

Rejection for registration (2021)

N	Date	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
1	17.03.2021	Lusefi	luseogliflozin	tablets film-coated	2,5mg; (100/10x10/) in blister	Taisho Pharmaceutical Co., Ltd. Omiya Factory, 403, Yoshinocho 1-chome, Kita-ku, Saitama-shi, Saitama, 331-9520	Japan	Servier JSC, 125196, 7/8/9, Lesnaya str., 7, Moscow	Russia	R
2	17.03.2021	Lusefi	luseogliflozin	tablets film-coated	5mg; (100/10x10/) in blister	Taisho Pharmaceutical Co., Ltd. Omiya Factory, 403, Yoshinocho 1-chome, Kita-ku, Saitama-shi, Saitama, 331-9520	Japan	Servier JSC, 125196, 7/8/9, Lesnaya str., 7, Moscow	Russia	R
3	17.03.2021	Leva-200 WS	levamisole (levamisole hydrochloride)	powder for oral solution	200mg/g; plastic container 1000g	Interchemie werken 'De Adelaar' B.V., Metaalweg 8, 5804 CG Venray	the Netherlands	Interchemie werken 'De Adelaar' B.V., Metaalweg 8, 5804 CG Venray	the Netherlands	R
4	17.03.2021	Glucantime 1,5g/5ml	meglumine antimoniate	solution for injection	300mg/ml; (5) ampoules 5ml	Haupt Pharma Livron 1 rue Comte de Sinard 26250 Livron Sur Drome	France	Sanofi-Aventis France, 82 avenue Raspail, 94250 Gentilly	France	R
5	17.03.2021	Orsoten	orlistat	capsules	120mg; (21/3x7/) in blister, (21/1x21/) in blister, (42/6x7/) in blister, (42/2x21/) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R

6	18.03.2021	Insty Max	salix alba, phyllanthus emblica, glycyrrhiza glabra, adhatoda vasica, sisymbrium irio, viola odorata, thea sinensis, valeriana officinalis, achillea millefolium, foeniculum vulgare, vitus vanifera	granules	750mg+400mg+400mg+300mg+165mg+100mg+100mg+100mg+100mg+75mg+50mg; (5) sachets 5,6g, (10) sachets 5,6g	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	OTC
7	18.03.2021	Galantamine Pharmathen 8mg prolonged-release capsules hard	galantamine (galantamine hydrobromide)	capsules prolonged-release, hard	8mg; (28/2x14/) in blister	Pharmathen International S.A., Industrial Park Sapes, Rodopi Prefecture, Block No 5, Rodopi 69300	Greece	Pharmathen S.A., Dervenakion 6, 15351 Pallini, Attiki	Greece	R
8	18.03.2021	Galantamine Pharmathen 16mg prolonged-release capsules hard	galantamine (galantamine hydrobromide)	capsules prolonged-release, hard	16mg; (28/2x14/) in blister	Pharmathen International S.A., Industrial Park Sapes, Rodopi Prefecture, Block No 5, Rodopi 69300	Greece	Pharmathen S.A., Dervenakion 6, 15351 Pallini, Attiki	Greece	R
9	23.04.2021	Novex Ibuprofen	ibuprofen	suspension oral	20mg/ml; glass bottle 120ml	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	OTC
10	28.04.2021	Elmucin	erdosteine	capsules	300mg; (20/2x10/) in blister	Obolenskoye PhC JSC, No:39, build. 1, Obolensk, Serpukhov district, 142279 Moscow region	Russia	Obolenskoye PhC JSC, No:39, build. 1, Obolensk, Serpukhov district, 142279 Moscow region	Russia	PoM

11	28.04.2021	Novex Paracetamol	paracetamol	suspension oral with strawberry flavour	120mg/5ml; glass bottle 120ml	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	OTC
12	21.04.2021	Pentalgin-ICN	metamizole (metamizole sodium), paracetamol, caffeine, phenobarbital, codeine (codeine phosphate)	tablets	300mg+300mg+50mg+10mg+8mg; (12/1x12/) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	PoM
13	18.05.2021	Proteflazid	proteflazid	suppositories vaginal	1,8mg; (10/2x5/)	SMCECOPHARM" LTD,116, Shevchenko str., Ulashanivka village, Shepetivsky district, Khmelnytsky region, 30070	Ukraine	"SMC"ECOPHARM" LTD, 19 (Building), Obolonska Naberezhna Str., Kyiv, 04210	Ukraine	PoM
14	18.05.2021	Phleboton	diosmin	tablets film-coated	1000mg; (30/1x30) in blister	P.P.F. "Hasco-Lek" S.A., ul. Zmigrodzka 242 E, 51-131 Wroclaw	Poland	P.P.F. "Hasco-Lek" S.A., ul. Zmigrodzka 242 E, 51-131 Wroclaw	Poland	PoM
15	26.06.2021	Atracurium Besylate 10mg/ml	atracurium (atracurium besylate)	solution for injection	25mg/2,5ml; (5) ampoules 3ml	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111- batch releaser, Kvality 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	PoM

16	26.06.2021	Atracurium Besylate 10mg/ml	atracurium (atracurium besylate)	solution for injection	50mg/5ml; (5) ampoules 5ml	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111- batch releaser, Kwalitiy 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	PoM
17	22.07.2021	Ingavirin (new indication)	pentanedioic acid (pentanedioic acid imidazolyl ethanamide)	capsules	90mg; (7/1x7/) in blister	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC
18	30.07.2021	Ingavirin	pentanedioic acid (pentanedioic acid imidazolyl ethanamide)	capsules	90mg; (7/1x7/) in blister, (10/1x10/) in blister	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC
19	20.08.2021	Trachisan	lidocaine hydrochloride, chlorhexidine (chlorhexidine gluconate)	solution gargle	1mg/ml+2mg/ml; glass bottle 200ml	Engelhard Arzneimittel GmbH & Co. KG, Herzbergstrasse 3, 61138 Niederdorfelden, Hessen,	Germany	Engelhard Arzneimittel GmbH & Co. KG, Herzbergstrasse 3, 61138 Niederdorfelden, Hessen,	Germany	OTC
20	08.10.2021	Herbion Inhaler	menthol crystal, camphor, eucalyptus oil, clove oil	pencil Inhalation	500mg+280mg+550mg+330mg; 0,03ml plastic container 1,5g	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	Herbion Pakistan Pvt. Ltd., Plot No. 30 Sector 28 Korangi Industrial Area, Karachi	Pakistan	OTC

21	08.10.2021	Lisof	ledipasvir, sofosbuvir	tablets film-coatd	90mg+400mg; (28) in plastic container	M/s Hetero Labs Limited Unit-V, SY.NO.439, 440, 441 & 458, Tsiic Formulation Sez, Polepalle(V), Jadcherla(M), Mahabubnagar(Dist.), Telangana(State)	India	M/s. Hetero Labs Limited, Hetero corporate, 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad, Telangana	India	PoM
22	25.10.2021	OUTTERA	paclitaxel	concentrate for solution for infusion	6mg/ml; glass vial 5ml	PharmaTech CJSC, 111 Raffi str., 0064, Yerevan- batch releaser, Kwality Pharmaceuticals Ltd, 1-A, Industrial Area, Raja Ka Bagh, Tehsil Nurpur, Distt. Kangra (H.P.), India- bulk manufacturer, packager, quality control	Republic of Armenia	PharmaTech CJSC, 111 Raffi str., 0064, Yerevan	Republic of Armenia	PoM
23	25.10.2021	OUTTERA	paclitaxel	concentrate for solution for infusion	6mg/ml; glass vial16,7ml	PharmaTech CJSC, 111 Raffi str., 0064, Yerevan- batch releaser, Kwality Pharmaceuticals Ltd, 1-A, Industrial Area, Raja Ka Bagh, Tehsil Nurpur, Distt. Kangra (H.P.), India- bulk manufacturer, packager, quality control	Republic of Armenia	PharmaTech CJSC, 111 Raffi str., 0064, Yerevan	Republic of Armenia	PoM
24	25.10.2021	OUTTERA	paclitaxel	concentrate for solution for infusion	6mg/ml; glass vial 25ml	PharmaTech CJSC, 111 Raffi str., 0064, Yerevan- batch releaser, Kwality Pharmaceuticals Ltd, 1-A, Industrial Area, Raja Ka Bagh, Tehsil Nurpur, Distt. Kangra (H.P.), India- bulk manufacturer, packager, quality control	Republic of Armenia	PharmaTech CJSC, 111 Raffi str., 0064, Yerevan	Republic of Armenia	PoM

25	25.10.2021	OUTTERA	paclitaxel	concentrate for solution for infusion	6mg/ml; glass vial 43,4ml	PharmaTech CJSC, 111 Raffi str., 0064, Yerevan- batch releaser, Kwality Pharmaceuticals Ltd, 1-A, Industrial Area, Raja Ka Bagh, Tehsil Nurpur, Distt. Kangra (H.P.), India- bulk manufacturer, packager, quality control	Republic of Armenia	PharmaTech CJSC, 111 Raffi str., 0064, Yerevan	Republic of Armenia	PoM
26	25.10.2021	OUTTERA	paclitaxel	concentrate for solution for infusion	6mg/ml; glass vial 50ml	PharmaTech CJSC, 111 Raffi str., 0064, Yerevan- batch releaser, Kwality Pharmaceuticals Ltd, 1-A, Industrial Area, Raja Ka Bagh, Tehsil Nurpur, Distt. Kangra (H.P.), India- bulk manufacturer, packager, quality control	Republic of Armenia	PharmaTech CJSC, 111 Raffi str., 0064, Yerevan	Republic of Armenia	PoM
27	22.10.2021	RIGVIR	rigvir (ECHO-7 virus strain)	solution for injection	>10 ⁶ TCID50/ml; glass vial 2ml	AS Kevelt, Teaduspargi 3/1, Tallinn, EE-12618	Estonia	SIA Latima, Atlasa iela 7C, Riga, LV-1026	Latvia	PoM
28	03.11.2021	Theraflex	glucosamine (glucosamine hydrochloride), chondroitin sulfate (chondroitin sulfate sodium)	capsules	500mg+400mg; (60) in plastic container, (100) in plastic container, (200) in plastic container	Contract Pharmacal Corporation, 135 Adams avenue, Hauppauge, New York 11788	USA	JSC BAYER, 3rd Rybinskaya st., 18, build. 2, 107113 Moscow	Russia	OTC
29	03.11.2021	Extractum Aloes fluidum	aloe liquid extract	solution for i/m injection	360mg/ml; (10) ampoules 1ml	Yerevan Chemical-Pharmaceutical firm OJSC, Yerevan, Ajaryan street, 2 Line, No6	Republic of Armenia	Yerevan Chemical-Pharmaceutical firm OJSC, Yerevan, Ajaryan street, 2 Line, No6	Republic of Armenia	R

30	03.11.2021	Omarens T	tamsulosin (tamsulosin hydrochloride)	tablets prolonged-release	0,4mg; (30/3x10/) in blister	Synthon Hispania, S.L.,C/ Castello, N 1, Sant Boi de Llobregat, Barcelona, 08830	Spain	Spey Medical Ltd, Lynton house 7- 12 Tavistock square, London, WC1H9LT	UK	PoM
31	23.11.2021	Mucosat	chondroitin sulfate	solution for intramuscular and intra- articular injection	100mg/ml; (5/1x5/ ampoules of 2ml in blister, (10/2x5/) ampoules of 2ml in blister	Ellara LLC, bld. 2, 20 Frank Stollwerk str., Pokrov, Petushinskiy dist., 601122 Vladimir Region	Russia	Diamed-Pharma LLC, 31 Sovetskaya str., Pervomayski micdist.,141069, Korolyov, Moscow region	Russia	PoM
32	22.12.2021	Rilast	rituximab	solution for infusion	100mg/10ml; glass vial 10ml	M/s. Hetero Biopharma Limited, Sy.No. 458 (Part), TSIIC Formulation SEZ, Polepally Village, Jadcherla Mandal, Mahaboobnagar District-509 301, Telagana State	India	M/s. Hetero Biopharma Limited, Sy.No. 458 (Part), TSIIC Formulation SEZ, Polepally Village, Jadcherla Mandal, Mahaboobnagar District-509 301, Telagana State	India	PoM
33	22.12.2021	Rilast	rituximab	solution for infusion	500mg/50ml; glass vial 10ml	M/s. Hetero Biopharma Limited, Sy.No. 458 (Part), TSIIC Formulation SEZ, Polepally Village, Jadcherla Mandal, Mahaboobnagar District-509 301, Telagana State	India	M/s. Hetero Biopharma Limited, Sy.No. 458 (Part), TSIIC Formulation SEZ, Polepally Village, Jadcherla Mandal, Mahaboobnagar District-509 301, Telagana State	India	PoM

34	27.12.2021	Levo-Tech	levofloxacin (levofloxacin hemihydrate)	drops eye	5mg/ml; vial-droper 5ml	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111	Republic of Armenia	PoM
35	27.12.2021	Ibuprofen-Hemofarm	ibuprofen	tablets film-coated	400mg; (30/3x10/) in blister	Hemofarm A.D., Vrsac, Beogradskii put bb- packager, quality control, batch releaser, Hemofarm d.o.o., Banja-Luka, Novakovici bb, Bosnia and Herzegovina- bulk manufacturer	Serbia	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	OTC
36	23.11.2021	Moxiral	moxifloxacin (moxifloxacin hydrochloride)	tablets film-coated	400mg; (5/1x5/) in blister, (7/1x7/) in blister, (10/2x5/) 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	PoM
37	23.11.2021	Tyrez	bisoprolol (bisoprolol fumarate)	tablets film-coated	2,5mg; (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	PoM
38	23.11.2021	Tyrez	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (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	PoM
39	23.11.2021	Tyrez	bisoprolol (bisoprolol fumarate)	tablets film-coated	10mg; (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	PoM

40	23.11.2021	Lamal	lamotrigine	tablets	25mg; (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	PoM
41	23.11.2021	Lamal	lamotrigine	tablets	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	PoM
42	23.11.2021	Lamal	lamotrigine	tablets	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	PoM
43	23.11.2021	Lamal	lamotrigine	tablets	200mg; (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	PoM
44	23.11.2021	Skopryl	lisinopril (lisinopril dihydrate)	tablets	10mg; (30/3x10/) in blister, (90/9x10/) 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	PoM
45	23.11.2021	Skopryl	lisinopril (lisinopril dihydrate)	tablets	20mg; (30/3x10/) and (90/9x10/) 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	PoM

46	23.11.2021	Pancef	cefixime (cefixime trihydrate)	granules for oral suspension	100mg/5ml; 32g powder in glass bottle 60ml and measuring spoon 5ml, 53g powder in 100ml glass bottle and measuring spoon 5ml	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- quality control, batch releaser, Alkaloid AD Skopje, Blvd. Partizanski odredi 98A, 1000 Skopje, Republic of North Macedonia- bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM
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