

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 12-1/19 on December 13, 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.	Magnesium sulfate	magnesium sulfate	solution for i/v and i/m injection	250mg/ml; (10) ampoules 5ml	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, No10/1, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	R	18987 13.12.2019
2.	Mekinist	trametinib (trametinib dimthyl sulfoxide)	tablets film-coated	2mg; (30) in plastic container	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos-packager, batch releaser, GlaxoSmithKline Manufacturing S.p.A., Strada Provinciale Asolana, 90, 43056	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	18988 13.12.2019

					San Polo di Torrile, Parma, Italy- bulk manufacturer, quality control					
3.	Tafinlar	dabrafenib	capsules hard	75mg; (120) in plastic container	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos- packager, batch releaser, Glaxo Operations UK Ltd, Priory Street, Ware, Hertfordshire SG12 0DJ, UK- bulk manufacturer, quality control	Spain	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	R	18989 13.12.2019
4.	Lecrolyn	cromoglicic acid (sodium cromoglicate)	drops eye	40mg/ml; 5ml plastic vial-dropper	Santen Oy, Niittyhaankatu 20, 33720 Tampere- batch releaser, NextPharma Oy, Niittyhaankatu 20, 33720 Tampere, Finland- bulk manufacturer, packager, quality control	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	OTC	18990 13.12.2019
5.	Heparin-	heparin (heparin	solution for i/v and s/c	5000UU/ml; (1) glass vial	Belmedpreparaty RUE, 220007,	Belarus	Belmedpreparat y RUE, 220007,	Belarus	R	18991

	Belmed	sodium)	injection	5ml, (5) glass vials 5ml	Minsk, Fabritsius St., 30		Minsk, Fabritsius St., 30			13.12.2019
6.	Fungoterbin	terbinafine (terbinafine hydrochloride)	cream for external use	10mg/g; aluminium or plastic laminated tube 15g	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	18992 13.12.2019
7.	Ascorutin	rutoside, ascorbic acid	tablets	50mg+50mg ; (50) in plastic container	Pharmstandard- UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	Pharmstandard -UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28, Republic of Bashkortostan	Russia	OTC	18993 13.12.2019
8.	Grani-Denk 1mg/ml	granisetron (granisetron hydrochloride)	concentrate for solution for injection/infu sion	1mg/ml; (5) ampoules 1ml	Solupharm Pharmazeutische Erzeugnisse GmbH, Industriestr. 3, 34212, Melsungen	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenst r. 79, 81675 Munchen	Germany	R	18995 13.12.2019
9.	Grani-Denk 1mg/ml	granisetron (granisetron	concentrate for solution for	1mg/ml; (5) ampoules	Solupharm Pharmazeutische Erzeugnisse	Germany	Denk Pharma GmbH & Co. KG,	Germany	R	18996 13.12.2019

		hydrochloride)	injection/infusion	3ml	GmbH, Industriestr. 3, 34212, Melsungen		Prinzregentenst r. 79, 81675 Munchen			
10.	Cosopt BK	timolol (timolol maleate), dorzolamide (dorzolamide hydrochloride)	drops eye	20mg/ml+5 mg/ml; plastic vial 5ml	Santen Oy, Niittyhaankatu 20, 33720 Tampere- batch releaser, Tubilux Pharma S.p.A., Via Costarica, 20/22, 0071 Pomezia, Italy- bulk manufacturer, packager, quality control	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	R	18997 13.12.2019
11.	Oxaliplatin Ebewe concentrate for solution for infusion 5 mg/ml	oxaliplatin	concentrate for solution for infusion	5mg/ml; 10ml glass vial	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet- Grossenbrach, Bayern, 97708,	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	R	18998 13.12.2019

					Germany- quality control (microbiological, sterility)					
12.	Oxaliplatin Ebewe concentrate for solution for infusion 5mg/ml	oxaliplatin	concentrate for solution for infusion	5mg/ml; 20ml glass vial	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet- Grossenbrach, Bayern, 97708, Germany- quality control (microbiological, sterility)	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	R	18999 13.12.2019
13.	Zinacef	cefuroxime (cefuroxime sodium)	powder for solution for injection	750mg; glass vial	GlaxoSmithKline Manufacturing SpA, Via A. Fleming, 2, Verona, 37135	Italy	Manufacturing SpA, Via A. Fleming, 2, Verona, 37135 for GlaxoSmithKli ne SpA, Via A.	Italy	R	19000 13.12.2019

							Fleming, 2, Verona, 37135			
14.	Bioson	dry extract of passiflora, doxylamine hydrogen succinate	tablets film- coated	300mg+3.75 mg, blisters (10)	Pharma Start LLC, Boulevard I. Lepse, 8, 03124, Kiev	Ukraine	Pharma Start LLC, Boulevard I. Lepse, 8, 03124, Kiev	Ukraine	OTC	19001 13.12.2019

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 12-1/19 on December 13, 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.	Femoston 2/10	pink tablet-estradiol, yellow tablet- estradiol + dydrogesterone	tablets film-coated	2mg+2mg+10mg; (28/14pink tablets + 14yellow tablets/) blister	ABBOTT Biologicals B.V., Veerweg 12, 8121 AA Olst	the Netherlands	ABBOTT Healthcare Products B.V., C.J. van Houtenlaan 36, NL-1381 CP Weesp	the Netherlands	R	19005 13.12.2019
2.	Eskomecol	chloramphenicol, dioxomethyltetrahydropyrimidine	ointment for external use	7,5mg/g+40mg/g; aluminium tube 25g	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	19006 13.12.2019
3.	Magnesium sulphate	magnesium sulfate	powder for oral solution	25g; sachets 25g	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	19007 13.12.2019

4.	Corvalol	alfa-bromisovalerianic acid ethyl ether, phenobarbital, peppermint oil	drops oral	20mg/ml+18,26mg/ml+1,42mg/ml; glass bottle 30ml	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	19008 13.12.2019
5.	Glycerin	glycerol	solution for local use (enema)	900mg/g; plastic container 5ml, plastic container 10ml	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	19009 13.12.2019
6.	Glycerin	glycerol	solution for external use	900mg/g; glass vial 30ml, plastic vial 100ml	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	19010 13.12.2019
7.	Erythromycin	erythromycin	granules for oral suspension	40mg/ml; glass bottle 40g	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	19011 13.12.2019

8.	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film- coated	5mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118- 120	Hungary	Egis Pharmaceutic als PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19012 13.12.2019
9.	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film- coated	7,5mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118- 120	Hungary	Egis Pharmaceutic als PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19013 13.12.2019
10.	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film- coated	10mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118- 120	Hungary	Egis Pharmaceutic als PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19014 13.12.2019
11.	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film- coated	15mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118- 120	Hungary	Egis Pharmaceutic als PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19015 13.12.2019

12.	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film- coated	20mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118- 120	Hungary	Egis Pharmaceutic als PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19016 13.12.2019
13.	Maxicold Rhino	phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid, paracetamol	powder for oral solution with raspberry flavour	10mg+20mg+ 50mg+325mg; (5) sachets 15g, (10) sachets 15g	Pharmstandard- Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTCPharm PJSC, 123317, Moscow, Testovskaya str., 10	Russia	OTC	19017 13.12.2019
14.	Maxicold Rhino	phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid, paracetamol	powder for oral solution with orange flavour	10mg+20mg+ 50mg+325mg; (5) sachets 15g, (10) sachets 15g	Pharmstandard- Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTCPharm PJSC, 123317, Moscow, Testovskaya str., 10	Russia	OTC	19018 13.12.2019
15.	Maxicold Rhino	phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid, paracetamol	powder for oral solution with lemon flavour	10mg+20mg+ 50mg+325mg; (5) sachets 15g, (10) sachets 15g	Pharmstandard- Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTCPharm PJSC, 123317, Moscow, Testovskaya str., 10	Russia	OTC	19019 13.12.2019

16.	Diprosan	betamethasone (betamethasone dipropionate), betamethasone (betamethasone sodium phosphate)	suspension for injection	5mg/ml+2mg/ml; (5) ampoules 1ml	Schering-Plough Labo N.V., Industriepark 30 B-2220, Heist-op-den-Berg	Belgium	Schering-Plough Central East AG, Weysstrasse 20, P.O. Box CH-6000 Lucerne 6	Switzerland	R	19020 13.12.2019
17.	Silvadev	silver sulfadiazine	cream for external use	10mg/g; aluminum tube 40g	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	19021 13.12.2019
18.	Naphthizin	naphazoline (naphazoline nitrate)	drops nasal	1mg/ml; plastic vial 10ml or plastic vial 10ml with measuring device or plastic vial-dropper 10ml	JSC "Farmak", 04080, Kiev, Kyrylivska str. 74	Ukraine	JSC "Farmak", 04080, Kiev, Kyrylivska str. 63	Ukraine	OTC	19022 13.12.2019
19.	Amoksiklav 156.25mg/5ml powder for oral suspension	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	powder for oral suspension	125mg/5ml+3 1,25mg/5ml; 100ml glass bottle and measuring spoon	Lek d.d., Perzonali 47, 2391 Prevalje-bulk manufacturer, packager, quality control (physicochemical), batch releaser, Nacionalni	Slovenia	Lek d.d., Verovskova str. 57, 1526 Ljubljana	Slovenia	R	19023 13.12.2019

					laboratorij za zdravje, okolje in hrano (NLZOH)2, Prvomajska ulica 1, Maribor, 2000, Slovenia- quality control (microbial- non sterile)					
20.	Amoksiklav 312,5mg/5ml forte	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	powder for oral suspension	250mg/5ml+6 2,5mg/5ml; 100ml glass bottle and measuring spoon	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	19024 13.12.2019
21.	Amoksiklav 625mg film- coated tablets	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film- coated	500mg+125m g; (15/3x5) in blister	Lek d.d., Perzonalni 47, 2391 Prevalje- bulk manufacturer, packager, quality control (physicochemical), batch releaser,	Slovenia	Lek d.d., Verovskova str. 57, 1526 Ljubljana	Slovenia	R	19025 13.12.2019

					Nacionalni laboratorij za zdravje, okolje in hrano (NLZOH)2, Prvomajska ulica 1, Maribor, 2000, Slovenia- quality control (microbial-non sterile)					
22.	Advagraf	tacrolimus	capsules prolonged-release	0,5mg; (50/5x10/) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	R	19026 13.12.2019
23.	Advagraf	tacrolimus	capsules prolonged-release	1mg; (50/5x10/) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	R	19027 13.12.2019
24.	Advagraf	tacrolimus	capsules prolonged-release	5mg; (50/5x10/) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	R	19028 13.12.2019
25.	Fraxiparine 2850IU	nadroparin calcium	solution for injection	2850IU AXa/0,3ml; (10) pre-filled	Aspen Notre Dame de Bondeville, 1 rue de l' Abbaye, 76960	France	Aspen Pharma Trading	Ireland	R	19029 13.12.2019

	AXa/0,3ml			syringes 0,3ml	Notre Dame de Bondeville		Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24			
26.	Fraxiparine 5700IU AXa/0,6ml	nadroparin calcium	solution for injection	5700IU AXa/0,6ml; (10) pre-filled syringes 0,6ml	Aspen Notre Dame de Bondeville, 1 rue de l' Abbaye, 76960 Notre Dame de Bondeville	France	Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24	Ireland	R	19030 13.12.2019
27.	Doxycycline	doxycycline (doxycycline hyclate)	capsules	100mg; (10/1x10/) in blister, (20/2x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, No3/3, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	R	19031 13.12.2019
28.	Methypred	methylprednisolone	tablets	4mg; (30) in plastic container	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	R	19032 13.12.2019

29.	Methypred	methylprednisolone	tablets	16mg; (30) in plastic container	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	R	19033 13.12.2019
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LIST

of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 12-1/19 on
December 13, 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.	Dexmedetomidine Kalceks	dexmedetomidine (dexmedetomidine hydrochloride)	concentrate for solution for infusion	100mcg/ml; (5) ampoules 2ml, (25) ampoules 2ml	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057-batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia-bulk manufacturer, packager, quality control	Latvia	Kalceks JSC, 53 Krustpils Street, Riga, LV-1057	Latvia	R	19001 13.12.2019
2.	Morfina hidrohlorids- Kalceks	morphine (morphine hydrochloride)	solution for injection	10mg/ml; (10/2x5/) ampoules 1ml in plastic liner	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057-batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia-bulk manufacturer,	Latvia	Kalceks JSC, 53 Krustpils Street, Riga, LV-1057	Latvia	R	19002 13.12.2019

					packager, quality control					
3.	Tadala-Denk 20mg	tadalafil	tablets film-coated	20mg; (4/1x4/) in blister, (28/7x4/) in blister	Aesica Pharmaceuticals GmbH, Alfred- Nobel-Strasse 10, 40789 Monheim- batch releaser, Advance Pharma GmbH, Wallenroder str. 8-14, 13435 Berlin, Germany- bulk manufacturer, Aesica Pharmaceuticals GmbH, Mittelstrasse 15, 40789 Monheim am Rhein, Germany- packager, quality control (physicochemical), ifp Privates Institut fuer Produktqualitaet GmbH, Wagner- Regeny-Strasse 8 12489 Berlin Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	19003 13.12.2019

4.	Prevenar 13	pneumococcal polysaccharide conjugate vaccine (pneumococcal polysaccharide serotype 1, pneumococcal polysaccharide serotype 3, pneumococcal polysaccharide serotype 4, pneumococcal polysaccharide serotype 5, pneumococcal polysaccharide serotype 6A, pneumococcal polysaccharide serotype 6B, pneumococcal polysaccharide serotype 7F, pneumococcal polysaccharide serotype 9V, pneumococcal polysaccharide serotype 14, pneumococcal	suspension for injection	2.2mcg/dose+ 2.2mcg/dose+ 2.2mcg/dose+ 2.2mcg/dose+ 2.2mcg/dose+ 4.4mcg/dose+ 2.2mcg/dose+ 2.2mcg/dose+ 2.2mcg/dose+ 2.2mcg/dose+ 2.2mcg/dose+ 2.2mcg/dose+ 2.2mcg/dose; (50) vials 0,5ml	Pfizer Manufacturing Belgium N.V., Rijksweg 12, B-2870 Puurs	Belgium	Pfizer Europe MA EEIG, Boulevard de la Plaine 17 1050 Bruxelles	Belgium	R	19004 13.12.2019
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		polysaccharide serotype 18C, pneumococcal polysaccharide serotype 19A, pneumococcal polysaccharide serotype 19F, pneumococcal polysaccharide serotype 23F)								
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LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-1/19 on December 13, 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.	Mirena	levonorgestrel	intrauterine delivery system	52mg; (1) in blister	Bayer Oy, Pansiontie 47, Turku, FI-20210	Finland	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	R	15649/1/1 13.12.2019
2.	Maalox	aluminium hydroxide, magnesium hydroxide	suspension oral	35mg/ml+40 mg/ml; 250ml glass bottle	Sanofi S.p.a., Viale Europa 11, 21040 Origgio	Italy	Sanofi-Aventis France, 1-13 boulevard Romain Rolland, 75014 Paris	France	OTC	15248/1/1 13.12.2019
3.	Kefentech plaster	ketoprofen	plaster transdermal	30mg; (7) in pack	Jeil Health Science Inc, (Building B) 7 Cheongganggachang-ro, Baegam-myeon, Cheoin-gu, Yongin-si, Gyeonggi-do	Korea South	Jeil Health Science Inc, 343, Sapyeong-daero, Seocho-gu, Seoul	Korea South	R	16904/1/1 13.12.2019

4.	Thioctacid 600 HR	alfa-lipoic acid	tablets film- coated	600mg; (30) glass container, (100) glass container	MEDA Pharma GmbH & Co. KG, Benzstrasse1, 61352 Bad Homburg - batch releaser (bulk manufacturer, packager- MEDA Manufacturing GmbH Neurather Ring 1, 51063 Cologne, Germany)	Germany	MEDA Pharma GmbH & Co. KG, Benzstrasse1, 61352 Bad Homburg	Germany	R	14088/1/1 13.12.2019
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LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 12-1/19 on
December 13, 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.	Rowachol	a-pinene, b-pinene, menthol, menthone, borneol, camphene, cineole	capsules gastro-resistant, soft	13,6mg+3,4mg+32mg+6mg+5mg+5mg+2mg; (100/10x10/) blisters	Rowa Pharmaceuticals Ltd., Newtown, Bantry, Cork- batch releaser, bulk manufacturer (capsules liquid manufacturer), S.C. Swiss Caps Romania S.R.L., Str. Carol I no 1, Comuna Cornu, Jud. Prahova 107180, Romania- bulk manufacturer (liquid capsulation), MPF B.V., Appelfhof 13, Oudehaske, 8465RX, the Netherlands- primary packager, Norfachema UAB, Vytauto g. 6, LT-55175 Jonava, Lithuania- secondary packager	Ireland	Rowa Pharmaceutic als Ltd., Newtown, Bantry, Cork	Ireland	R	17883/1 13.12.2019
2.	Grippoflu Extra cold and flu	paracetamol, phenylephrine (phenylephrine hydrochloride),	powder for oral solution with	0,65g+0,01g+0,02g+0,05g; (3) sachets 13g, (8)	Marbiopharm JSC, 424006, the Republic of Mari El, Yoshkar-Ola, st.	Russia	Marbiopharm JSC, 424006, the Republic of Mari	Russia	OTC	14406/1 13.12.2019

		pheniramine (pheniramine maleate), ascorbic acid	lemon flavour	sachets 13g	Karl Marx 121		El,Yoshkar- Ola, st. Karl Marx 121			
3.	GripptoFlu cold and flu	paracetamol, phenylephrine (phenylephrine hydrochloride), pheniramine (pheniramine maleate), ascorbic acid	powder for oral solution with raspberry flavour	325mg+10mg+ 20mg+50mg; (10) sachets 13g	Marbiopharm JSC, 424006, the Republic of Mari El,Yoshkar-Ola, st. Karl Marx 121	Russia	Marbiopharm JSC, 424006, the Republic of Mari El,Yoshkar- Ola, st. Karl Marx 121	Russia	OTC	14510/1 13.12.2019
4.	Diazolin	mebhydrolin (mebhydrolin napadisylate)	dragee	100mg; (20/2x10/) blisters	Marbiopharm JSC, 424006, the Republic of Mari El,Yoshkar-Ola, st. Karl Marx 121	Russia	Marbiopharm JSC, 424006, the Republic of Mari El,Yoshkar- Ola, st. Karl Marx 121	Russia	OTC	14396/1 13.12.2019
5.	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film- coated	5mg; (28/4x7/) blisters, (56/8x7/) blisters	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceutic als PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	14285/3 13.12.2019

6.	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film- coated	7,5mg; (28/4x7/) blisters, (56/8x7/) blisters	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceutic als PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	14288/3 13.12.2019
7.	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film- coated	10mg; (28/4x7/) blisters, (56/8x7/) blisters	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceutic als PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	14289/3 13.12.2019
8.	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film- coated	15mg; (28/4x7/) blisters, (56/8x7/) blisters	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceutic als PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	14286/3 13.12.2019
9.	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film- coated	20mg; (28/4x7/) blisters, (56/8x7/) blisters	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceutic als PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	14287/3 13.12.2019

10.	Glycerin	glycerol	suppositories rectal	1,24g; (10/2x5/) in blister	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	17035/2 13.12.2019
11.	Glycerin	glycerol	suppositories rectal	2.11g; (10/2x5/) in blister	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	17036/2 13.12.2019
12.	Dibase 50,000I.U./2.5ml oral solution	colecalfiferol (vitamin D3)	solution oral	50000IU/2.5ml; glass bottle 2.5ml	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	Abiogen Pharma S.p.A., Via Meucci, 36 - Ospedaletto - Pisa	Italy	R	18336/1 13.12.2019
13.	Enalapril	enalapril (enalapril maleate)	tablets	5mg; (20/2x10/) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	R	16823/1 13.12.2019

14.	Enalapril	enalapril (enalapril maleate)	tablets	10mg; (20/2x10/) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	R	16822/1 13.12.2019
15.	Enalapril	enalapril (enalapril maleate)	tablets	20mg; (20/2x10/) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	R	16821/1 13.12.2019
16.	Tyrosur	tyrothricin	gel for topical use	1mg/g; 5g aluminium tube	Engelhard Arzneimittel GmbH& Co. KG, Herzbergstrasse 3, 61138 Niederdorfelden	Germany	Engelhard Arzneimittel GmbH& Co. KG, Herzbergstras se 3, 61138 Niederdorfeld en	Germany	OTC	16046/1 13.12.2019
17.	Immunate	human blood coagulation factor VIII, Von Willebrand Factor(VWF:RCo)	powder and solvent for solution for injection	250IU+190IU; (1) glass vial, glass vial 5ml with solvent, (1) transfer/filter set, (1) disposable syringe 5ml, (1)	Baxter AG, Industriestrasse 67, A- 1221 Vienna-batch releaser, secondary packager, Baxter AG, Lange Allee 24, A-1221 Vienna, Austria-bulk manufacturer, primary	Austria	Baxter AG, Industriestras se 67, A-1221 Vienna	Austria	R	14723/1 13.12.2019

				disposable needle, (1) winged infusion set	packager					
18.	Immunate	human blood coagulation factor VIII, Von Willebrand Factor(VWF:RCo)	powder and solvent for solution for injection	500IU+375IU; (1) glass vial, glass vial 5ml with solvent, (1) transfer/filter set, (1) disposable syringe 5ml, (1) disposable needle, (1) winged infusion set	Baxter AG, Industriestrasse 67, A- 1221 Vienna-batch releaser, secondary packager, Baxter AG, Lange Allee 24, A-1221 Vienna, Austria-bulk manufacturer, primary packager	Austria	Baxter AG, Industriestras se 67, A-1221 Vienna	Austria	R	14724/1 13.12.2019
19.	Immunate	human blood coagulation factor VIII, Von Willebrand Factor(VWF:RCo)	powder and solvent for solution for injection	1000IU+750IU; (1) glass vial, glass vial 10ml with solvent, (1) transfer/filter set, (1) disposable syringe 10ml, (1) disposable needle, (1) winged infusion set	Baxter AG, Industriestrasse 67, A- 1221 Vienna-batch releaser, secondary packager, Baxter AG, Lange Allee 24, A-1221 Vienna, Austria-bulk manufacturer, primary packager	Austria	Baxter AG, Industriestras se 67, A-1221 Vienna	Austria	R	14722/1 13.12.2019

20.	Relief	phenylephrine (phenylephrine hydrochloride)	supposito- ries rectal	5mg; (12/2x6/) in strip	Istituto De Angeli S.r.l., Localita Prulli 103/c- 50066 Reggelo	Italy	Bayer Consumer Care AG, Peter Merian- Strasse 84, 4052 Basel	Switzerland	OTC	16561/1 13.12.2019
21.	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	VALEANT LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	R	18526/1 13.12.2019
22.	Biprol	bisoprolol (bisoprolol fumarate)	tablets film- coated	5mg; (30/3x10/) in blister	Hemofarm LLC, 249032, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	R	17885/1 13.12.2019
23.	Biprol	bisoprolol (bisoprolol fumarate)	tablets film- coated	10mg; (30/3x10/) in blister	Hemofarm LLC, 249032, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	R	17886/1 13.12.2019

24.	Wilprafen	josamycin	tablets film- coated	500mg; (10/1x10/) in blister	Dragenopharm Apotheker Puschl GmbH, Gollstrasse 1, 84529 Tittmoning	Germany	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	R	16348/1 13.12.2019
25.	Liprimar	atorvastatin (atorvastatin calcium)	tablets film- coated	10mg; (30/3x10/) In blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstatte Freiburg, Mosswaldalee 1, 79090 Frieberg - batch releaser, packager, 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	17334/1 13.12.2019
26.	Liprimar	atorvastatin (atorvastatin calcium)	tablets film- coated	20mg; (30/3x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstatte Freiburg, Mosswaldalee 1, 79090 Frieberg - batch releaser, packager, 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	17332/1 13.12.2019

27.	Liprimar	atorvastatin (atorvastatin calcium)	tablets film- coated	40mg; (30/3x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstatte Freiburg, Mosswaldalee 1, 79090 Frieburg - batch releaser, packager, 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	17333/1 13.12.2019
28.	Liprimar	atorvastatin (atorvastatin calcium)	tablets film- coated	80mg; (30/3x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstatte Freiburg, Mosswaldalee 1, 79090 Frieburg - batch releaser, packager, 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	17331/1 13.12.2019
29.	Erythromycin	erythromycin	granules for oral suspension	40mg/ml; glass bottle 40g	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	13972/1 13.12.2019

30.	Polydexa with phenylephrine	neomycin (neomycin sulfate), polymyxin B (polymyxin B sulfate), dexamethasone (dexamethasone metasulfobenzoate sodium), phenylephrine (phenylephrine hydrochloride)	spray nasal	6500IU/ml+100 00IU/ml+0,25mg/ml+2,5mg/ml; plastic container 15ml	Laboratoires SOPHARTEX, 21 Rue du Pressoir, 28500 VERNOUILLET	France	Laboratoires Bouchara-Recordati, Immeuble le Wilson, 70 Avenue du General de Gaulle, 92800 Puteaux	France	R	13655/1 13.12.2019
31.	Furotalgine 2.5mg/31.25mg/87.5mg/ml ear drops, solution	nitrofurantoin, tetracaine (tetracaine hydrochloride), phenazone	drops ear (solution)	2,5mg/ml+31,25 mg/ml+87,5mg/ml; (1) glass or plastic vial with dropper 5ml	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	R	15459/2 13.12.2019
32.	Ciprofloxacin	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	250mg; (10/1x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	R	17176/1 13.12.2019

33.	Ciprofloxacin	ciprofloxacin (ciprofloxacin hydrochloride)	tablets film-coated	500mg; (10/1x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, ul. Chapaeva, Borisov 222518, Minsk region	Belarus	R	17177/1 13.12.2019
34.	Haemate P 250IU FVIII/600IU VWF	human blood coagulation factor VIII, human Von Willebrand Factor (VWF:RCO)	powder and solvent for solution for injection/ infusion	250IU+600IU; (1) glass vial, 5ml glass vial with solvent, (1) transfer/filter device 20/20	CSL Behring GmbH, Emil-von-Behring- Strasse 76, 35041 Marburg	Germany	CSL Behring GmbH, Emil- von-Behring- Strasse 76, 35041 Marburg	Germany	R	14804/2 13.12.2019
35.	Haemate P 500IU FVIII/1200IU VWF	human blood coagulation factor VIII, human Von Willebrand Factor (VWF:RCO)	powder and solvent for solution for injection/ infusion	500IU+1200IU; (1) glass vial, 10ml glass vial with solvent, (1) transfer/filter device 20/20	CSL Behring GmbH, Emil-von-Behring- Strasse 76, 35041 Marburg	Germany	CSL Behring GmbH, Emil- von-Behring- Strasse 76, 35041 Marburg	Germany	R	14805/2 13.12.2019

36.	Haemate P 1000IU FVIII/2400IU VWF	human blood coagulation factor VIII, human Von Willebrand Factor (VWF:RCo)	powder and solvent for solution for injection/ infusion	1000IU+2400IU ; (1) glass vial, 15ml glass vial with solvent, (1) transfer/filter device 20/20	CSL Behring GmbH, Emil-von-Behring- Strasse 76, 35041 Marburg	Germany	CSL Behring GmbH, Emil- von-Behring- Strasse 76, 35041 Marburg	Germany	R	14806/2 13.12.2019
37.	Singulair	montelukast (montelukast sodium)	tablets chewable	4mg; (14/1x14/), in blister, (28/2x14/), in blister	Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem-batch releaser, packager, Merck Sharp & Dohme Ltd., Shotton Lane, Cramlington, Northumberland NE23 3JU, United Kingdom - bulk manufacturer	the Netherlands	Schering- Plough Central East Ag, Weystrasse 20, 6000 Lucerne 6	Switzerland	R	15400/2 13.12.2019
38.	Singulair	montelukast (montelukast sodium)	tablets chewable	5mg; (14/1x14/), in blister, (28/2x14/), in blister	Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem-batch releaser, packager, Merck Sharp & Dohme Ltd., Shotton Lane, Cramlington, Northumberland NE23 3JU, United Kingdom - bulk manufacturer	the Netherlands	Schering- Plough Central East Ag, Weystrasse 20, 6000 Lucerne 6	Switzerland	R	15399/2 13.12.2019

39.	Singulair	montelukast (montelukast sodium)	tablets film-coated	10mg; (14/1x14/), in blister, (28/2x14/), in blister	Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem-batch releaser, packager, Merck Sharp & Dohme Ltd., Shotton Lane, Cramlington, Northumberland NE23 3JU, United Kingdom - bulk manufacturer	the Netherlands	Schering-Plough Central East Ag, Weystrasse 20, 6000 Lucerne 6	Switzerland	R	15398/2 13.12.2019
40.	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-batch releaser, secondary packager, Valdepharm, Parc Industriel d incaville-BP 606, 27100 Val de Reuil Cedex, France-bulk manufacturer, primary packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	14657/1 13.12.2019
41.	Macropen	midecamycin	tablets film-coated	400mg; (16/2x8/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto-batch releaser, Merck KGaA & Co., Werk Spittal, Hosslgasse 20, 9800 Spittal an der Drau, Austria- bulk manufacturer, packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	17206/1 13.12.2019

42.	Melarena	melatonin	tablets film- coated	3mg; (10/1x10/) in blister, (30/3x10/) in blister	Hemofarm LLC, 249032, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	18525/1 13.12.2019
43.	Gangleron	ganglefene	capsules	40mg; (60/5x12/) blisters, (30) plastic container	the Scientific Technological Center of Organic and Pharmaceutical Chemistry, A.L. Mndjoyan Institute of Fine Organic Chemistry NAS RA , Yerevan, Azatutyun avenue 26 - batch releaser (Arpimed LLC, Kotayk Marz,	Republic of Armenia	Abovyan, 2nd Micro- District, 19 Building	Republic of Armenia	R	13683/1 13.12.2019
44.	Legalon 140	silymarin	capsules	140mg; (20/2x10/), (30/3x10/) and (60/6x10/) in blister	Madaus GmbH, Luetticher Strasse 5, Troisdorf, 53842	Germany	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg	Germany	OTC	17155/1 13.12.2019
45.	Urolesan	abies oil, mentha piperita oil, daucus carota fluid extract, humulus lupulus fluid extract, origanum fluid extract	drops oral	67,6mg/ml+16,9 mg/ml+194,35 mg/ml+278,8mg g/ml+192,95mg /ml; 25ml bottle-dropper	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovska ya, 6/8	Ukraine	OTC	17231/1 13.12.2019

46.	Sutent	sunitinib (sunitinib malate)	capsules hard	12,5mg; (30) plastic bottle	Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno	Italy	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York, NY 10017-5755	USA	R	18436/2 13.12.2019
47.	Sutent	sunitinib (sunitinib malate)	capsules hard	25mg; (30) plastic bottle	Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno	Italy	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York, NY 10017-5755	USA	R	18437/2 13.12.2019
48.	Sutent	sunitinib (sunitinib malate)	capsules hard	50mg; (30) plastic bottle	Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno	Italy	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York, NY 10017-5755	USA	R	18438/2 13.12.2019
49.	Glucovance	glibenclamide, metformin (metformin hydrochloride)	tablets film-coated	5mg+500mg; (30/2x15/) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400 Semoy	France	Merck Sante s.a.s., 37 rue Saint Romain - 69379 Lyon Cedex 08	France	R	15072/1 13.12.2019

50.	Glucovance	glibenclamide, metformin (metformin hydrochloride)	tablets film- coated	2,5mg+500mg; (30/2x15/) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400 Semoy	France	Merck Sante s.a.s., 37 rue Saint Romain - 69379 Lyon Cedex 08	France	R	15073/1 13.12.2019
51.	Maalox	aluminium hydroxide, magnesium hydroxide	tablets chewable	400mg+400mg; (40/4x10/) in blister	Sanofi S.p.A., Strada Statale N17 km 22, 67019 Scoppito	Italy	Sanofi- Aventis France, 1-13, boulevard Romain Rolland, 75014 Paris	France	OTC	15547/2 13.12.2019
52.	Sartuzin	fluoxetine (fluoxetine hydrochloride)	capsules hard	20mg; (12/3x4/) and (28/4x7/) in blister	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorphos is, Attica	Greece	R	18042/1 13.12.2019
53.	Moditen depo	fluphenazine (fluphenazine decanoate)	solution for i/m injection	25mg/ml; (5/1x5/) ampoules 1ml, 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	16167/1 13.12.2019
54.	Meloxicam STADA	meloxicam	tablets	15mg; (20/2x10/) in blister	Hemofarm LLC, 249032, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	R	17728/1 13.12.2019

55.	Melon	ambroxol (ambroxol hydrochloride), salbutamol (salbutamol sulfate), guaifenesin	syrup	15mg/5ml+1mg /5ml+50mg/5ml ; 100ml plastic container	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi-batch releaser, secondary packager, Geno Pharmaceuticals Pvt. Ltd, Karaswada Mapusa, Goa 403526, India -bulk manufacturer, primary packager	Georgia	Aversi- Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi	Georgia	R	17338/1 13.12.2019
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