireland	R	19044 25.12.2019

10	Deflacortin	deflazacort	tablets	6mg; (20/1x20/) in blister	LACER, S.A., C/ Boters, 5. Parc Tecnologic del Valles, Cerdanyola del Valles, Barcelona, 08290	Spain	Eurodrug Laboratories S.A., Kortrijksesteenweg 214, 9830 Sint-Martens-Latem	Belgium	R	19046 25.12.2019
11	Deflacortin	deflazacort	tablets	30mg; (20/2x10/) in blister	LACER, S.A., C/ Boters, 5. Parc Tecnologic del Valles, Cerdanyola del Valles, Barcelona, 08290	Spain	Eurodrug Laboratories S.A., Kortrijksesteenweg 214, 9830 Sint-Martens-Latem	Belgium	R	19047 25.12.2019

LIST

of the medicines recommended for the mutual recognition of the EAEU registration by the Center according to the meeting decision N 12-2/19 on December 25, 2019

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	Lonsurf	tipiracil (tipiracil hydrochloride), trifluridine	tablets film-coated	6,14mg+15mg; (20/2x10/) in blister, (40/4x10/) in blister, (60/6x10/) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy-packager, batch releaser, Taiho Pharmaceutical Co. Ltd., Kitajima Plant, 1-1, Iuchi, Takabo, Kitajima-cho, Itano-gun, 771-0206 Tokushima, Japan- bulk manufacturer	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	19053 25.12.2019
2	Lonsurf	tipiracil (tipiracil hydrochloride), trifluridine	tablets film-coated	8,19mg+20mg; (20/2x10/) in blister, (40/4x10/) in blister, (60/6x10/) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy-packager, batch releaser, Taiho Pharmaceutical Co. Ltd., Kitajima Plant, 1-1, Iuchi, Takabo, Kitajima-cho, Itano-gun, 771-0206 Tokushima, Japan- bulk manufacturer	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	19053 25.12.2019

LIST

of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 12-2/19 on December 25, 2019

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	KetoFLEX	ketoprofen	solution for injection	50mg/ml; (10) ampoules 2ml	Vetprom AD, Otez Paissij str. 26, Radomir 2400	Bulgaria	Dahnson-BG Co Ltd., Otez Paissij str. 26, Radomir 2400	Bulgaria	R	19048 25.12.2019
2	DicloFLEX 5% gel	diclofenac (diclofenac sodium)	gel	50mg/g; aluminium tube 50g	Vetprom AD, Otez Paissij str. 26, Radomir 2400	Bulgaria	Dahnson-BG Co Ltd., Otez Paissij str. 26, Radomir 2400	Bulgaria	OTC	19049 25.12.2019
3	Hedespan	ivy leaves dry extract	syrup	7mg/ml; 100ml glass bottle with measuring cup	Vetprom AD, Otez Paissij str. 26, Radomir 2400	Bulgaria	Dahnson-BG Co Ltd., Otez Paissij str. 26, Radomir 2400	Bulgaria	OTC	19050 25.12.2019
4	Rolenium	, fluticasone (fluticasone propionate), salmeterol (salmeterol xinafoate)	powder for inhalation, pre-dispensed	250mcg/dose+50mcg/dose; (1) inhalation device (60 doses)	Elpen Pharmaceutical CO., INC, Marathonos Ave. 95, Pikermi Attiki, 19009	Greece	Thesay Pharma Drug Store LLC, The Oberoi Centre, Business Bay, P. O. Box. 117929, Dubai	United Arab Emirates	R	19051 25.12.2019

5	Rolenium	, fluticasone (fluticasone propionate), salmeterol (salmeterol xinafoate)	powder for inhalation, pre-dispensed	500mcg/dose+50mcg/dose; (1) inhalation device (60 doses)	Elpen Pharmaceutical CO., INC, Marathonos Ave. 95, Pikermi Attiki, 19009	Greece	Thesay Pharma Drug Store LLC, The Oberoi Centre, Business Bay, P. O. Box. 117929, Dubai	United Arab Emirates	R	19052 25.12.2019
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LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 12-2/19 on December 25, 2019

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	ACC 200mg Hot Drink	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 für mikrobiologische Qualitätssicherung GmbH, Benninghofer Weg 2, Mettmann, 40822, Germany- quality control (microbiological)	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	19054 25.12.2019
2	Doxy-500 WS	doxycycline (doxycycline hyclate)	powder oral	500mg/g; plastic container 1000g	Interchemie werken 'De Adelaar' B.V., Metaalweg 8, 5804 CG Venray	the Netherlands	Interchemie werken 'De Adelaar' B.V., Metaalweg 8, 5804 CG Venray	the Netherlands	R	19055 25.12.2019
3	Metronidazole Denta	metronidazole (metronidazole benzoate), chlorhexidine (chlorhexidine gluconate 20% solution)	gel for gums	10mg/g+0,5mg/g; aluminium tube 20g	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	OTC	19056 25.12.2019

4	Axastrol	anastrozole	tablets film-coated	1mg; (28/2x14/) in blister	Remedica Ltd, Limassol Industrial Estate, Aharnon street, 3056 Limassol	Cyprus	Grindeks JSC, Krustpils str. 53, LV-1057, Riga	Latvia	R	19057 25.12.2019
5	Vametal	ondansetron (ondansetron hydrochloride dihydrate)	solution for i/v and i/m injection	2mg/ml; glass vial 2ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Medicus S.A., 10 Valaoritou str., GR 144 52, Metamorphosis, Attika	Greece	R	19058 25.12.2019
6	Vametal	ondansetron (ondansetron hydrochloride dihydrate)	solution for i/v and i/m injection	2mg/ml; glass vial 4ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Medicus S.A., 10 Valaoritou str., GR 144 52, Metamorphosis, Attika	Greece	R	19059 25.12.2019
7	Vametal	ondansetron (ondansetron hydrochloride dihydrate)	tablets film-coated	8mg; (15/3x5/) in blister	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Medicus S.A., 10 Valaoritou str., GR 144 52, Metamorphosis, Attika	Greece	R	19060 25.12.2019
8	Betamethasone cream	betamethasone (betamethasone valerate)	cream for external use	1mg/g; aluminium tube 15g	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	19061 25.12.2019

9	Thioctacid 600 HR	alfa-lipoic acid	tablets film-coated	600mg; (30) in glass container, (100) in glass container	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg-batch releaser, MEDA Manufacturing GmbH, Neurather Ring 1, Koeln, Nordrhein-Westfalen, 51063, Germany- bulk manufacturer, packager, quality control (physicochemical), Labor LS SE & Co. KG , Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany-quality control	Germany	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg	Germany	R	19062 25.12.2019
10	Levofloxacin 0.5%	levofloxacin (levofloxacin hemihydrate)	solution for infusion	5mg/ml; 50ml plastic pack, 100ml plastic pack	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	R	19063 25.12.2019
11	Floxaval	levofloxacin (levofloxacin hemihydrate)	tablets film-coated	500mg; (10/1x10/) in blister	Delorbis Pharmaceuticals Ltd, 17 Athinon str.,Ergates Industrial Area, 2643 Ergates, Lefkosia	Cyprus	Delorbis Pharmaceuticals Ltd, 17 Athinon str.,Ergates Industrial Area,2643 Ergates, P.O. Box 28629,2081 Lefkosia	Cyprus	R	19064 25.12.2019
12	Cytosar	cytarabine	powder lyophilized for solution for injection	100mg; (1) glass vial and (1) solvent in ampoule 5ml	Actavis Italy S.p.A., Viale Pasteur, 10, 20014 Nerviano, Milan	Italy	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	R	19065 25.12.2019

13	Cytosar	cytarabine	powder lyophilized for solution for injection	500mg; (1) glass vial and (1) solvent in ampoule 10ml	Actavis Italy S.p.A., Viale Pasteur, 10, 20014 Nerviano, Milan	Italy	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	R	19066 25.12.2019
14	Escapelle	levonorgestrel	tablets	1,5mg; (1) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	OTC	19067 25.12.2019
15	Ofloxacin 0.2%	ofloxacin	solution for infusion	2mg/ml; plastic pack in light-proof bag 50ml, plastic pack in light-proof bag 100ml, plastic pack in light-proof bag 200ml	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	R	19068 25.12.2019
16	Nasonex	mometasone (mometasone furoate)	spray nasal (suspension)	50mcg/dose; 18g (140 dose) plastic bottle with spray pump 18g (140 dose)	Schering-Plough Labo N.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Schering-Plough Central East AG, Weystrasse 20, CH 6000 Lucerne 6	Switzerland	R	19069 25.12.2019
17	Glucosamine Plus	glucosamine (glucosamine hydrochloride), chondroitin sulfate (chondroitin sulfate sodium)	tablets film-coated	500mg+400mg; (30) in plastic container, (60) in plastic container, (100) in plastic container	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansoura-Aleppo	Syria	IBN AL-Haytham Pharma Industries Co., P.O.Box 16232, Al Mansoura-Aleppo	Syria	OTC	19070 25.12.2019
18	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	19071 25.12.2019

19	Panthenol Pharmstandard	dexpanthenol	aerosol	50mg/g; aluminium container 58g	Pharmstandard- Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard- Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	19072 25.12.2019
20	Diclac ID 75	diclofenac (diclofenac sodium) with immediate release, diclofenac (diclofenac sodium) with prolonged release	tablets modified- release	12,5mg+ 62,5mg; (20/2x10/) in blister	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	R	19073 25.12.2019
21	Diclac ID 150	diclofenac (diclofenac sodium) with immediate release, diclofenac (diclofenac sodium) with prolonged release	tablets modified- release	25mg+125mg; (100/10x10/) in blister	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	R	19074 25.12.2019
22	Hydroxycarbamide medac	hydroxycarbamide	capsules	500mg; (50/5x10/) in blister, (100/10x10/) in blister	Medac GmbH, Theaterstrasse 6, 22880 Wedel - batch releaser, Haupt Pharma Amareg GmbH, Donaustauer Strasse 378, 93055 Regensburg, Germany - bulk manufacturer, packager, quality control	Germany	Medac GmbH, Theaterstrasse 6, 22880 Wedel	Germany	R	19075 25.12.2019

23	Perjeta	pertuzumab	concentrate for solution for infusion	30mg/ml; (1) glass vial 14ml	Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim- bulk manufacturer, primary packager, quality control, batch releaser, F. Hoffmann-La Roche Ltd, 4303 Kaiseraugst, Switzerland- secondary packager	Germany	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070	Switzerland	R	19076 25.12.2019
24	Verospiron 50mg	spironolactone	capsules	50mg; (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	19077 25.12.2019
25	Cefazolin	cefazolin (cefazolin sodium)	powder for solution for i/m and i/v injection	1000mg; (50) glass vials 10ml	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	R	19078 25.12.2019
26	Biokson	ceftriaxone (ceftriaxone sodium triseskvihydrate)	powder for solution for i/m and i/v injection	1000mg; (1) glass vial 10ml	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	R	19079 25.12.2019
27	Ibufene	ibuprofen	suspension oral	20mg/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	OTC	19080 25.12.2019

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-2/19 on December 25, 2019

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	Lamisil	terbinafine (terbinafine hydrochloride)	cream	10mg/g; 15g aluminium tube, 15g laminated tube	GlaxoSmithKline Consumer Healthcare S.A., Route de l' Etraz, 1260 Nyon	Switzerland	GlaxoSmithKline Consumer Healthcare S.A., Route de l' Etraz, 1260 Nyon	Switzerland	OTC	16653/1/1 25.12.2019
2	Lamisil DermGel	terbinafine	gel	10mg/g; 15g aluminium tube	GlaxoSmithKline Consumer Healthcare S.A., Route de l' Etraz, 1260 Nyon	Switzerland	GlaxoSmithKline Consumer Healthcare S.A., Route de l' Etraz, 1260 Nyon	Switzerland	OTC	17906/1/1 25.12.2019
3	Voltaren Emulgel	diclofenac (diclofenac diethylamine)	gel for external use	10mg/g; 20g, 50g and 100g laminated tube	GlaxoSmithKline Consumer Healthcare S.A., Route de l' Etraz, 1260 Nyon	Switzerland	GlaxoSmithKline Consumer Healthcare S.A., Route de l' Etraz, 1260 Nyon	Switzerland	OTC	17180/2/1 25.12.2019
4	Mexidol	ethylmethylhydroxypyridine succinate	solution for i/v and i/m injection	50mg/ml; (10/2x5/) ampoules 2ml in blister	ООО "Ellara", 601122, Vladimir reg., Petushinsky district, Pokrov, str. Franza Shtolverka, b. 20/2	Russia	LLC "RPC "PHARMASOFT", 115407, Moscow, Sudostroitel'naya str., bld. 41, floor 1, premises 12	Russia	R	17420/1/1 25.12.2019

5	Mexidol	ethylmethylhydroxypyridine succinate	solution for i/v and i/m injection	50mg/ml; (5/1x5/) ampoules 5ml, in blister	OOO "Ellara", 601122, Vladimir reg., Petushinsky district, Pokrov, str. Franza Shtolverka, b. 20/2	Russia	LLC "RPC "PHARMASOFT", 115407, Moscow, Sudostroitel'naya str., bld. 41, floor 1, premises 12	Russia	R	17421/1/1 25.12.2019
6	Odeston	hymecromone	tablets	200mg; (50/5x10/) blisters	Adamed Pharma S.A., 5 Marszalka J. Pilsudskiego Str., 95-200 Pabianice, Poland	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	OTC	14256/1/1 25.12.2019
7	AmoxiClav-Denk 500/62,5	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	500mg+62,5mg; (16/2x8/) in blister	PenCef Pharma GmbH, Breitenbachstrasse 13-14, 13509 Berlin	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	15999/1/1 25.12.2019
8	Sinaflan	fluocinolone acetonide	ointment	0,25mg/g; 15g aluminium tube	Biohimik PJSC, Republic of Mordovia, 430030, Saransk, Vasenko str., 15A	Russia	"PROMOMED RUS " LLC, 101000, Moscow, Arkhangelsk pereulok,1, build.1	Russia	R	16851/1/1 25.12.2019
9	Phosphogliv	phospholipids (lipoid S 80), sodium glycyrrhizinate (glycyrrhizinic acid trisodium salt)	capsules	65mg+35mg; (50/5x10/) blisters	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	14207/1/1 25.12.2019

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-2/19 on December 25, 2019

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	Pofol Injection I.V.	propofol	emulsion for i/v injection	10mg/ml; (1) 50ml glass vial	Dongkook Pharmaceutical Co., Ltd., 33-19, Yongso 2-gil, Gwanghyewon-myeon, Jincheon-gun, Chungcheongbuk-do	Korea South	Dongkook Pharmaceutical Co., Ltd., 7, Teheran-ro 108-gil, Gangnam-gu, Seoul	Korea South	R	16152/1 25.12.2019
2	Ceftriaxone-BCPP	ceftriaxone (ceftriaxone sodium)	powder for solution for i/m and i/v injection	1000mg; (1) glass vial, (5) glass vials	SIC "Borshchahivskiy Chemical-Pharmaceutical Plant" PJSC, 17, Mira St, Kyiv, 03134	Ukraine	SIC "Borshchahivskiy Chemical-Pharmaceutical Plant" PJSC, 17, Mira St, Kyiv, 03134	Ukraine	R	18508/1 25.12.2019
3	Dermovate	clobetasol (clobetasol propionate)	cream	0,5mg/g; aluminium tube 25g	GlaxoSmithKline Pharmaceuticals S.A., 189 Grunwaldzka street, 60-322 Poznan	Poland	GlaxoSmithKline Export Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	18211/1 25.12.2019

4	Dermovate	clobetasol (clobetasol propionate)	ointment	0,5mg/g; aluminium tube 25g	GlaxoSmithKline Pharmaceuticals S.A.,189 Grunwaldzka street, 60-322 Poznan	Poland	GlaxoSmithKline Export Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	18211/1 25.12.2019
5	Omnitus	butamirate (butamirate citrate)	tablets modified-release film-coated	50mg; (10/1x10/) in blister	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	OTC	18292/2 25.12.2019
6	Gonadotropin chorionic	gonadotrophin chorionic	powder lyophilized for solution for i/m injection	500U; (5) glass vial and (5) solvent in ampoule 1ml	Moscow Endocrine Plant FSUE, 25, Novokhokhlovskaya st., Moscow 109052	Russia	Moscow Endocrine Plant FSUE, 25, Novokhokhlovskaya st., Moscow 109052	Russia	R	14731/1 25.12.2019
7	Gonadotropin chorionic	gonadotrophin chorionic	powder lyophilized for solution for i/m injection	1000IU; (5) glass vial and (5) solvent in ampoule 1ml	Moscow Endocrine Plant FSUE, 25, Novokhokhlovskaya st., Moscow 109052	Russia	Moscow Endocrine Plant FSUE, 25, Novokhokhlovskaya st., Moscow 109052	Russia	R	14732/1 25.12.2019
8	Methotrexate	methotrexate	tablets film-coated	2,5mg; (20/2x10/) blisters	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	R	14186/1 25.12.2019
9	Methotrexate	methotrexate	tablets film-coated	5mg; (20/2x10/) blisters	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	R	14187/1 25.12.2019

10	CoLosar-Denk 100/12,5	losartan (losartan potassium), hydrochlorothiazide	tablets film- coated	100mg+12,5mg; (28/2x14/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	18435/1 25.12.2019
11	Oramorph	morphine (morphine sulfate)	solution oral	20mg/ml; 20ml glass vial with dropper	L.Molteni & C. Dei F.lli Alitti Societa di Esercizio S.p.A, S. S. 67, Localita Granatieri, Scandicci, 50018	Italy	L.Molteni & C. Dei F.lli Alitti Societa di Esercizio S.p.A, S. S. 67, Localita Granatieri, Scandicci, 50018	Italy	R	16911/1 25.12.2019
12	Oramorph	morphine (morphine sulfate)	solution oral	2mg/ml; 100ml glass bottle and measuring pipette 5ml	L.Molteni & C. Dei F.lli Alitti Societa di Esercizio S.p.A, S. S. 67, Localita Granatieri, Scandicci, 50018	Italy	L.Molteni & C. Dei F.lli Alitti Societa di Esercizio S.p.A, S. S. 67, Localita Granatieri, Scandicci, 50018	Italy	R	16579/2 25.12.2019
13	Ermucin	erdosteine	granules for oral suspension	225mg; (10) sachets 4,425mg	Fine Foods & Pharmaceuticals N.T.M. S.p.A., Via Grignano, 43, 24041, Brembate (BG)	Italy	UAB "MRA", Totoriu str. 20-9, LT-01121 Vilnius	Republic of Lithuania	R	18075/1 25.12.2019

14	Ermucin	erdosteine	capsules hard	300mg; (10/1x10/) and (20/2x10/) in blister	Edmond Pharma S.r.l., Strada Statale dei Giovi 131-20037 Paderno Dugnano (MI)- batch releaser, bulk manufacturer, Lamp San Prospero S.p.A., Via della Pace, 25/A-41030 San Prospero (MO), Italy- packager	Italy	UAB "MRA", Totoriu str. 20-9, LT-01121 Vilnius	Republic of Lithuania	R	18076/1 25.12.2019
15	Motilium	domperidone	tablets film-coated	10mg; (10/1x10/) blister, (30/1x30/) blister	Janssen-Cilag, Domaine de Maigremont, 27100 Val de Reuil	France	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	R	14183/1 25.12.2019
16	Tenikam	tenoxicam	powder lyophilized for solution for injection	20mg; (1) glass vial and solvent in ampoule 2ml	GM Pharmaceuticals Ltd, PSP group 65, Qyemo Phonichala str., Tbilisi- batch releaser, secondary packager, Anfarm Hellas S.A., Sximatari Viotias, 32009, Greece- bulk manufacturer, primary packager	Georgia	GM Pharmaceuticals Ltd, PSP group 65, Qyemo Phonichala str., Tbilisi	Georgia	R	16289/1 25.12.2019
17	Hemomycin	azithromycin (azithromycin dihydrate)	powder for oral suspension	200mg/5ml; 60ml glass bottle with 10g powder and measuring spoon 5ml	Hemofarm A.D., 26300 Vrsac, Beogradskii put bb- batch releaser, Hemofarm A.D. Vrsac, branch plant Sabac, 15000, Sabac, Hajduk Veljkova str. No: bb, Serbia- bulk manufacturer, packager	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradskii put bb	Serbia	R	14173/2 25.12.2019

18	Certican	everolimus	tablets	0,25mg; (60/6x10/) blisters	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	R	18513/2 25.12.2019
19	Certican	everolimus	tablets	0,25mg; (60/6x10/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	R	18514/2 25.12.2019
20	Certican	everolimus	tablets	0,75mg; (60/6x10/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	R	14174/2 25.12.2019
21	Certican	everolimus	tablets	0,75mg; (60/6x10/) blisters	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	R	18076/1 25.12.2019
22	Momederm	mometasone (mometasone furoate)	ointment for external use	1mg/g; 15g aluminium tube	Pharmaceutical Company Jelfa S.A., ul. Wincentego Pola 21, 58-500 Jelenia Gora	Poland	VALEANT LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	R	16365/1 25.12.2019
23	Flixonase	fluticasone (fluticasone propionate)	spray nasal (suspension)	50mcg/dose; glass bottle fitted with a metering, atomising pump (120 dose), nasal adaptor and a dust cover	Glaxo Wellcome S.A., Avenida Extremadura, 3,Pol. Ind.Allandaduero, 09400 Aranda de Duero, Burgos	Spain	GlaxoSmithKline, S.A., Severo Ochoa, 2 28760- Tres Cantos (Madrid)	Spain	R	18379/1 25.12.2019

24	Allochol	cattle bile dried, dried garlic, charcoal activated, nettle leaves	tablets coated	(80mg+40mg+25mg+5mg); (10/1x10/) blister, (50) plastic container	Irbitskiy himfarmzavod JSC, 643 RU, Irbit, St. Sverdlovsk, K. Marksa str., 124	Russia	Irbitskiy himfarmzavod JSC, 643 RU, Irbit, St. Sverdlovsk, Kirova str., 172	Russia	OTC	13588/1 25.12.2019
25	Nuvaring	etonogestrel, ethinylestradiol	vaginal delivery system (vaginal ring)	11,7mg+2,7mg; (1) sachet	N.V. Organon, Kloosterstraat 6, 5349 AB Oss	the Netherlands	Schering-Plough Central East AG, Weyrstrasse 20, 6000 Lucerne 6	Switzerland	R	18919/1 25.12.2019
26	Ramizek Combi	ramipril, amlodipine (amlodipine besilate)	capsules hard	5mg+5mg, (30/5x6/) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice-batch releaser, Adamed Pharma S.A., 33, Szkolna St., 95-054 Ksawerow, Poland-bulk manufacturer, packager	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza St., 05-152 Czosnow	Poland	R	17762/2 25.12.2019
27	Ramizek Combi	ramipril, amlodipine (amlodipine besilate)	capsules hard	10mg+5mg, (30/5x6/) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice-batch releaser, Adamed Pharma S.A., 33, Szkolna St., 95-054 Ksawerow, Poland-bulk manufacturer, packager	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza St., 05-152 Czosnow	Poland	R	17763/2 25.12.2019

28	Ramizek Combi	ramipril, amlodipine (amlodipine besilate)	capsules hard	10mg+10mg, (30/5x6/ in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice-batch releaser, Adamed Pharma S.A., 33, Szkolna St., 95-054 Ksawerow, Poland-bulk manufacturer, packager	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza St., 05-152 Czosnow	Poland	R	17761/2 25.12.2019
29	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	15060/1 25.12.2019
30	Strepsils with Menthol and Eucalyptus	dichlorobenzyl alcohol, amylmetacresol, levomenthol	lozenges	1,2mg+0,6mg+8mg; (24/2x12/) and (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	15039/1 25.12.2019
31	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	14095/2 25.12.2019

32	Viread	tenofovir disoproxil fumarate	tablets film-coated	300mg; (30) plastic container	Gilead Sciences Ireland UC, IDA Business and Technology Park, Carrigtohill, Co. Cork - batch releaser, Takeda GmbH, Lehnitzstrasse 70-98, Oranienburg 16515, Germany-bulk manufacturer, Catalent Germany Schorndorf GmbH, Steinbeisstrasse 1und 2, 73614, Schorndorf, Germany-packager	Ireland	Gilead Sciences Inc., 333 Lakeside Drive, Foster City, CA 94404	USA	R	18517/1 25.12.2019
33	Viread	tenofovir disoproxil fumarate	tablets film-coated	300mg; (30) plastic container	Gilead Sciences Ireland UC, IDA Business and Technology Park, Carrigtohill, Co. Cork-packager, batch releaser, Takeda GmbH, Lehnitzstrasse 70-98, Oranienburg 16515, Germany-bulk manufacturer	Ireland	Gilead Sciences Inc., 333 Lakeside Drive, Foster City, CA 94404	USA	R	18518/1 25.12.2019
34	Apo-Sildenafil	sildenafil (sildenafil citrate)	tablets	25mg; (4/1x4/) blister	Apotex Inc., 150 Signet Drive, Toronto, Ontario, M9L 1T9-batch releaser, bulk manufacturer, Apotex Inc., 4100 Weston Road, Toronto, Ontario, M9L 2Y6, Canada -packager	Canada	Apotex Inc., 150 Signet Drive, Toronto, Ontario, M9L 1T9	Canada	R	14357/1 25.12.2019

35	Apo-Sildenafil	sildenafil (sildenafil citrate)	tablets	50mg; (4/1x4/) blister	Apotex Inc., 150 Signet Drive, Toronto, Ontario, M9L 1T9-batch releaser, bulk manufacturer, Apotex Inc., 4100 Weston Road, Toronto, Ontario, M9L 2Y6, Canada -packager	Canada	Apotex Inc., 150 Signet Drive, Toronto, Ontario, M9L 1T9	Canada	R	14356/1 25.12.2019
36	Spasmopriv Forte	fenoverine	capsules	200mg; (10/1x10/) in blister, (20/2x10/) in blister	Laboratorios Legrand S.A., Calle 19 No. 68 B-50, Bogota, D.C.	Colombia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	R	18440/1 25.12.2019
37	D-panthenol-Nizhpharm-PLUS	dexpantenol, chlorhexidine (chlorhexidine digluconate)	cream for external use	52,5mg/g+8,02mg/g; aluminium tube 30g	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	18493/1 25.12.2019
38	Lavomax	tilorone (tilorone dihydrochloride)	tablets coated	125mg; (10/1x10/) in blister	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	17935/2 25.12.2019

39	Clomentin	escitalopram (escitalopram oxalate)	tablets film-coated	20mg; (28/2x14/) in blister	Delorbis Pharmaceuticals Ltd., 17 Athinon Street, Ergates Industrial Area, 2643 Ergates, Lefkosia-secondary packager, batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia-bulk manufacturer, primary packager, quality control	Cyprus	Delorbis Pharmaceuticals Ltd., 17 Athinon Street, Ergates Industrial Area, 2643 Ergates, P.O. Box 28629, 2081 Lefkosia	Cyprus	R	18723/1 25.12.2019
40	Ibufene	ibuprofen	suspension oral	20mg/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	OTC	13545/1 25.12.2019