

Rejection for registration (2020)

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	09.01.2020	Omeprazole-Agio	omeprazole	capsules	20mg; (100/10x10/) in blister	Agio Pharmaceuticals LTD, T-82, MIDC Bhosari, Pune - 411026, Maharashtra state	India	Agio Pharmaceuticals Limited, A-38, Nandjot Industrial Estate, Kurla-Andheri Road, Safedpool, Mumbai - 400 072	India	PoM
2	06.02.2020	Ibuprofen 400mg film-coated tablets	ibuprofen	tablets film-coated	400mg; (10/1x10/) in blister, (20/2x10/) in blister, (50/5x10/) in blister, (100/10x10/) in blister	S Kant Healthcare LTD, Plot 1802-1805, GIDC Phase III, Vapi -396 195	India	Troge Medical GmbH, Milchstrasse 19, 20148 Hamburg	Germany	PoM
3	25.03.2020	Doctor Cold	paracetamol, phenylephrine (phenylephrine hydrochloride), chlorpheniramine (chlorpheniramine maleate), caffeine	tablets	500mg+5mg+2mg+15mg; (4/1x4/) in blister	Akriti Pharmaceuticals Pvt. Ltd., Plot No. D-10, D-11, M.I.D.C. Indl. Estate, Nira Road, Jejuri, Tal. Purandar (Saswad), Dist. Pune-412 303, Maharashtra	India	for Akriti Pharmaceuticals Pvt. Ltd., 117, Block No. 2, Emerald Plaza, Hiranandani Meadows, Barrister Nath Pai Road, Thane (West) 400 610	India	PoM
4	15.04.2020	Rinon	milrinone lactate	solution for injection	1mg/ml; (1) glass vial 10ml	Swiss Parenterals Ltd., 808, 809, 810, Kerala Industrial Estate, G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220, Gujarat	India	Swiss Parenterals Ltd., 808, 809, 810, Kerala Industrial Estate, G.I.D.C, Near Bavla, Dist. Ahmedabad-382 220, Gujarat	India	PoM

5	16.04.2020	Ingavirin	pentanedioic acid (pentanedioic acid imidazolyl ethanamide)	capsules	60mg; (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
6	16.04.2020	Ingavirin	pentanedioic acid (pentanedioic acid imidazolyl ethanamide)	capsules	90mg; (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
7	12.05.2020	Piracezine	piracetam, cinnarizine	capsules	400mg+25mg; (60/6x10/) in blister	Minskintercaps U.V., 26/3 bild. No2, Inzhenernaya str., 220075, Minsk	Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Belarus	PoM
8	12.05.2020	Tenoxin	tenoxicam	powder lyophilized for solution for injection	20mg; (3) glass vials 3ml and (3) solvent in ampoules 2ml	Egyptian International Pharmaceutical Industries Company (EIPICO), 10th of Ramadan City, Industrial Area B1,P.O. box 149,Tenth	Egypt	Egyptian International Pharmaceutical Industries Company (EIPICO), 10th of Ramadan City, Industrial Area B1,P.O. box 149,Tenth	Egypt	PoM
9	22.05.2020	AgmenTRONN 1000	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	875mg+125mg; (10) in blister	Flamingo Pharmaceuticals Ltd, R-662,T.T.C. Ind. Area, Rabale, Navi Mumbai 400 701	India	Flamingo Pharmaceuticals Ltd, R-662,T.T.C. Ind. Area, Rabale, Navi Mumbai 400 701	India	PoM

10	22.05.2020	AgmenTRONN 625	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film-coated	500mg+125mg; (10) in blister	Flamingo Pharmaceuticals Ltd, R-662,T.T.C. Ind. Area, Rabale, Navi Mumbai 400 701	India	Flamingo Pharmaceuticals Ltd, R-662,T.T.C. Ind. Area, Rabale, Navi Mumbai 400 701	India	PoM
11	08.07.2020	Monamox-500	amoxicillin (amoxicillin trihydrate)	capsules	500mg; (100/10x10/) in blister	Zee Laboratories, Uchani, G.T. Road, Karnal-132001, Haryana	India	Zee Laboratories, Uchani, G.T. Road, Karnal-132001, Haryana	India	PoM
12	09.07.2020	Zecid-20	omeprazole	capsules	20mg; (100/10x10/) in blister	Zee Laboratories, Uchani, G.T. Road, Karnal-132001, Haryana	India	Zee Laboratories, Uchani, G.T. Road, Karnal-132001, Haryana	India	PoM
13	09.07.2020	CardioMagnes	acetylsalicylic acid, magnesium hydroxide	tablets coated	75mg+12,5mg; (50) in plastic container	NOKI JV LTD Co., Nor-Kharberd, Ararat region	Republic of Armenia	NOKI JV LTD Co., Nor-Kharberd, Ararat region	Republic of Armenia	OTC

14	09.07.2020	Sildenafil	sildenafil (sildenafil citrate)	tablets coated	100mg; (10/1x10/) in blister	NOKI JV LTD Co., Nor-Kharberd, Ararat region	Republic of Armenia	NOKI JV LTD Co., Nor-Kharberd, Ararat region	Republic of Armenia	PoM
15	23.07.2020	Paxten	ceftazidime	powder for solution for injection	1000mg; (1) glass vial 20ml, (50) glass vials 20ml	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111-secondary packager, batch releaser, Topico Pharmaceuticals Pvt. Ltd., Plot 38, Kukatpally, Hyderabad, Telagana, India-bulk manufacturer, primary packager	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111, Republic of Armenia	Republic of Armenia	PoM
16	23.07.2020	Paxten	ceftazidime	powder for solution for injection	500mg; (1) glass vial 10ml, (50) glass vials 10ml	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111-secondary packager, batch releaser, Topico Pharmaceuticals Pvt. Ltd., Plot 38, Kukatpally, Hyderabad, Telagana, India-bulk manufacturer, primary packager	Republic of Armenia	PharmaTech CJSC, 0064, Yerevan, Raffi str. 111, Republic of Armenia	Republic of Armenia	PoM
17	06.08.2020	Folic Acid	folic acid	tablets	5mg; (50) in plastic container	PJSC Technolog, 8, Stara prorizna street, Uman, Cherkassy region, 20300	Russia	PJSC Technolog, 8, Stara prorizna street, Uman, Cherkassy region, 20300	Russia	PoM
18	07.09.2020	Omezol	omeprazole	capsules gastro-resistant	20mg; (10/1x10/) in strip	Tufenkji Group LLC, Kochinyan 13/16, Yerevan-packager, quality control, batch releaser, Centurion Laboratories Pvt. Ltd., P-2 Savli Bio-Tech Park, At Manjusar, Tal-Savli, Vadodara-390016, India-bulk manufacturer	Republic of Armenia	Tufenkji Group LLC, Kochinyan 13/16, Yerevan, Republic of Armenia	Republic of Armenia	PoM

19	07.09.2020	Ogivri	trastuzumab	powder lyophilized for solution for injection	420mg; (1) glass vial and solvent in vial 20ml	Biocon Limited, Special Economic Zone Plot Nos. 2,3,4 & 5 Phase-IV, Bommasandra-Jigani Link Road, Bommasandra Post, Bangalore- 560 099	India	Mylan Pharmaceuticals Pvt Ltd, Plot No: 1/-A/2, MIDC, Industrial Estate, Taloja, Panvel, Raigad, Maharashtra-410208	India	PoM
20	07.09.2020	Mobicam	meloxicam	tablets	7,5mg; (20/2x10/) in blister	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi- packager, quality control, batch releaser, REPLEK FARM Ltd. Skopje, 188 str. Kozle, 1000 Skopje, Republic of North Macedonia- bulk manufacturer	Georgia	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi	Georgia	PoM
21	07.09.2020	Mobicam	meloxicam	tablets	15mg; (20/2x10/) in blister	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi- packager, quality control, batch releaser, REPLEK FARM Ltd. Skopje, 188 str. Kozle, 1000 Skopje, Republic of North Macedonia- bulk manufacturer	Georgia	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi	Georgia	PoM
22	09.10.2020	Genferon Light	interferon alfa 2-b, taurin	drops nasal	10000IU+0.8mg; (1) glass vial 10ml	BIOCAD CJSC, Petrovo-Dalnee, Krasnogorsky district, Moscow Region, 143422	Russia	BIOCAD CJSC, 34 bld., lit. A, Svyazi st.,Strelna, Petrodvortsoviy district, Saint Petersburg, 198515	Russia	PoM

23	09.10.2020	Genferon Light	interferon alfa 2-b, taurin	spray nasal	50000IU+1mg; (1) glass vial (100 dose)	BIOCAD CJSC, Petrovo-Dalnee, Krasnogorsky district, Moscow Region, 143422 for BIOCAD CJSC, 34 bld., lit. A, Svyazi st.,Strelna, Petrodvortsoviy district, Saint Petersburg, 198515, Russia	Russia	BIOCAD CJSC, 34 bld., lit. A, Svyazi st.,Strelna, Petrodvortsoviy district, Saint Petersburg, 198516	Russia	OTC
24	17.11.2020	OMNOPON NEO	morphine (morphine hydrochloride), noscapine, papaverine (papaverine hydrochloride), codeine	solution for injection	11,5mg/ml+5.4mg/ml+0.72 mg/ml+1.44mg/ml; (100/20x5/) ampoules 1ml in blister	KPE Zdorovye narodu LLC, 61002, Kharkov, Kulykivska str. 41	Ukraine	KPE Zdorovye narodu LLC, 61013, Kharkov, Shevchenko str. 22	Ukraine	PoM
25	30.11.2020	Carbamazepine	carbamazepine	tablets	200mg; (50/5x10/) in blister	PJSC Technolog, 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PJSC Technolog, 8, Stara prorizna street, Uman, Cherkassy region, 20300	Ukraine	PoM
26	30.11.2020	Lidocaine 2% with epinephrine 1:80 000	lidocaine (lidocaine hydrochloride), epinephrine	solution for injection	20mg/ml+0,0125mg/ml; (50/5x10/) plastic cartridges 1,8ml in blister	New Stetic S.A. Carrera 53, No 50-09, GUARNE, ANTIOQUIA	Colombia	New Stetic S.A. Carrera 53, No 50-09, GUARNE, ANTIOQUIA	Colombia	PoM
27	30.11.2020	Lidocaine 2% with epinephrine 1:80 000	lidocaine (lidocaine hydrochloride), epinephrine	solution for injection	20mg/ml+0,0125mg/ml; (50/5x10/) glass cartridges 1,8ml in blister	New Stetic S.A. Carrera 53, No 50-09, GUARNE, ANTIOQUIA	Colombia	New Stetic S.A. Carrera 53, No 50-09, GUARNE, ANTIOQUIA	Colombia	PoM
28	10.12.2020	Lixiana	edoxaban (edoxaban tosylate)	tablets film-coated	60mg; (14/1x14/) in blister, (28/2x14/) in blister, (98/7x14/) in blister	SERVIER RUS Ltd, 108828, build.1/1, Sofyino, vill. Krasnopakhorskoye, Moscow-packager, quality control, batch releaser, Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen, Germany-bulk manufacturer	Russia	Servier JSC, 125196, Lesnaya str., 7, Moscow, Russia	Russia	PoM

29	10.12.2020	Lixiana	edoxaban (edoxaban tosylate)	tablets film-coated	30mg; (14/1x14/) in blister, (28/2x14/) in blister, (98/7x14/) in blister	SERVIER RUS Ltd, 108828, build.1/1, Sofyino, vill. Krasnopakhorskoye, Moscow-packager, quality control, batch releaser, Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen, Germany-bulk manufacturer	Russia	Servier JSC, 125196, Lesnaya str., 7, Moscow	Russia	PoM
30	10.12.2020	Lixiana	edoxaban (edoxaban tosylate)	tablets film-coated	15mg; (14/1x14/) in blister	Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen	Germany	Servier JSC, 125196, Lesnaya str., 7, Moscow	Russia	PoM
31	10.12.2020	Lixiana	edoxaban (edoxaban tosylate)	tablets film-coated	30mg; (14/1x14/) in blister, (28/2x14/) in blister, (98/7x14/) in blister	Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen	Germany	Servier JSC, 125196, Lesnaya str., 7, Moscow	Russia	PoM
32	10.12.2020	Lixiana	edoxaban (edoxaban tosylate)	tablets film-coated	15mg; (14/1x14/) in blister	SERVIER RUS Ltd, 108828, build.1/1, Sofyino, vill. Krasnopakhorskoye, Moscow-packager, quality control, batch releaser, Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen, Germany-bulk manufacturer	Russia	Servier JSC, 125196, Lesnaya str., 7, Moscow	Russia	PoM
33	10.12.2020	Lixiana	edoxaban (edoxaban tosylate)	tablets film-coated	60mg; (14/1x14/) in blister, (28/2x14/) in blister, (98/7x14/) in blister	Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276, Pfaffenhofen	Germany	Servier JSC, 125196, Lesnaya str., 7, Moscow	Russia	PoM
34	11.12.2020	Linkus Kids	althea officinalis, sisymbrium irio, hedera hellix	syrup	100mg/ml+10mg/ml+7mg/ml; 90ml glass bottle, 120ml glass bottle, 150ml glass bottle	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

35	11.12.2020	FEMION	tribulus terrestris, withania somnifera, zingiber officinalis, mucuna pruriens, asparagus racemosus, saraca indica, valeriana hardwickii, foeniculum vulgare, coriandrum sativum, vitex agnus castus	capsules	100mg+100mg+50mg+25mg+25mg+25mg+25mg+17mg+17mg+16mg; (20) plastic vial, (60) plastic vial	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
36	11.12.2020	Anastrozol	anastrozole	tablets film-coated	1mg; (30/3x10/) in blister	Pharmasyntez Nord JSC, the road to Kamenka, 74, A, 194356 St. Petersburg	Russia	Pharmasyntez Nord JSC, the road to Kamenka, 74, A, 194356 St. Petersburg	Russia	PoM
37	30.12.2020	Imatinib	imatinib (imatinib mesylate)	tablets film-coated	400mg; (30/3x10/) in blister	Pharmasyntez Nord JSC, the road to Kamenka, 74, A, 194356 St. Petersburg	Russia	Pharmasyntez Nord JSC, the road to Kamenka, 74, A, 194356 St. Petersburg	Russia	PoM
38	30.12.2020	Imatinib	imatinib (imatinib mesylate)	tablets film-coated	100mg; (30/3x10/) in blister	Pharmasyntez Nord JSC, the road to Kamenka, 74, A, 194356 St. Petersburg	Russia	Pharmasyntez Nord JSC, the road to Kamenka, 74, A, 194356 St. Petersburg	Russia	PoM