

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 2-1/20 on February 14, 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	Dexdor	dexmedetomidine (dexmedetomidine hydrochloride)	concentrate for solution for infusion	100mcg/ml; (5) ampoules 2ml, (25) ampoules 2ml	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	R	14794/1 14.02.2020
2	Avamys	fluticasone (fluticasone furoate)	spray nasal (suspension)	27,5mcg/dose; (1) glass bottle with metering pump (120 dose)	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	19111 14.02.2020

LIST

of the medicines recommended for the registration (new packaging) by the Center according to the meeting decision N 2-1/20 on February 14, 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	Furasol	furazidin (furazidin potassium)	powder for solution for external use	100mg; (5) sachets 1g, (15) sachets 1g	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	Olainfarm JSC, 5 Rupnicu Str., Olaine, LV-2114	Latvia	OTC	16001/1 14.02.2020

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 2-1/20 on February 14, 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	Paraflu for adults	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	19113 14.02.2020
2	Paraflu 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	19114 14.02.2020
3	Postinor	levonorgestrel	tablets	0,75mg; (2/1x2/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	OTC	19115 14.02.2020
4	Co-Prenessa	perindopril (perindopril erbumine), indapamide	tablets	8mg+2,5mg; (30/3x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	19116 14.02.2020

5	Solcovagin	nitric acid 70%, glacial acetic acid, oxalic acid dihydrate, zinc nitrate hexahydrate	solution for topical use	537mg/ml+20,4mg/ml+58,6mg/ml+6mg/ml; (2) glass vial 0,5ml	Legacy Pharmaceuticals Switzerland GmbH, Ruhrbergstrasse 21, 4127 Birsfelden	Switzerland	MEDA Pharmaceuticals Switzerland GmbH, Hegnaustrasse 60, 8602 Wangen-Bruttisellen	Switzerland	R	19117 14.02.2020
6	Tramadol Denk 50	tramadol (tramadol hydrochloride)	tablets effervescent	50mg; (10) in plastic container	Losan Pharma GmbH Otto-Hahn-Str. 13, 15 79395 Neuenburg	Germany	Denk Pharma GmbH & Co. KG, Germany Prinzergerstr. 79, 81675 Munchen	Germany	R	19118 14.02.2020
7	Arixtra	fondaparinux (fondaparinux sodium)	solution for injection	5mg/ml; (10/2x5/) pre-filled syringes 0.5ml in blister	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	19119 14.02.2020
8	Solcoseryl	protein-free hemodialysate from calves blood	ointment	2,07mg/g; aluminium tube 20g	Legacy Pharmaceuticals Switzerland GmbH, Ruhrbergstrasse 21, 4127 Birsfelden	Switzerland	MEDA Pharmaceuticals Switzerland GmbH, Hegnaustrasse 60, 8602 Wangen-Bruttisellen	Switzerland	OTC	19120 14.02.2020

9	Solcoseryl	protein-free hemodialysate from calves blood	gel	4,15mg/g; aluminium tube 20g	Legacy Pharmaceuticals Switzerland GmbH, Ruhrbergstrasse 21, 4127 Birsfelden	Switzerland	MEDA Pharmaceuticals Switzerland GmbH, Hegnaustrasse 60, 8602 Wangen-Bruttisellen	Switzerland	OTC	19121 14.02.2020
10	Belara	chlormadinone (chlormadinone acetate), ethinylestradiol	tablets film-coated	2mg+0,03mg; (21/1x21/) in blister, (63/3x21/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	19122 14.02.2020

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 2-1/20 on February 14, 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	Lotar	losartan (losartan potassium)	tablets film-coated	50mg; (30/3x10/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	R	17226/1/1 14.02.2020
2	Lotar	losartan (losartan potassium)	tablets film-coated	100mg; (30/2x15/) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	R	17225/1/1 14.02.2020
3	Yarina Plus	drospirenone, ethinylestradiol, levomefolate calcium	tablets film-coated	3mg+30mcg+451mcg; (28/21+7/) (orange and light orange) in blister	Bayer Weimar GmbH & Co. KG, Dobereinerstrasse 20, 99427 Weimar, Germany - bulk manufacturer, Bayer AG, Mullerstrasse 178, 13353, Berlin - packager, batch releaser	Germany	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	R	17621/1/2 14.02.2020

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 2-1/20 on February 14, 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	No-spa	drotaverine (drotaverine hydrochloride)	tablets	40mg; (24/1x24/) blister, (100) plastic container	Chinoin Pharmaceutical and Chemical Works Private Co. Ltd., 2112 Veresegyhaz, Levai u. 5	Hungary	Sanofi-Aventis Private Co. Ltd., 1045 Budapest, To u. 1-5	Hungary	OTC	16868/2 14.02.2020
2	Alteyka Arterium	althaeae radix dry extract	syrup	7,5mg/5ml; 100ml plastic or glass bottle and measuring spoon, 100ml plastic or glass container and measuring spoon, 200ml plastic or glass bottle and measuring spoon	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	Halychpharm JSC, 79024, city of Lviv, st. Oprishkovskaya, 6/8	Ukraine	OTC	17207/1 14.02.2020
3	Revit	vitamin A, vitamin B1, vitamin B2, vitamin C	dragee	2500IU+1mg+1mg+35 mg; (100) plastic container	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	OTC	13749/1 14.02.2020

4	Alotendin	bisoprolol (bisoprolol fumarate), amlodipine (amlodipine besilate)	tablets	5mg+5mg; (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (90/9x10) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	18843/1 14.02.2020
5	Alotendin	bisoprolol (bisoprolol fumarate), amlodipine (amlodipine besilate)	tablets	5mg+10mg; (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (90/9x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	18844/1 14.02.2020
6	Alotendin	bisoprolol (bisoprolol fumarate), amlodipine (amlodipine besilate)	tablets	10mg+5mg; (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (90/9x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	18845/1 14.02.2020
7	Alotendin	bisoprolol (bisoprolol fumarate), amlodipine (amlodipine besilate)	tablets	10mg+10mg; (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (90/9x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	18846/1 14.02.2020
8	Campto CS	irinotecan (irinotecan hydrochloride trihydrate)	concentrate for solution for infusion	20mg/ml vial; plastic vial 5ml	Pfizer (Perth) Pty Limited, 15 Brodie Hall Drive Technology Park Bentley WA 6102	Australia	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	R	18309/1 14.02.2020

9	Campto CS	irinotecan (irinotecan hydrochloride trihydrate)	concentrate for solution for infusion	20mg/ml vial; plastic vial 15ml	Pfizer (Perth) Pty Limited, 15 Brodie Hall Drive Technology Park Bentley WA 6102	Australia	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	R	18310/1 14.02.2020
10	Pregnyl	gonadotrophin chorionic	powder lyophilized for solution for i/m and s/c injection	1500IU; (3) ampoules 2ml and (3) solvent in ampoules 1ml	N.V. Organon, Molenstraat 110, 5342 CC OSS, the Netherlands (legal address - N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands)	the Netherlands	Schering-Plough Central East AG, Weyrstrasse 20, P.O. Box CH-6000 Lucerne 6	Switzerland	R	14757/1 14.02.2020
11	Pregnyl	gonadotrophin chorionic	powder lyophilized for solution for i/m and s/c injection	5000IU; ampoule 2ml and 1ml solvent in ampoule	N.V. Organon, Molenstraat 110, 5342 CC OSS, the Netherlands (legal address - N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands)	the Netherlands	Schering-Plough Central East AG, Weyrstrasse 20, P.O. Box CH-6000 Lucerne 6	Switzerland	R	14758/1 14.02.2020
12	Nolicin	norfloxacin	tablets film-coated	400mg; (20/2x10/) 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	17063/1 14.02.2020

13	Atoris	atorvastatin (atorvastatin calcium)	tablets film-coated	40mg; (30/3x10/) blisters	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	14652/1 14.02.2020
14	Nalgesin forte	naproxen (naproxen sodium)	tablets film-coated	550mg; (10/1x10/) in blister, (20/2x10/) 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	15806/1 14.02.2020
15	Amiodarone	amiodarone (amiodarone hydrochloride)	concentrate for solution for infusion	50mg/ml; (10) ampoules 3ml, in blister, (10) ampoules 3ml label banderol, (10) ampoules 3ml dividella	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, No11/1, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	R	17535/2 14.02.2020
16	Heparin ointment	heparin (heparin sodium), benzocaine, benzyl nicotinate	ointment for external use	100IU/g+40mg/g+0,8 mg/g; 25g aluminium or plastic tube	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	16651/1 14.02.2020

17	Triplixam	perindopril (perindopril arginine), indapamide, amlodipine (amlodipine besilate)	tablets film-coated	5mg+1,25mg+5mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	18423/1 14.02.2020
18	Triplixam	perindopril (perindopril arginine), indapamide, amlodipine (amlodipine besilate)	tablets film-coated	5mg+1,25mg+10mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	18424/1 14.02.2020
19	Triplixam	perindopril (perindopril arginine), indapamide, amlodipine (amlodipine besilate)	tablets film-coated	10mg+2,5mg+5mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	18425/1 14.02.2020
20	Triplixam	perindopril (perindopril arginine), indapamide, amlodipine (amlodipine besilate)	tablets film-coated	10mg+2,5mg+10mg; (30) plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284, Ireland	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	18426/1 14.02.2020

21	Prestilol 5mg/5mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	5mg+5mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	16164/1 14.02.2020
22	Prestilol 5mg/10mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	5mg+10mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	16163/1 14.02.2020
23	Prestilol 10mg/5mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	10mg+5mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	16162/1 14.02.2020
24	Prestilol 10mg/10mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	10mg+10mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	16161/1 14.02.2020

25	Lantus	insulin glargine	solution for s/c injection	100U/ml; (5) cartridges 3ml, in SoloStar pen-syringes	Sanofi-Aventis Deutschland GmbH, Industriepark Hoechst, Bruningstrasse 50, D-65926 , Frankfurt am Main	Germany	Sanofi-Aventis Deutschland GmbH, Industriepark Hoechst, Bruningstrasse 50, D-65926 , Frankfurt am Main	Germany	R	18144/1 14.02.2020
26	Tramadol Denk 50	tramadol (tramadol hydrochloride)	tablets effervescent	50mg; (10) plastic container	Losan Pharma GmbH Otto-Hahn-Str. 13 79395 Neuenburg for Denk Pharma GmbH & Co. KG, Germany Prinzergerenstr. 79, 81675 Munchen	Germany	Losan Pharma GmbH Otto-Hahn-Str. 13 79395 Neuenburg for Denk Pharma GmbH & Co. KG, Germany Prinzergerenstr. 79, 81675 Munchen	Germany	R	14160/1 14.02.2020
27	Noliprel arginine	perindopril arginine, indapamide	tablets film-coated	2,5mg+0,625mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	16806/1 14.02.2020
28	Noliprel Bi-Forte	perindopril (perindopril arginine), indapamide	tablets film-coated	10mg+2,5mg; (30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co Wicklow	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	16673/1 14.02.2020

29	Noliprel Forte arginine	perindopril arginine, indapamide	tablets film-coated	5mg+1,25mg; (30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	R	16807/1 14.02.2020
30	Lipertance	atorvastatin (atorvastatin calcium trihydrate), perindopril arginine, amlodipine (amlodipine besilate)	tablets film-coated	10mg+5mg+5mg; (30) in plastic container, (100) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50,rue Carnot, 92284 Suresnes cedex	France	R	15824/1 14.02.2020
31	Lipertance	atorvastatin (atorvastatin calcium trihydrate), perindopril arginine, amlodipine (amlodipine besilate)	tablets film-coated	20mg+5mg+5mg; (30) in plastic container, (100) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50,rue Carnot, 92284 Suresnes cedex	France	R	15825/1 14.02.2020
32	Lipertance	atorvastatin (atorvastatin calcium trihydrate), perindopril arginine, amlodipine (amlodipine besilate)	tablets film-coated	20mg+10mg+5mg; (30) in plastic container, (100) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50,rue Carnot, 92284 Suresnes cedex	France	R	15826/1 14.02.2020

33	Lipertance	atorvastatin (atorvastatin calcium trihydrate), perindopril arginine, amlodipine (amlodipine besilate)	tablets film-coated	20mg+10mg+10mg; (30) in plastic container, (100) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50,rue Carnot, 92284 Suresnes cedex	France	R	15827/1 14.02.2020
34	Lipertance	atorvastatin (atorvastatin calcium trihydrate), perindopril arginine, amlodipine (amlodipine besilate)	tablets film-coated	40mg+10mg+10mg; (30) in plastic container, (100) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50,rue Carnot, 92284 Suresnes cedex	France	R	15828/1 14.02.2020
35	Retabolil	nandrolone (nandrolone decanoate)	solution for injection, oily	50mg/ml; (1) ampoule 1ml	Gedeon Richter OJSC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter OJSC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	14170/1 14.02.2020
36	Ketorolac	ketorolac (ketorolac trometamol)	tablets film-coated	10mg; (10), (20/2x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapaev str., Borisov 222518,	Belarus	R	15987/1 14.02.2020
37	Rispolept Consta	risperidone	powder and solvent for prolonged-release suspension for injection	25mg; (1) glass vial with powder, (1) pre-filled syringe with 2ml solvent, (1) vial adapter, (2) needles (25mm and 51mm)	Cilag AG, Hochstrasse 201, CH-8200 Schaffhausen	Switzerland	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	R	16072/3 14.02.2020
38	Lorista HD	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+25mg; (28/2x14/), in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	14781/2 14.02.2020

39	Enap-H	enalapril (enalapril maleate), hydrochlorothiazide	tablets	10mg+25mg; (20/2x10/) 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	16396/1 14.02.2020
40	Glimepiride Denk 2	glimepiride	tablets	2mg; (30/3x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	R	17345/1 14.02.2020
41	Triderm	betamethasone (betamethasone dipropionate), clotrimazole, gentamicin (gentamicin sulfate)	ointment	0,5mg/g+10mg/g+1mg/g; 15g aluminium tube	Schering-Plough Labo N.V., Industriepark 30, Heist-op-den-Berg, 2220	Belgium	Schering-Plough Central East AG, Weystrasse 20, P.O. Box CH-6000 Lucerne 6	Switzerland	R	17677/1 14.02.2020
42	Co-Prelessa	perindopril (perindopril erbumine), indapamide	tablets	2mg+0,625mg; (30/3x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	16092/1 14.02.2020
43	Co-Prelessa	perindopril (perindopril erbumine), indapamide	tablets	4mg+1,25mg; (30/3x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	16091/1 14.02.2020

44	Mezym forte 10000 capsules	pancreatin (lipase, amylase, protease)	capsules hard gastro-resistant	10000U+not less than9000U+not less than 500U (20) in plastic container	Berlin-Chemie A.G.,Glienicker Weg 125, D-12489 Berlin-batch releaser, Adare Pharmaceuticals Srl., Via Martin Luther King, 13, Pessano Con Bornago, 20060, Italy-bulk manufacturer, Artesan Pharma GmbH & Co. KG, Albrecht-Thaer-Str. 9, 29439 Luchow, Germany- packager	Germany	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, 1611	Luxembourg	OTC	16050/2 14.02.2020
45	Mezym forte 25000 capsules	pancreatin (lipase, amylase, protease)	capsules hard gastro-resistant	25000U+not less than 22500U+not less than 1250U (20) plastic container	Berlin-Chemie A.G.,Glienicker Weg 125, D-12489 Berlin-batch releaser, Adare Pharmaceuticals Srl., Via Martin Luther King, 13, Pessano Con Bornago, 20060, Italy-bulk manufacturer, Artesan Pharma GmbH & Co. KG, Albrecht-Thaer-Str. 9, 29439 Luchow, Germany- packager	Germany	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, 1611	Luxembourg	OTC	16051/2 14.02.2020
46	Actrapid Penfill	insulin human	solution for injection	100IU/ml; (5) glass cartridges 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	Novo Nordisk A/S, Novo Alle, DK- 2880 Bagsvaerd	Denmark	R	18294/1 14.02.2020

47	Actrapid	insulin human (recombinant DNA)	solution for injection	100IU/ml; (1) glass vial 10ml	Novo Nordisk Production SAS, 45 avenue d'Orleans, F-28000, Chartres	France	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	R	17514/1 14.02.2020
48	Actrapid	insulin human (recombinant DNA)	solution for injection	100IU/ml; glass vial 10ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd - batch releaser, bulk manufacturer, primary packager, Novo Nordisk A/S, Hallas Alle, DK-4400 Kalundborg, Denmark-secondary packager	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	R	18619/1 14.02.2020
49	Mixtard 30	insulin human (recombinant DNA)	suspension for injection	100IU/ml; (1) glass vial 10ml	Novo Nordisk Production SAS, 45 avenue d'Orleans, F-28000, Chartres	France	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	R	17159/3 14.02.2020
50	On.setron-Denk 4mg ODT	ondansetron	tablets orodispersible	4mg; (6/1x6/), in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	14741/1 14.02.2020
51	On.setron-Denk 8mg ODT	ondansetron	tablets orodispersible	8mg; (6/1x6/), in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	15449/1 14.02.2020

52	Insulatard	insulin human (recombinant DNA)	suspension for injection	100IU/ml; glass vial 10ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd - batch releaser, bulk manufacturer, primary packager, Novo Nordisk A/S, Hallas Alle, DK-4400 Kalundborg, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	R	18617/1 14.02.2020
53	Insulatard Penfill	insulin human	suspension for injection	100IU/ml; (5) glass cartridges 3ml	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	R	18296/1 14.02.2020
54	Insulatard	insulin human (recombinant DNA)	suspension for injection	100IU/ml; (1) glass vial 10ml	Novo Nordisk Production SAS, 45 avenue d`Orleans, F-28000, Chartres	France	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	R	17160/1 14.02.2020