

**LIST**

of the medicines recommended for the registration by the Center according to the meeting decision N 11-1/20 on November 13, 2020

President \_\_\_\_\_ E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Evoloxa	zoledronic acid (zoledronic acid monohydrate)	powder lyophilized for solution for infusion	4mg; (1) glass vial 5ml	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111- batch releaser, Kwality Pharmaceuticals Ltd , Plot No. 1-A Industrial Area, Raja Ka Bagh, Tehsil Nurpur, district Kangra, Himachal Pradesh, India- bulk manufacturer, packager, quality control	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	R	19473 13.11.2020
2	Loranex	desloratadine	tablets coated	5mg; (10/1x10/) in blister	GM Pharmaceuticals Ltd, 65, Qyemo Phonichala str., 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, 65, Qyemo Phonichala str., 0165 Tbilisi	Georgia	R	19474 13.11.2020
3	Brufen Rapid	ibuprofen	capsules soft	200mg; (20/2x10/) in blister	Geltec Private Limited, No. 24, 26/3, 27/2, Yadavanahalli, Attibele, Bangalore-Hosur Road, Bangalore- 562107, Karnataka	India	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	OTC	19475 13.11.2020

4	Brufen Rapid	ibuprofen	capsule soft	400mg; 20(2x10) in blister	Geltec Private Limited, No. 24, 26/3, 27/2, Yadavanahalli, Attibele, Bangalore-Hosur Road, Bangalore- 562107, Karnataka	India	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	OTC	19476 13.11.2020
5	Nalgesin	naproxen (naproxen sodium)	tablets film-coated	220mg; (10/1x10/) in blister, (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	OTC	19477 13.11.2020
6	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/) in blister	Rowa Pharmaceuticals Ltd., Newtown, Bantry, Cork- quality control (physicochemical), batch releaser, SwissCaps Romania SRL, No. 20 Carol I Street, Comuna Cornu, Jud. Prahova 107180, Romania- bulk manufacturer, Sharp Clinical Services (UK) Limited, Unit 28, Heads of the Valley Industrial Estate, Rhymney, Tredegar, NP22 5RL, UK- primary packager, Norfachema UAB, Vytauto g. 6, LT-55175 Jonava, Lithuania- secondary packager, Eurofins Biopharma Product Testing Ireland Limited, Clogherane, Dungarvan, Co. Waterford, Ireland- quality control (microbiological)	Ireland	Rowa Pharmaceuticals Ltd., Newtown, Bantry, Cork	Ireland	R	19478 13.11.2020

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 11-1/20 on November 13, 2020

President \_\_\_\_\_ E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Metoprolol	metoprolol (metoprolol tartrate)	tablets	50mg; (30/3x10/) in blister	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	19486 13.11.2020
2	Adipin	amlodipine (amlodipine besilate)	tablets film-coated	5mg; (30/3x10/) in blister	GM Pharmaceuticals Ltd, 65, Qvemo Phonichala str., 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, 65, Qvemo Phonichala str., 0165 Tbilisi	Georgia	R	19487 13.11.2020
3	Adipin	amlodipine (amlodipine besilate)	tablets film-coated	10mg; (30/3x10/) in blister	GM Pharmaceuticals Ltd, 65, Qvemo Phonichala str., 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, 65, Qvemo Phonichala str., 0165 Tbilisi	Georgia	R	19488 13.11.2020
4	Artrum	ketoprofen	gel for external use	25mg/g; 50g aluminium tube	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	R	19489 13.11.2020

5	Artrum	ketoprofen	gel for external use	50mg/g; 50g aluminium tube	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	R	19490 13.11.2020
6	Polvertic	betahistine (betahistine dihydrochloride)	tablets	24mg; (20/2x10/) in blister, (30/3x10/) in blister, (40/4x10/) in blister, (50/5x10/) in blister, (60/6x10/) in blister, (100/10x10/) in blister	Medana Pharma JSC, 98-200 Sieradz, W. Lokietka 10- batch releaser, Catalent Germany Schorndorf GmbH, Steinbeisstrasse Iund 2, 73614, Schorndorf, Germany- bulk manufacturer, Medana Pharma JSC, str. Polskiej Organizacji Wojskowej 57, 98-200 Sieradz, Poland- packager, quality control	Poland	Medana Pharma S.A., 98-200 Sieradz, W. Lokietka 10	Poland	R	19491 13.11.2020
7	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- packager, quality control, batch releaser, 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	19492 13.11.2020

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 11-1/20 on November 13, 2020

President \_\_\_\_\_ E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Fenistil New	dimetindene (dimetindene maleate)	drops oral (solution)	1mg/ml; glass bottle 20ml	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	18328/1/1 13.11.2020
2	Concor	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (30/3x10/) in blister, (30/1x30/) in blister, (50/5x10/) in blister, (50/2x25/) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, 35 Valovaya Street, Moscow 115054	Russia	R	18384/1/2 13.11.2020
3	Concor	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg; (30/3x10/) in blister, (30/1x30/) in blister, (50/5x10/) in blister, (50/2x25/) in blister	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt	Germany	Merck LLC, 35 Valovaya Street, Moscow 115054	Russia	R	18385/1/2 13.11.2020

4	Antilice	pyrethrins (permethrin+tetramethrin), piperonyl butoxide	shampoo	1,65mg/ml+16,5mg/ml; plastic bottle 90ml	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	18682/2/1 13.11.2020
5	Flixotide 50 micrograms Evohaler	fluticasone (fluticasone propionate)	suspension, pressurised inhalation	50mcg/dose; inhaler in aluminium container (120 doses)	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos	Spain	Glaxo Wellcome UK Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	17551/1/1 13.11.2020
6	Flixotide 125 micrograms Evohaler	fluticasone (fluticasone propionate)	suspension, pressurised inhalation	125mcg/dose; inhaler in aluminium container (120 doses)	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos	Spain	Glaxo Wellcome UK Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	17552/1/1 13.11.2020

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision 11-1/20 on November 13, 2020

President \_\_\_\_\_ E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Spazmaton	metamizole (metamizole sodium), pitofenone (pitofenone hydrochloride), fempiverinium bromide	tablets	500mg+5mg+0,1mg; (20/2x10/), in blister, (50/5x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov" 64, Chapaev str., Borisov 222518, Minsk region	Belarus	OTC	14973/1 13.11.2020
2	Aquavit-D3	colecalfiferol	solution oral	375 mkg/ml(15000 IU/ml); glass vial-dropper 10ml	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PJSC "Technolog", 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	R	14797/2 13.11.2020
3	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	19118/1 13.11.2020

4	Letrozole Denk 2.5	letrozole	tablets film-coated	2,5mg; (30/3x10/) in blister	Haupt Pharma Munster GmbH, Schleebruggenkamp 15, 48159 Munster	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	R	15773/2 13.11.2020
5	Coldrex HotRem	paracetamol, phenylephrine (phenylephrine hydrochloride), ascorbic acid	powder for oral solution with honey and lemon flavour	750mg+10mg+60mg; (10) sachets 5g	SmithKline Beecham S.A. Ctra. de Ajalvir, KM-2500-28806, Alcala de Henares, Madrid	Spain	GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	OTC	15357/2 13.11.2020
6	Eneas	enalapril (enalapril maleate), nitrendipine	tablets	10mg+20mg; (30/3x10/) in blister	Ferrer International, S.A., Joan Buscalla,1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer International, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	R	16256/1 13.11.2020
7	Spasmovax ORO	phloroglucinol (phloroglucinol dihydrate), 1,3,5-trimethoxybenzene	tablets	80mg+80mg; (20/2x10/) in blister	Doppel Farmaceutici S.r.l., Via Volturno 48, Quinto De` Stampi, 20089 Rozzano (MI)	Italy	SCHARPER S.p.A., Viale Ortles 12, 20139 Milan	Italy	R	17008/3 13.11.2020
8	Spasmovax	phloroglucinol	solution for i/m and i/v injection	10mg/ml; (10) ampoules 4ml	Doppel Farmaceutici S.r.l., Via Volturno 48, Quinto De Stampi, 20089 Rozzano (MI)	Italy	SCHARPER S.p.A., Viale Ortles 12, 20139 Milan	Italy	R	16373/3 13.11.2020



9	Metoprolol	metoprolol (metoprolol tartrate)	tablets	50mg; (30/3x10/) in blister	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	14885/1 13.11.2020
10	Inestom	levocarnitine	solution oral	100mg/ml; (10) glass vial 10ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorphosis, Attica	Greece	R	16829/1 13.11.2020
11	Inestom	levocarnitine	solution for injection	200mg/ml; (5) ampoules 5ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorphosis, Attica	Greece	R	16830/1 13.11.2020
12	Artrum	ketoprofen	gel for external use	25mg/g; 50g aluminium tube	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	R	14845/2/2 13.11.2020
13	Artrum	ketoprofen	gel for external use	50mg/g; 50g aluminium tube	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	Biosintez PJSC, Druzhby st. 4, 440033, Penza	Russia	R	14846/2/2 13.11.2020
14	Avelox	moxifloxacin	tablets coated	400mg; (5/1x5/) in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen, Germany	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	R	16379/2 13.11.2020

15	Amoxicillin	amoxicillin (amoxicillin trihydrate)	tablets dispersible	250mg; (20/2x10/) and (100/10x10/) in blister	Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl	Austria	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	R	17676/1 13.11.2020
16	Dramina	dimenhydrinate	tablets	50mg; (5/1x5/), (10/1x10/) in blister	JADRAN-GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	JADRAN-GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	OTC	17101/1 13.11.2020
17	Rolenium	fluticasone (fluticasone propionate), salmeterol (salmeterol xinafoate)	powder inhalation, pre-dispensed	100mcg/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	19159/1 13.11.2020
18	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	19050/1 13.11.2020
19	Rolenium	, fluticasone (fluticasone propionate), salmeterol (salmeterol xinafoate)	powder 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	19051/1 13.11.2020

20	Multi-tabs Kid	vitamin A, vitamin D3, vitamin E, vitamin B1, vitamin B2, vitamin B6, vitamin B12, nicotinamide, pantothenic acid, folic acid hydrate, vitamin C, iron, zinc, copper, manganese, chromium, selenium, iodine	tablets chewable raspberry-strawberry	400mcg+10mcg+5mg+0.7mg+0.8mg+0.9mg+1mcg+9mg+3mg+20mcg+40mg+10mg+5mg+1mg+1mg+20mcg+25mcg+70mcg; (30/3x10/) and (60/6x10/) in blister	Pfizer Consumer Manufacturing Italy S.R.L., Via Nettunense, 90, Aprilia, 04011	Italy	Pfizer Innovations LLC, Presnenskaya nab., building 10, Moscow, 123112	Russia	OTC	17376/3/2 13.11.2020
21	Meropenem-Asteria	meropenem	powder for solution for i/v injection/infusion	500mg; (1), (5), (10) glass vials	Hankook Korus Pharm Co., Ltd, 78 Daepungsandan-ro, Daeso-myeon, Eumseong-gun, Chungcheongbuk-do	Korea South	Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan	Republic of Armenia	R	15178/2/1 13.11.2020
22	Clotrimazole	clotrimazole	tablets vaginal	100mg; (6/1x6/), in blister	GlaxoSmithKline Pharmaceuticals S.A., 189 Grunwaldzka street, 60-322 Poznan	Poland	GlaxoSmithKline Pharmaceuticals S.A., 189 Grunwaldzka street, 60-322 Poznan	Poland	R	15051/2 13.11.2020
23	Captopril+HCT Denk 50/25	captopril, hydrochlorothiazide	tablets	50mg+25mg; (30/3x10/) and (100/10x10/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	17814/3 13.11.2020

24	Bridion	sugammadex (sugammadex sodium)	solution for i/v injection	100mg/ml; (10) glass vial 2ml	N.V. Organon, Molenstraat 110, 5342 CC Oss- batch releaser, secondary packager, Patheon Manufacturing Services LLC, 5900 Martin Luther King Jr. Highway, Greenville, North Carolina 27834, USA- bulk manufacturer, primary packager	the Netherlands	Schering-Plough Central East AG, Weyrstrasse 20, 6000 Lucerne 6	Switzerland	R	17793/1 13.11.2020
25	Liprimar	atorvastatin (atorvastatin calcium)	tablets film-coated	10mg; (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	17334/2 13.11.2020
26	Liprimar	atorvastatin (atorvastatin calcium)	tablets film-coated	20mg; (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	17332/2 13.11.2020

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	17333/2 13.11.2020
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	17331/2 13.11.2020
29	Ketonal 50mg capsules	ketoprofen	capsules	50mg; (25) glass container	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	R	18826/2 13.11.2020

30	Kisqali	ribociclib(ribociclib succinate)	tablets film-coated	200mg; (21/1x21/) in blister, (63/3x21/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr -batch releaser, packager, Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd., 10 Tuas Bay Lane, 637461 Singapore, Singapore-bulk manufacturer	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	18535/3 13.11.2020
31	Dicetel	pinaverium (pinaverium bromide)	tablets film-coated	50mg; (20/1x20/), in blister	Abbott Healthcare SAS, Route de Belleville, Lieu dit Maillard, 01400 Chatillon sur Chalaronne	France	Abbott Products SAS, 42 rue Rouget de Lisle, 92150 Suresnes	France	R	15013/1 13.11.2020
32	Dicetel	pinaverium (pinaverium bromide)	tablets film-coated	100mg; (30/2x15/), in blister	Abbott Healthcare SAS, Route de Belleville, Lieu dit Maillard, 01400 Chatillon sur Chalaronne	France	Abbott Products SAS, 42 rue Rouget de Lisle, 92150 Suresnes	France	R	15012/1 13.11.2020
33	Adipin	amlodipine (amlodipine besilate)	tablets film-coated	5mg; (30/3x10/), in blister	GM Pharmaceuticals Ltd, PSP group 65, Qyemo Phonichala str., Tbilisi	Georgia	GM Pharmaceuticals Ltd, PSP group 65, Qyemo Phonichala str., Tbilisi	Georgia	R	15305/1 13.11.2020
34	Adipin	amlodipine (amlodipine besilate)	tablets film-coated	10mg; (30/3x10/), in blister	GM Pharmaceuticals Ltd, PSP group 65, Qyemo Phonichala str., Tbilisi	Georgia	GM Pharmaceuticals Ltd, PSP group 65, Qyemo Phonichala str., Tbilisi	Georgia	R	15306/1 13.11.2020

35	Bilobil forte	ginkgo biloba dry extract	capsules	80mg; (20/2x10/) in blister, (60/6x10/) 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	15631/1 13.11.2020
36	Controloc	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	40mg; (14/1x14/) in blister, (28/2x14/) in blister	Takeda GmbH, Lehnitz str. 70-98, 16515 Oranienburg	Germany	Takeda GmbH, Byk-Gulden str. 2, D-78467, Konstanz	Germany	R	18685/1 13.11.2020
37	Cardiomagnyl	acetylsalicylic acid, magnesium hydroxide	tablets film-coated	75mg+15.2mg; (30) and (100) in glass container	Takeda GmbH, Lehnitzstrasse 70-98, Oranienburg 16515	Germany	Takeda Pharmaceuticals LLC, Usatchva str. 2, bld. 1, Moscow 119048	Russia	OTC	17292/1 13.11.2020
38	Cardiomagnyl	acetylsalicylic acid, magnesium hydroxide	tablets film-coated	150mg+30,39mg; (30) and (100) in glass container	Takeda GmbH, Lehnitzstrasse 70-98, Oranienburg 16515	Germany	Takeda Pharmaceuticals LLC, Usatchva str. 2, bld. 1, Moscow 119048	Russia	OTC	17291/1 13.11.2020
39	Xefocam	lornoxicam	powder lyophilized for solution for i/v and i/m injection	8mg; (5) glass vial	Takeda Austria GmbH, St. Peter Strasse 25, A-4020 Linz - batch releaser, packager, Wasserburger Arzneimittelwerk GmbH, Herderstrasse 2, D-83512 Wasserburg, Germany - bulk manufacturer	Austria	Takeda Austria GmbH, St. Peter Strasse 25, A-4020 Linz	Austria	R	17046/1 13.11.2020

40	Betaderm	betamethasone (betamethasone dipropionate), gentamicin (gentamicin sulfate)	ointment for external use	0,5mg/g+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	14918/1 13.11.2020
41	Teotard	theophylline	capsules modified-release	200mg; (40/4x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto-batch releaser, packager, Temmler Ireland Limited, Killorglin, County, Kerry, Ireland-bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	16544/1 13.11.2020
42	Teotard	theophylline	capsules modified-release	350mg; (40/4x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto-batch releaser, packager, Temmler Ireland Limited, Killorglin, County, Kerry, Ireland-bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	16545/1 13.11.2020
43	Somazina	citicoline (citicoline sodium)	solution for injection	250mg/ml; (5/1x5/) ampoules 4ml in blister	Ferrer International, S.A., Joan Buscalla,1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer International, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	R	19328/1 13.11.2020
44	Xarelto	rivaroxaban	tablets film-coated	15mg; (28/2x14/), in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	R	17615/1/2 13.11.2020



45	Xarelto	rivaroxaban	tablets film-coated	20mg; (28/2x14/), in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	R	17614/1/2 13.11.2020
46	Myfortic	mycophenolic acid (mycophenolate sodium)	tablets gastro-resistant	180mg; (120/12x10/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	16977/3 13.11.2020
47	Myfortic	mycophenolic acid (mycophenolate sodium)	tablets gastro-resistant	180mg; (120/12x10/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	R	18043/2 13.11.2020
48	Herbion plantain syrup	liquid aqueous extract of the narrowleaf plantain leaves, liquid aqueous extract of the common mallow flower, ascorbic acid	syrup	1250mg/5ml+1250mg/5ml+65mg/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	16497/2 13.11.2020
49	Nebilet Plus 5/12.5	nebivolol (nebivolol hydrochloride), hydrochlorothiazide	tablets film-coated	5mg+12,5mg; (28/2x14/) in blister	Berlin-Chemie A.G., Glienicker Weg 125, D-12489 Berlin-batch releaser, packager, Berlin-Chemie A.G., Tempelhofer Weg 83, D-12347 Berlin, Germany-bulk manufacturer for Menarini International Operations Luxembourg S.A., 1, avenue de la Gare, 1611, Luxembourg	Germany			R	16257/1 13.11.2020

50	Nebilet Plus 5/25	nebivolol (nebivolol hydrochloride), hydrochlorothiazide	tablets film-coated	5mg+25mg; (28/2x14/) in blister	Berlin-Chemie A.G., Glienicke Weg 125, D-12489 Berlin-batch releaser, packager, Berlin-Chemie A.G., Tempelhofer Weg 83, D-12347 Berlin, Germany-bulk manufacturer	Germany	Menarini International Operations Luxembourg S.A., 1, avenue de la Gare, 1611	Luxembourg	R	16258/1 13.11.2020
51	Diprosalic	betamethasone (betamethasone dipropionate), salicylic acid	lotion	0,5mg/g+20mg/g; 30ml plastic container-dropper	Cenexi HSC, 2 Rue Louis Pasteur, 14200 Herouville Saint-Clair	France	Schering-Plough Central East AG, Weyrstrasse 20, P.O. Box CH-6000 Lucerne 6	Switzerland	R	18902/1 13.11.2020
52	Herceptin	trastuzumab	powder for concentrate for solution for infusion	440mg; (1) glass vial and solvent in vial 20ml	F. Hoffmann-La Roche AG Wurmisweg, Kaiseraugst, 4303- secondary packager, quality control, batch releaser, Genentech Inc., DNA Way 1, South San Francisco, CA 94080, USA-bulk manufacturer, primary packager, F. Hoffmann-La Roche AG, Wurmisweg, Kaiseraugst, 4303, Switzerland-solvent manufacturer	Switzerland	F. Hoffmann-La Roche Ltd., Grenzachstrasse, 124, CH-4070, Basel	Switzerland	R	18964/2 13.11.2020
53	Herceptin	trastuzumab	solution for s/c injection	600mg/5ml; glass vial 6ml	F. Hoffmann-La Roche Ltd., 4303 Kaiseraugst	Switzerland	F. Hoffmann-La Roche Ltd., Grenzachstrasse, 124, CH-4070, Basel	Switzerland	R	18186/2 13.11.2020

54	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	19063/1 13.11.2020
55	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	19064/1 13.11.2020
56	Combilipen	thiamine (thiamine hydrochloride), pyridoxine (pyridoxine hydrochloride), cyanocobalamin, lidocaine (lidocaine hydrochloride)	solution for i/m injection	50mg/ml+50mg/ml+0, 5mg/ml+10mg/ml; (5/1x5/) ampoules 2ml, blisters, (10/2x5/) ampoules 2ml, blisters	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	Pharmstandard-UfaVITA OJSC, 450077, Ufa, str. Khudaiberdina 28	Russia	R	14651/1 13.11.2020
57	Depakine enteric 300	valproate sodium (valproic acid)	tablets gastro-resistant	300mg; (100/10x10/) in blister	Sanofi-Aventis S.A., Ctra. C35 La Batlloria a Hostalric, km 63.09,17404 Riells I Viabrea (Girona)	Spain	Sanofi Winthrop Industrie, 1, rue de la Vierge-Ambares et Lagreve, 33565 Carbon Blanc-Cedex	France	R	15910/1 13.11.2020