

Эмийн зөвлөлийн 2025 оны 03 дугаар сарын хурлаар шийдвэрлэсэн эмийн мэдээлэл

Эмийн зөвлөлийн ээлжит хурал 03 дугаар сарын 28-ны өдөр хуралдаж, дараах асуудлыг хэлэлцэн шийдвэрлэлээ. Үүнд:

ИМПОРТЫН ЭМ

1. ШИНЭЭР БҮРТГЭСЭН ИМПОРТЫН ЭМ-58

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№	Бүртгэлийн дугаар	Худалдааны нэр	Олон улсын нэршил	Тун, хэмжээ, хэлбэр	Үйлдвэрлэгч, Гарал үүслийн улс, лиценз эзэмшигч
Бодлогоор бүртгэх					
1	FT20250328BP09034	Newroxban	Rivaroxaban	15mg; Tablet N30	GenuPharma Inc; South Korea
2	FT20250328BP09035	Newroxban	Rivaroxaban	20mg; Tablet N30	GenuPharma Inc; South Korea
3	FT20250328BP09036	YUVARO	Rivaroxaban	15mg; Tablet N30	Yuyu Pharma, Inc.; Republic of Korea
4	FT20250328BP09037	YUVARO	Rivaroxaban	20mg; Tablet N30	Yuyu Pharma, Inc.; Republic of Korea
Энгийн бүртгэл					
1	F20250328BO09017	Ferro-Denk 50	Iron (II)-fumarate	50mg; Film-coated tablets; N50	Lomapharm GmbH; Federal Republic of Germany; Denk Pharma GmbH & Co.KG
2	F20250328JP09018	MEZATRIN® 500	Azithromycin	500mg; Film coated caplet; N6	PT.SANBE Farma; Indonesia
3	F20250328MP09019	D-Fen	Diclofenac Sodium	75mg/ml; 3ml; Solution for injection; N10	Swiss parenterals Ltd; India
4	F20250328JP09020	Osevita-75	Oseltamivir	75mg; Oral Capsules; N10	M/S United Bioceuticals pvt Ltd; India; Naples Biopharm FZCO
5	F20250328CP09021	Atorvastatin-Alium	Atorvastatin	10mg; Film coated tablets; N30	JSC "ALIUM"; Russia
6	F20250328CP09022	Atorvastatin-Alium	Atorvastatin	20mg; Film coated tablets; N30	JSC "ALIUM"; Russia
7	F20250328CP09023	Atorvastatin-Alium	Atorvastatin	40mg; Film coated tablets; N30	JSC "ALIUM"; Russia
8	F20250328RP09024	Aladka	Xylometazolin; Neomycin; Dexamethasone phosphate	7.5mg+52.500IU+15mg; Nasal spray; 15ml; N1	Duoc Khoa Pharmaceutical Joint Stock Company (DK pharma); Vietnam
9	F20250328CP09025	Cardiv®	Nicardipine HCl	1mg; 10ml; Liquid for injection; N10	PT.Otto Pharmaceutical Industries; Indonesia
10	F20250328NP09026	Neurocon CR 400 Prolonged release tablets	Carbamazepine	400mg; Prolonged release tablets; N30	M/S 4Care Lifescience Pvt.Ltd; India; M/S DMP Healthcare Pvt.Ltd
11	F20250328MP09027	Adiflam-SR Prolonged Release Tablet	Diclofenac	100mg; Prolonged Release Tablet; N100	Leben Laboratories Pvt Ltd; India RP International
12	F20250328AP09028	Razole-DMP 20	Rabeprazole Sodium	20mg; Delayed-Release tablets; N30	M/S 4Care Lifescience Pvt.Ltd; India; M/S DMP Healthcare Pvt.Ltd
13	F20250328AP09029	Gudbis	Colloidal Bismuth Subcitrate	120mg; Tablet; N40	Plethico Laboratories Pvt.Ltd; India
14	F20250328DO09030	Liniment Wishnevsky	tar + xeroform	3g+3g; Ointment; 30g; N1	Altaivitamini JSC; Russia

15	F20250328CP09031	Aurora	Rosuvastatin Calcium	10mg; Tablets; N10	Ferozsans Laboratories Limited; Pakistan
16	F20250328CP09032	Aurora	Rosuvastatin Calcium	20mg; Tablets; N10	Ferozsans Laboratories Limited; Pakistan
17	F20250328BP09033	Kidmin 7.2% amino acid		200ml, Solution for infusion; N1	PT. Otsuka Indonesia; Indonesia
18	F20250328AO09038	Urdoxa®	Ursodeoxycholic acid	250mg; Capsules; N50; N100	JSC Alium; Russia
Түргэвчилсэн бүртгэл					
1	FT20250328LP08987	Carbotinol Inj. 450mg/45ml	Carboplatin	450mg/45ml; Solution for injection; N1	Korea United Pharm.Inc; Republic of Korea
2	FT20250328LP08988	Epizin for Injection	Epirubicin Hydrochloride	50mg; 30ml; Lyophilized powder for injection; N1	Korea United Pharm.Inc; Republic of Korea
3	FT20250328LP08989	Dactinomycin for Injection 0.5mg	Dactinomycin	0.5mg; Lyophilized powder for injection; N1	Korea United Pharm.Inc; Republic of Korea
4	FT20250328LP08990	Unistin Inj. 50mg/50ml	Cisplatin	50mg/50ml; Solution for injection; N1	Korea United Pharm.Inc; Republic of Korea
5	FT20250328LP08991	DTI for Injection 200mg	Dacarbazine	200mg; 20ml; Lyophilized powder for injection; N1	Korea United Pharm.Inc; Republic of Korea
6	FT20250328BP08992	Saline PL "FUSO"	Sodium Chloride	0.9%-50ml; 100ml; Injection; N10	FUSO Pharmaceutical Industries, Ltd; Japan
7	FT20250328BP08993	Veen-F injection "FUSO"	Sodium chloride Potassium chloride Calcium chloride hydrate Sodium acetate hydrate	3g+0.15g +0.10g +1.90g; Injection; 500ml; N20	FUSO Pharmaceutical Industries, Ltd; Japan
8	FT20250328GP08994	Diezan 2mg Tablet	Dienogest	2mg; Tablet; N28	Dalim BioTech Co., Ltd; Republic of Korea
9	FT20250328NP08995	Neopat Tab. 200mg	Lacosamide	200mg; Tablet; N100	Whan In Pharm. Co.,Ltd; Republic of Korea
10	FT20250328SP08996	Olostin Tab. 5 mg	Olopatadine Hydrochloride	5mg; Tablet; N30	Whan In Pharm. Co.,Ltd; Republic of Korea
11	FT20250328RP08997	Curost Granule	Montelukast Sodium	4mg; Granule; N30	Ahngook Pharmaceutical Co., Ltd; Republic of Korea; Won deuk- Kwon
12	FT20250328AP08998	Ornithine Aspartate Injection	Ornithine Aspartate	5g/10ml; Injection liquid; N5	Fuan Pharmaceutical Group Qingyutang Pharmaceutical Co., Ltd; China
13	FT20250328VP08999	Rexinol	Reduced Glutathione	1.2g; Lyophilized powder for injection; N10	Reyoung Pharmaceutical Co., Ltd China
14	FT20250328LP09000	Kapetral 150 mg film-coated tablets	Capecitabine	150mg; Film coated tablet; N60	Remedica Ltd; Cyprus
15	FT20250328LP09001	Kapetral 500 mg film-coated tablets	Capecitabine	500mg; Film coated tablet; N120	Remedica Ltd; Cyprus
16	FT20250328JP09002	GS Vancomycin	Vancomycin Hydrochloride	1g; Freeze-dried powder for injection; N10	Genuone Sciences Inc.; Republic of Korea
17	FT20250328DP09003	Topicro oinment 0.1%	Tacrolimus Monohydrate	0.1%-10g; Ointment; N1	Kolon Pharma; Republic of Korea
18	FT20250328JP09004	Kandizol	Fluconazole	150mg; Capsule; N1; N2	NOBEL İLAÇ SANAYİİ ve TİCARET A.Ş.; Turkey
19	FT20250328JP09005	Imipenem/ Cilastatin AptaPharma 500mg/ 500mg	Imipenem/ Cilastatin	500mg/500mg; 20ml; Powder for solution for infusion; N10	ACS Dobfar S.p.A; Slovenia; Apta Medica Internacional d.o.o.

20	FT20250328HP09006	JW Oxytocin Injection	Oxytocin	50mg; Intravenous injection; N50	JW Pharmaceutical Corporation; Republic of Korea
21	FT20250328SP09007	Allervid Eye Drops 0.2%	Olopatadine Hydrochloride	0.2%-3ml; Ophthalmic solution; Single dose; N12	OPTUS Pharmaceutical Co., Ltd; Republic of Korea
22	FT20250328SP09008	Tearin Free Eye Drops	Sodium Hyaluronate	0.1%-0.5ml; Ophthalmic solution; Single dose; N60	OPTUS Pharmaceutical Co., Ltd; Republic of Korea
23	FT20250328SP09009	Betame Eye Drops 0.1%	Betamethasone Sodium Phosphate	1mg/ml; Eye Drop Solution; 5ml; N1	Aseptic Innovatice Medicine.Co.,LTD; Taiwan
24	FT20250328LP09010	Phesgo®	Pertuzumab+ trastuzumab	1200mg/600mg-15ml; Solution for injection; N1	F. Hoffmann-La Roche Ltd, Kaiseraugst; Switzerland; F. Hoffmann-La Roche Ltd, Switzerland
25	FT20250328LP09011	Phesgo®	Pertuzumab+ trastuzumab	600mg/600mg- 10ml; Solution for injection; N1	F. Hoffmann-La Roche Ltd, Kaiseraugst; Switzerland; F. Hoffmann-La Roche Ltd, Switzerland
26	FT20250328BP09012	Sodium Chloride Injection	Sodium Chloride	0.9%; 100ml; 250ml; 500ml; 1000ml; Intravenous Injection; N	Shijiazhuang No.4 Pharmaceutical Co., Ltd; China; Su Xuejun
27	FT20250328BP09013	Ringer Lactate Injection	Ringer Lactate	3.2g+6.0g+0.4g+0.27g; 250ml; 500ml; 1000ml; Intravenous Injection; N1	Shijiazhuang No.4 Pharmaceutical Co., Ltd; China; Su Xuejun
28	FT20250328BP09014	Glucose Injection	Glucose	0.9%-100ml; 5%-250ml; 5%-500ml; Intravenous Injection; N1	Shijiazhuang No.4 Pharmaceutical Co., Ltd; China; Su Xuejun
29	FT20250328BP09015	Compound Amino Acid Injection	Compound Amino Acid	250ml; Intravenous Injection; N1	Shijiazhuang No.4 Pharmaceutical Co., Ltd; China; Su Xuejun
30	FT20250328JP09016	Tamiselvir Caps.75mg	Oseltamivir Phosphate	75mg; Hard capsules; N10	Korea United Pharm.Inc; Republic of Korea
31	FT20250328MP09039	Rocium injection	Rocuronium Bromide	50mg/vial; Injection liquid; N10	Fuan Pharmaceutical Group Qingyutang Pharmaceutical Co., Ltd; China; Nanjing Hengdao Medical Technology Co., Ltd
32	FT20250328GP09040	Jeterofil ODF 20mg	Tadalafil	20mg; Orodispersible film; N10	CMG Pharmaceutical Co., Ltd; Republic of Korea
33	FT20250328CP09041	Liprimar®	Atorvastatin	10mg; Film-coated tablet; N30	Pfizer Manufacturing Deutschland GmbH; Federal Republic of Germany; Viatris Specialty LLC
34	FT20250328CP09042	Liprimar®	Atorvastatin	20mg; Film-coated tablet; N30	Pfizer Manufacturing Deutschland GmbH; Federal Republic of Germany; Viatris Specialty LLC
35	FT20250328CP09043	Liprimar®	Atorvastatin	40mg; Film-coated tablet; N30	Pfizer Manufacturing Deutschland GmbH; Federal Republic of Germany; Viatris Specialty LLC
36	FT20250328CP09044	Liprimar®	Atorvastatin	80mg; Film-coated tablet; N30	Pfizer Manufacturing Deutschland GmbH; Federal Republic of Germany; Viatris Specialty LLC

2. БҮРТГЭЛИЙН ХУГАЦААГ СУНГАСАН ИМПОРТЫН ЭМ-21

№	Бүртгэлийн дугаар	Ерөнхий нэршил	Худалдааны нэршил	Эмийн тун, хэмжээ, хэлбэр	Үйлдвэрлэгч	Улс	Лиценз эзэмшигч	Хүчинтэй хугацаа
1.	F20200417AP07315	Macrogol+Sodium chloride+Potassium chloride+Sodium bicarbonate+Sodium sulphate	Pecol	118g + 2.93g + 1.484g + 3.37g + 11.36g- 137.15g N1; powder for oral solution	M/s Caseth Pharmaceuticals Private Limited	Republic of India	M/s Caseth Pharmaceuticals Private Limited	4/17/2025
2.	FT20200417JP07309	Meropenem	Meropenem	1g N10; powder for solution for injection	JW Pharmaceutical Corporation	Republic of Korea	JW Pharmaceutical Corporation	4/17/2025
3.	FT20200417JP07310	Imipenem+Cilastatin	Imipenem+Cilastatin	500mg+500mg N10; powder for solution for injection	JW Pharmaceutical Corporation	Republic of Korea	JW Pharmaceutical Corporation	4/17/2025
4.	F20200221NH07471	Bupivacaine hydrochloride (heavy)	Bupiver-H	5mg/мл-4мл N5x10; solution for injection	M/s Verve Human Care Laboratories	Republic of India	M/s Verve Human Care Laboratories	2/21/2025

№	Бүртгэлийн дугаар	Ерөнхий нэршил	Худалдааны нэршил	Эмийн тун, хэмжээ, хэлбэр	Үйлдвэрлэгч	Улс	Лиценз эзэмшигч	Хүчинтэй хугацаа
5.	F20141119SO04059	Sodium Hyaluronate	Matafres	0.4ml N5; Eye drops	Avizor, S.A	Republic of Indonesia	PT Kalbe Farma Tbk	11/19/2024
6.	F20060222AP01409	Pure Lecithin+ Vitamin B1+ Vitamin B2+ Vitamin B6+ Vitamin B12+ Nicotinamide+ Vitamin E	Lesichol-300	300mg+6mg+6mg+6mg+6mg+30mg+6mg N10x6; soft capsule	PT.Pertiwi Agung	Republic of Indonesia	PT.Pertiwi Agung	2/20/2025
7.	F20150623RO04841	Xylomethazoline hydrochloride	Snup	45mcg/dosage N1; Nasal spray	Famar Health Care Services Madrid, S.A.U.,	Spain	Stada Arzneimittel AG	6/23/2025
8.	F20150623RO04842	Xylomethazoline hydrochloride	Snup	90mcg-15ml ; Nasal spray	Famar Health Care Services Madrid, S.A.U.,	Spain	Stada Arzneimittel AG	6/23/2025
9.	FT20200708JP07701	Cefaclor hydrate	Cefaclor capsule 250mg	250mg N10x10; capsules	Ildong Pharmaceutical Co., Ltd	Republic of Korea	Ildong Pharmaceutical Co.,Ltd	7/8/2025
10.	F20020306BP06228	Purified soybean oil	Intralipid	20%-250ml N1; injection	Fresenius Kabi SSPC	People's republic of China	Fresenius Kabi SSPC	3/6/2025
11.	F20020306BP00916	Amino Acid	Novamin	8.5%-250ml N1; injection	Fresenius Kabi SSPC	People's republic of China	Fresenius Kabi SSPC	3/6/2025
12.	FT20170126NP05965	paracetamol + pseudoephedrine hydrochloride+ dextromethorphan+ dl-Methylephedrine HCl+ guaifenesin+ diphenhydramine	Doctor Aibolit	200mg+15mg+8mg+10mg+40mg N10; Soft capsules (day and night)	RPBio., Inc	Republic of Korea	Yuyu Pharma Inc	1/26/2025
13.	FT20200616RP07678	Budesonide micronized	Pulmican Suspension	0.5mg-2ml; N30; suspension for inhalation	Kuhnle Biopharma Co., LTD	Republic of Korea	Kuhnle Pharm. Co.,Ltd	6/16/2025
14.	F20150325AO04441	Multivitamin and Multimineral syrup	Maxavit forte	150ml N1; Syrop	Oxford Laboratories PVT.Ltd	Republic of India	Oxford Laboratories PVT. Ltd	3/25/2025
15.	F20020626MO00941	Ibuprofen	Ibuprofen-denk 400	400mg N100; Film-coated tablets	Denk Pharma GmbH & Co.KG	Republic of Germany	Denk Pharma GmbH & Co.KG	6/26/2025
16.	F20020626NO00943	Paracetamol	Para-denk 125	125mg N10; Suppositories	Rubie Pharm Arzneimittel GmbH	Republic of Germany	Denk Pharma GmbH & Co.KG	6/26/2025
17.	F20020626NO02355	Paracetamol	Para-denk 250	250mg N10; Suppositories	Rubie Pharm Arzneimittel GmbH	Republic of Germany	Denk Pharma GmbH & Co.KG	6/26/2025
18.	FT20170620JP06208	Ciprofloxacin hydrochloride	Cipro-denk 750	750mg N10; Film-coated tablets	Allphamed PHARBIL Arzneimittel GmbH	Republic of Germany	Denk Pharma GmbH & Co.KG	6/20/2025
19.	FT20170620JP06207	Levofloxacin hemihydrate	Levoflox-denk 5mg/ml	5mg/ml- 100mg N1; Solution for infusion	Solupharm Pharmazeutische Erzeugnisse GmbH	Republic of Germany	Denk Pharma GmbH & Co.KG	6/20/2025
20.	F20100312MP02329	Aceclofenac	Clanza's	100mg N100; Soft capsule	Korea United Pharm. Inc	Republic of Korea	Korea United Pharma. Inc	3/12/2025
21.	FT20170620AP06160	Itopride hydrochloride	Itomed	50mg N40; film-coated tablets	Pro.Med.Cs Praha a.s.	Czech republic	Pro.Med.Cs Praha a.s.	6/20/2025

БИОБЭЛДМЭЛ

1. ШИНЭЭР БҮРТГЭСЭН БИОБЭЛДМЭЛ-2

№	Бүртгэлийн дугаар	Эмийн худалдааны нэршил	Эмийн олон улсын нэршил	Эмийн тун, хэмжээ	Эмийн хэлбэр	Үйлдвэрлэгчийн нэр, улс	Лиценз эзэмшигчийн нэр, улс
1	F20250328BP 08985	Эпосино/ Eposino	Хүний рекомбинант эритропоэтин/Human Recombinant Erythropoietin	4000ОУН/мл, №1 4000IU/ml №1	тариурт дүүргэсэн тарилгын уусмал/ injection solution with prefilled syringe	Kexing Biopharm Co.Ltd, Republic of China	Kexing Biopharm Co.Ltd, Republic of China
2	F20250328BP 08986	Эпосино/ Eposino	Хүний рекомбинант эритропоэтин/Human Recombinant Erythropoietin	10000ОУН/мл №1 10000IU/ml, №1	тариурт дүүргэсэн тарилгын уусмал/ injection solution with prefilled syringe	Kexing Biopharm Co.Ltd, Republic of China	Kexing Biopharm Co.Ltd, Republic of China

2. БҮРТГЭЛИЙН ХУГАЦААГ СУНГАСАН-3

№	Бүртгэлийн дугаар	Эмийн олон улсын нэршил	Эмийн худалдааны нэршил	Эмийн тун, хэмжээ, хэлбэр	Эмийн хэлбэр	Олгох нөхцөл, АТС код	Үйлдвэрлэгчийн нэр, улс	Лиценз эзэмшигчийн нэр, улс
1	FT20170223M H06023	Ботулакс 100/ Botulax 100	Ботулин токсин A/ Botulin toxin type A	100нэгж/х.ш ил №1 100 Units/ vial №1	тарилгын уусмал бэлтгэх лиофилизат нунтаг/ Lyophilized powder for injection	Эмнэлгийн нөхцөлд, M03AX01	Hugel INC, Republic of Korea	Hugel INC, Republic of Korea
2	FT20170223M H06025	Нейронок с 100нэгж/ Neuronox 100U	Ботулин токсин A/ Botulin toxin type A	100нэгж/х.ш ил №1 100Units/ vial №1	тарилгын уусмал бэлтгэх лиофилизат нунтаг/ Lyophilized powder for injection	Эмнэлгийн нөхцөлд, M03AX01	Medytox INC, Republic of Korea	Medytox INC, Republic of Korea
3	FT20170330A P06091	Актрапид/ Actrapid	Хүний инсулин/ Human insulin rDNA	100 ОУН/мл-10мл, №1 100IU/ml-10ml, №1	тарилгын уусмал/ solution for injection	жороор, A10AB01	Novo Nordisk Production SAS, France	Novo Nordisk A/S

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