

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 2-2/20 on February 28, 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	Torendo	risperidone	tablets film-coated	1mg; (30/3x10/) in blister, (60/6x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, KRKA, tovarna zdravil, d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	19122 28.02.2020
2	Torendo	risperidone	tablets film-coated	2mg; (30/3x10/) in blister, (60/6x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, KRKA, tovarna zdravil, d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	19123 28.02.2020

3	Torendo	risperidone	tablets film-coated	4mg; (30/3x10/) in blister, (60/6x10/) in blister	<p>KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, KRKA, tovarna zdravil, d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia- quality control (physicochemical)</p>	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	19124 28.02.2020
4	Tro-xime 750mg powder for solution for injection/infusion	cefuroxime (cefuroxime sodium)	powder for solution for injection/infusion	750mg; (1) glass vial 10ml, (10) glass vials 10ml	<p>Reyoung Pharmaceutical Co. Ltd., No1 Ruiyang Road, Yiyuan County, Shandong Province- packager, quality control, batch releaser, Titan Pharmaceutical Co., Ltd (Guangdong), Lantang Town, Zijin County, Heyuan City, China- bulk manufacturer</p>	China	Troge Medical GmbH, Milchstrasse 19, 20148 Hamburg	Germany	R	19125 28.02.2020

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 2-2/20 on February 28, 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	Crurovit	cilostazol	tablets	50mg; (28/2x14) in blister, (56/4x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19126 28.02.2020
2	Crurovit	cilostazol	tablets	100mg; (28/2x14/) in blister, (56/4x14/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19127 28.02.2020
3	Solcoseryl	hemodialysate from calves blood protein-free, polidocanol	paste dental adhesive	2,125mg/g+10mg/g; aluminium tube 5g	Legacy Pharmaceuticals Switzerland GmbH, Ruhrbergstrasse 21, 4127 Birsfelden	Switzerland	MEDA Pharmaceuticals Switzerland GmbH, Hegnaustrasse 60, 8602 Wangen-Bruttisellen	Switzerland	OTC	19128 28.02.2020

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 2-2/20 on February 28, 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	Eylea	aflibercept	solution for injection	40mg/ml; (1) glass vial 0.278ml and needle	Bayer AG, Mullerstrasse 178, 13353, Berlin- batch releaser, secondary packager, Regeneron Pharmaceuticals, Inc., 81 Columbia Turnpike, Rensselaer, New York 12144, USA- bulk manufacturer, Vetter Pharma-Fertigung GmbH & Co. KG, Eisenbahnstr. 2-4, 88085 Langenargen, Germany- primary packager	Germany	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	R	17023/1/1 28.02.2020
2	Rehydron	sodium chloride, potassium chloride, sodium citrate, glucose anhydrous	powder dose	3,5g+2,5g+2,9g+10g; (20) sachet 18,9g	Recipharm Parets S.L.U, C/Ramon and Cajal 2 , 08150 Parets del Valles (Barcelona)	Spain	Orion Corporation, Orionintie 1, 02200 Espoo	Finland	OTC	17096/1/1 28.02.2020

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 2-2/20 on February 28, 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	Extract Belladonnae	extract belladonnae	suppositories rectal	15mg; (10/2x5/) in blister	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	16875/1 28.02.2020
2	Rovamycine	spiramycin	tablets film-coated	3000000IU; (10/1x10/) in blister	SANOFI S.P.A., S.S. 17 km 22, 67019 Scoppito	Italy	Sanofi-Aventis France, 82 avenue Raspail, 94250 Gentilly	France	R	17549/1 28.02.2020
3	Norcolut	norethisterone	tablets	5mg; (20/2x10/) in blister	Gedeon Richter OJSC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter OJSC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	15064/1 28.02.2020
4	Flavamed cough solution	ambroxol (ambroxol hydrochloride)	solution oral	15mg/5ml; glass bottle 60ml and measuring spoon, glass bottle 100ml and measuring spoon	Berlin-Chemie AG, Glienicke Weg 125, 12489 Berlin	Germany	Berlin-Chemie AG, Glienicke Weg 125, 12489 Berlin	Germany	OTC	14422/1 28.02.2020

5	Jeanine	ethinylestradiol, dienogest	tablets coated	0.03mg+2mg; (21/1x21/), in blister	Bayer Weimar GmbH & Co. KG, Dobereinerstrasse 20, 99427 Weimar	Germany	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	R	14769/228.02.2020
6	Tiregis D	telmisartan, hydrochlorothiazide	tablets	40mg+12,5mg; (28/2x14/) blisters, (56/4x14/) blisters	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120-batch releaser, Actavis Ltd., BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta-bulk manufacturer, packager	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	14629/1 28.02.2020
7	Tiregis D	telmisartan, hydrochlorothiazide	tablets	80mg+12,5mg; (28/2x14/) blisters, (56/4x14/) blisters	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120-batch releaser, Actavis Ltd., BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta-bulk manufacturer, packager	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	14630/1 28.02.2020
8	Tiregis D	telmisartan, hydrochlorothiazide	tablets	80mg+25mg; (28/2x14/) blisters, (56/4x14/) blisters	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120-batch releaser, Actavis Ltd., BLB 016, Bulebel Industrial Estate, Zejtun, ZTN 3000, Malta-bulk manufacturer, packager	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	14631/1 28.02.2020

9	Enap-HL	enalapril (enalapril maleate), hydrochlorothiazide	tablets	10mg+12,5mg; (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	16395/1 28.02.2020
10	Levo-Denk 500	levofloxacin (levofloxacin hemihydrate)	tablets film-coated	500mg; (10/1x10/) in blister	Rottendorf Pharma GmbH, Ostfelder Strasse 51-61, 59320 Ennigerloh	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	R	17529/1 28.02.2020
11	Orgalutran	ganirelix (ganirelix acetate)	solution for s/c injection	0,25mg/0,5ml (0,5mg/ml); (5) pre-filled syringes 0,5ml	N.V. Organon, Molenstraat 110, 5342 CC OSS-secondary packager, batch releaser (legal address - N.V. Organon, Kloosterstraat 6, 5349 AB Oss, the Netherlands), Vetter Pharma-Fertigung GmbH & Co. KG, Schutzenstrasse 87 and 99/101, D-88212 Ravensburg, Germany-bulk manufacturer, primary packager	the Netherlands	Schering-Plough Central East AG, Weyrstrasse 20, 6000 Lucerne 6	Switzerland	R	14458/3 28.02.2020

12	Orgalutran	ganirelix (ganirelix acetate)	solution for s/c injection	0,25mg/0,5ml; (5) pre-filled syringes 0,5ml	N.V. Organon, Kloosterstraat 6, 5349 AB Oss- batch releaser, secondary packager, Vetter Pharma-Fertigung GmbH & Co. KG, Schutzenstrasse 87 and 99/101, D-88212 Ravensburg, Germany- bulk manufacturer, primary packager, quality control	the Netherlands	Schering-Plough Central East AG, Weystrasse 20, CH 6000 Lucerne 6	Switzerland	R	18830/2 28.02.2020
13	Izigel M	ibuprofen, levomenthol	gel for external use	50mg/g;+30mg/g; aluminium tube 40g	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	GM Pharmaceuticals Ltd, Phonichala 65	Georgia	OTC	18813/1 28.02.2020
14	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	16289/2 28.02.2020
15	Emanera	esomeprazole (esomeprazole magnesium)	capsules gastro-resistant	20mg; (7/1x7/) blister, (14/2x7/) blisters, (15/3x5/) blisters, (28/4x7/) blisters, (30/3x10/) blisters, (56/8x7/) blisters, (60/6x10/) 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	14184/1 28.02.2020



16	Emanera	esomeprazole (esomeprazole magnesium)	capsules gastro-resistant	40mg; (7/1x7/) blister, (14/2x7/) blisters, (15/3x5/) blisters, (28/4x7/) blisters, (30/3x10/) blisters, (56/8x7/) blisters, (60/6x10/) 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	14185/1 28.02.2020
17	Chondroxide	chondroitin sulfate (chondroitin sulfate sodium)	ointment for external use	50mg/g; 30g aluminium or plastic tube	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	18230/2 28.02.2020
18	Trachisan Lozenges	lidocaine (lidocaine hydrochloride), chlorhexidine (chlorhexidine digluconate), tyrothricin	lozenges	1mg+1mg+0.5mg; (20/2x10/) in blister	Engelhard Arzneimittel GmbH & Co. KG, Herzbergstrasse 3, 61138 Niederdorfelden	Germany	Engelhard Arzneimittel GmbH & Co. KG, Herzbergstrasse 3, 61138 Niederdorfelden	Germany	OTC	15619/1 28.02.2020
19	Clopi-Denk 75	clopidogrel (clopidogrel besylate)	tablets film-coated	75mg; (30/3x10/) blisters	Artesan Pharma GmbH & Co. KG, Wendlandstrasse 1, 29439 Luechow	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	14053/1 28.02.2020
20	Airtal	aceclofenac	tablets film-coated	100mg; (20/2x10/) blisters, (60/6x10/) blisters	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest, Hungary	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest, Hungary	Hungary	R	14086/2 28.02.2020

21	Diclac 75mg/3ml	diclofenac (diclofenac sodium)	solution for injection	75mg/3ml; (5) ampoules 3ml, (10) ampoules 3ml	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	R	15834/1 28.02.2020
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	19027/1 28.02.2020
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	19028/1 28.02.2020
24	Advagraf	tacrolimus	capsules prolonged-release	3mg; (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	17388/2 28.02.2020
25	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	19029/1 28.02.2020

26	Soluferr	iron (III)-hydroxide sucrose complex	solution for i/v injection	20mg/ml; (5) ampoules 5ml	Help S.A. Pedini, Ioanninon, Ioannina, 45500	Greece	Moosmann Pharmaceuticals LLC, Vanahovit 8, Proshyan v., Ashtarak Ave., Kotayk Marz 2413	Republic of Armenia	R	14210/2 28.02.2020
27	Aminosol-Neo	L-isoleucine, L-leucine, L-valine, L-lysine (L-lysine monoacetate), L-methionine, L-threonine, L-phenylalanine, L-alanine, L-arginine, glicine, L-histidine, L-proline, L-serine, L-tyrosine, taurine, L-tryptophan	solution for infusion	5mg/ml+7.4mg/ml+6.2mg/ml+6.6mg/ml+4.3mg/ml+4.4mg/ml+5.1mg/ml+14mg/ml+12mg/ml+11mg/ml+3mg/ml+11.2mg/ml+6.5mg/ml+0.4mg/ml+1mg/ml+2mg/ml; 500ml glass vial	Hemofarm A.D. 26300, Vrsac, Beogradskii put bb-batch releaser, Hemomont d.o.o., 81000,Podgorica, Ilije Plamenca str. bb, Montenegro-bulk manufacturere, packager	Serbia	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	R	16259/1 28.02.2020
28	Predizin	trimetazidine (trimetazidine dihydrochloride)	tablets prolonged-release film-coated	35mg; (60/6x10/) blisters	Gedeon Richter Poland Sp.z o.o., ul. Ks. J. Poniatowskiego 5 , Grodzisk Mazowiecki, 05-825 - batch releaser Gedeon Richter Poland Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager)	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	14457/1 28.02.2020
29	Norcolut	norethisterone	tablets	5mg; (20/2x10/) in blister	Gedeon Richter OJSC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter OJSC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	15064/2 28.02.2020

30	Egilok	metoprolol (metoprolol tartrate)	tablets	25mg; (60) in glass container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65 -batch releaser, packager, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary-bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	R	18268/1 28.02.2020
31	Egilok	metoprolol (metoprolol tartrate)	tablets	50mg; (60) in glass container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65 -batch releaser, packager, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary-bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	R	18269/1 28.02.2020
32	Egilok	metoprolol (metoprolol tartrate)	tablets	100mg; (30) in glass container, (60) in glass container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65 -batch releaser, packager, Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120, Hungary-bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	R	18270/1 28.02.2020
33	Dopegyt	methyldopa (methyldopa sesquihydrate)	tablets	250mg; (50) in glass container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	R	15403/2 28.02.2020

34	Halothane	halothane	liquid for inhalation	100%; 250ml glass bottle	Piramal Enterprises Limited, Sy.No.7-70, 70/1 & 70/2, Digwal Village, Kohir Mandal, Sangareddy District - 502 321, Telangana	India	Piramal Enterprises Limited, Piramal Towers, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400013	India	R	16775/1 28.02.2020
35	Herbion Iceland moss syrup	iceland moss thick extract	syrup	6mg/ml; 150ml glass bottle and measuring spoon	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	15784/1 28.02.2020
36	Herbion cowslip syrup	liquid aqueous cowslip root extract, liquid aqueous garden thyme herb extract	syrup	1030mg/5ml+2060mg/5ml; 150ml glass bottle and measuring spoon	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto-batch releaser, KRKA, tovarna zdravil, d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia-bulk manufacturer, packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	16498/1 28.02.2020
37	Valsacor	valsartan	tablets film-coated	80mg; (28/4x7/), 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	14916/1 28.02.2020
38	Valsacor	valsartan	tablets film-coated	160mg; (28/4x7/), 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	14917/1 28.02.2020

39	Enap	enalapril (enalapril maleate)	tablets	5mg; (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	16392/1 28.02.2020
40	Enap	enalapril (enalapril maleate)	tablets	10mg; (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	16394/1 28.02.2020
41	Enap	enalapril (enalapril maleate)	tablets	20mg; (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	16393/1 28.02.2020
42	Roxera	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (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	18128/1 28.02.2020
43	Panzynorm 10000	pancreatin (lipase, amylase, protease)	capsules hard gastro-resistant	10000U+7200U+400U (21/3x7/), 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	OTC	14914/1 28.02.2020

44	MabThera	rituximab	concentrate for solution for infusion	100mg/10ml; (2) glass vials 10ml	F. Hoffmann-La Roche Ltd., Wurmisweg CH-4303 Kaiseraugst-secondary packager, batch releaser, Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim, Germany-bulk manufacturer, primary packager, quality control	Switzerland	F. Hoffmann La Roche Ltd., Grenzacherstrasse 124 Basel	Switzerland	R	18901/1 28.02.2020
45	Auxilen	dexketoprofen (dexketoprofen trometamol)	solution for injection/infusion	50mg/2ml; (5/1x5/) ampoules 2ml 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, packager, quality control	Latvia	Kalceks JSC, 53 Krustpils Street, Riga, LV-1057	Latvia	R	18965/1 28.02.2020
46	Feiba 25U/ml	factor VIII inhibitor bypassing activity	powder and solvent for solution for infusion	500U (25U/ml); (1) glass vial with powder, (1) glass vial with 20 ml solvent, (1) BaxJect ii Hi-Flow, (1) disposable syringe, (1) disposable needle, (1) butterfly needle with clamp	Baxter AG, Industriestrasse 67, A-1221 Vienna	Austria	Baxalta Innovations GmbH, Industriestrasse 67, A-1221 Vienna	Austria	R	16611/2 28.02.2020

47	Feiba 50U/ml	factor VIII inhibitor bypassing activity	powder and solvent for solution for infusion	1000U (50U/ml); (1) glass vial with powder, (1) glass vial with 20 ml solvent, (1) BaxJect ii Hi-Flow, (1) disposable syringe, (1) disposable needle, (1) butterfly needle with clamp	Baxter AG, Industriestrasse 67, A-1221 Vienna	Austria	Baxalta Innovations GmbH, Industriestrasse 67, A-1221 Vienna	Austria	R	16612/2 28.02.2020
48	Apidra	insulin glulisine	solution for s/c injection	100U/ml; (5) Solostar pre-filled pens 3ml	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	18560/1 28.02.2020
49	Aerius	desloratadine	syrup	0,5mg/ml; bottle 60ml and measuring spoon, bottle 120ml and measuring spoon	Schering-Plough Labo N.V., Industriepark 30 B-2220, Heist-op-den-Berg	Belgium	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	R	13975/4 28.02.2020