

Хүний эмийн зөвлөлийн 2024 оны 06 дугаар сарын хурлаар шийдвэрлэсэн эмийн мэдээлэл

Хүний эмийн зөвлөлийн ээлжит хурал 06 дугаар сарын 18-ны өдөр хуралдаж, дараах асуудлыг хэлэлцэн шийдвэрлэлээ. Үүнд:

ИМПОРТЫН ЭМ

1. ШИНЭЭР БҮРТГЭСЭН ИМПОРТЫН ЭМ-78

Үүнээс:

1.1. Бодлогоор-3

1.2. Энгийн бүртгэл-35

1.3. Түргэвчилсэн бүртгэл-40

| №                 | Бүртгэлийн дугаар | Худалдааны нэр                              | Олон улсын нэршил/найрлага                                                                  | Тун, хэмжээ, хэлбэр                                                              | Үйлдвэрлэгч, Гарал үүслийн улс, лиценз эзэмшигч         |
|-------------------|-------------------|---------------------------------------------|---------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|---------------------------------------------------------|
| Бодлогоор бүртгэх |                   |                                             |                                                                                             |                                                                                  |                                                         |
| 1                 | F20240618CP08827  | Sterile Noradernaline Concentrate BP 2mg/ml | Noradernaline Acid Tartrate                                                                 | 2mg/2ml; Solution for Injection; N10                                             | Ciron Drugs and Pharmaceuticals Pvt.Ltd; India          |
| 2                 | F20240618LP08828  | Rexta                                       | Oxaliplatin                                                                                 | 100mg/20ml; Solution for injection; N1                                           | PT Global Onkolab Farma; Indonesia                      |
| 3                 | F20240618LP08829  | Brexel                                      | Docetaxel                                                                                   | 80mg/8ml; Solution for injection; N1                                             | PT Global Onkolab Farma; Indonesia                      |
| Энгийн бүртгэл    |                   |                                             |                                                                                             |                                                                                  |                                                         |
| 1                 | F20240618AO08755  | Legalon 140                                 | Sylimarín                                                                                   | 140mg; Capsule; N100                                                             | Madaus GmbH; Germany                                    |
| 2                 | F20240618RP08756  | Fexofen-180                                 | Fexofenadine hydrochloride tablets USP 180mg                                                | 180mg; Tablets; N60                                                              | M/S Aristo Pharmaceuticals PRIVATE LIMITED; India;      |
| 3                 | F20240618JP08757  | Gudfyl LB Kit                               | Amoxicillin+ lactic Acid Bacillus+ Clarithromycin+ Esomeprazole                             | 1000mg+60million spores+ 500mg+ 20mg; Tablets; N60                               | Vapi Care Pharm; India; Plethico Laboratories Pvt Ltd.; |
| 4                 | F20240618NP08758  | Uniola 5 MD                                 | Olanzapine Orally Disintegrating Tablets USP 5mg                                            | 5mg; Orally Disintegrating Tablets; N30                                          | Brussels Laboratories Pvt.Ltd; India; RP International  |
| 5                 | F20240618NP08759  | Uniola 10 MD                                | Olanzapine Orally Disintegrating Tablets USP 10mg                                           | 10mg; Orally Disintegrating Tablets; N30                                         | Brussels Laboratories Pvt.Ltd; India; RP International  |
| 6                 | F20240618NP08760  | Uniola-10                                   | Olanzapine Tablets USP 10mg                                                                 | 10mg; Tablets; N30                                                               | Brussels Laboratories Pvt.Ltd; India; RP International  |
| 7                 | F20240618GP08761  | Grand Fun                                   | Tadalafil                                                                                   | 20mg; Tablet; N4                                                                 | Brussels Laboratories Pvt.Ltd; India; RP International  |
| 8                 | F20240618JP08762  | MyHep ALL                                   | Sofosbuvir + Velpatasvir                                                                    | 400mg+ 100mg; Film Coated Tablets; N28                                           | Mylan Laboratories Limited; India                       |
| 9                 | F20240618RP08763  | Sinurhon Tablet                             | Phenylephrine hydrochloride + Chlorpheniramine maleate + Paracetamol + Caffeine (anhydrous) | 5mg+2mg+500mg+30mg; Tablets; N120                                                | Leben Laboratories Pvt. Ltd.; India; RP International   |
| 10                | F20240618JP08764  | Cebay-100 Dry Syrup                         | Cefixime                                                                                    | 100mg; Dry Syrup for oral administration; N1                                     | Leben Laboratories Pvt. Ltd.; India; RP International   |
| 11                | F20240618DO08765  | Fungoderil                                  | Naftifine hydrochloride                                                                     | 10mg; Solution for external use; 15ml; 25ml; N1                                  | Nizhpharm JS, Russian Federation; Russia                |
| 12                | F20240618RO08766  | Elmucin                                     | Erdosteine                                                                                  | 300mg; Capsules; N10                                                             | JSC "Alium"; Russia                                     |
| 13                | F20240618JP08767  | Meropenem                                   | Meropenem                                                                                   | 500mg; Powder for the preparation of solution for intravenous administration; N1 | PJSC "Sintez"; Russian Federation                       |

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| 14                          | F20240618JP08768  | Meropenem                                | Meropenem                                        | 1000mg; Powder for the preparation of solution for intravenous administration; N1 | PJSC "Sintez"; Russian Federation                                                                                                 |
| 15                          | F20240618CO08769  | ETHYL ICOSAPENTATE CAPSULES 300mg "TOWA" | Ethyl Icosapentate                               | 300mg; Capsules; N100                                                             | TOWA Pharmaceutical Co.,Ltd; Japan                                                                                                |
| 16                          | F20240618CP08770  | Lextran                                  | Cholestyramine for oral suspension USP           | 4.0gm/ 5gm; Powder for oral suspension; N20                                       | Lexine Technochem Pvt.Ltd; India; Mr.Akhil Shah                                                                                   |
| 17                          | F20240618JP08771  | Cilapenem                                | Imipenem /Cilastatin                             | 500mg+ 500mg; Powder for solution for infusion; N1                                | Belmedpreparaty RUE; Republic of Belarus                                                                                          |
| 18                          | F20240618NH08772  | Profoliv                                 | Propofol                                         | 10mg/ml; 20ml; Emulsion for injection/ infusion; N1                               | Ms Livealth Biopharma Pvt. Ltd; India                                                                                             |
| 19                          | F20240618NP08773  | Thioealth                                | Tiopental Sodium                                 | 1gm/vial; Powder for solution for injection; N1                                   | Ms Livealth biopharmapvt. Ltd; India                                                                                              |
| 20                          | F20240618JP08774  | Mezatriin® 250 Capsule                   | Azithromycin                                     | 250mg; Capsule; N30                                                               | PT.Caprifarmindo Laboratories; Indonesia; PT.Sanbe Farma                                                                          |
| 21                          | F20240618DP08775  | Pibaksin®                                | Mupirocin                                        | 20mg/g-10g; ointment; N1                                                          | PT.Caprifarmindo Laboratories; Indonesia; PT.Sanbe Farma                                                                          |
| 22                          | F20240618HP08776  | Sanexon® 4                               | Methylprednisolone                               | 4mg; Tablets; N100                                                                | PT.Sanbe Farma; Indonesia                                                                                                         |
| 23                          | F20240618HP08777  | Sanexon® 16                              | Methylprednisolone                               | 16mg; Tablets; N30                                                                | PT. Sanbe Farma; Indonesia                                                                                                        |
| 24                          | F20240618BP08778  | Plasminex®                               | Tranexamic Acid                                  | 100mg/ml;5ml; Solution for injection;N10                                          | PT.Sanbe Farma; Indonesia                                                                                                         |
| 25                          | F20240618NO08779  | Paracetamol 125mg suppositories          | Paracetamol                                      | 125mg; Suppositories; N6                                                          | Farmaprim LTD; Republic of Moldova                                                                                                |
| 26                          | F20240618NO08780  | Paracetamol 250mg suppositories          | Paracetamol                                      | 250mg; Suppositories; N6                                                          | Farmaprim LTD; Republic of Moldova                                                                                                |
| 27                          | F20240618RO08781  | Flavamed                                 | Ambroxol hydrochloride                           | 15mg/5ml; 100ml; Oral solution; N1                                                | Berlin-Chemie AG (Menarini Group); Germany                                                                                        |
| 28                          | F20240618RO08782  | Flavamed forte                           | Ambroxol hydrochloride                           | 30mg/5ml; 100ml; Oral solution; N1                                                | Berlin-Chemie AG (Menarini Group); Germany                                                                                        |
| 29                          | F20240618RO08783  | Flavamed                                 | Ambroxol hydrochloride                           | 30mg; Tablets; N20                                                                | Berlin-Chemie AG (Menarini Group); Germany                                                                                        |
| 30                          | F20240618RO08784  | Flavamed max                             | Ambroxol hydrochloride                           | 60mg; effervescent tablets; N10                                                   | Berlin-Chemie AG (Menarini Group); Germany                                                                                        |
| 31                          | F20240618BO08785  | Brightest Eye Drops                      | Cyanocobalamin                                   | 0.2mg/ml; Solution; 5ml; 10ml; N1                                                 | Aseptic innovatice medicine.Co., Ltd; Taiwan                                                                                      |
| 32                          | F20240618BO08786  | Hi Tears                                 | Polyvinyl Alcohol                                | 14mg/ml; Solution; 5ml; 10ml; N1                                                  | Aseptic innovatice medicine.Co., Ltd; Taiwan                                                                                      |
| 33                          | F20240618RP08830  | LEVO-M                                   | Levocetirizine hydrochloride+ Montelukast Sodium | 5mg+10mg; Tablet; N30                                                             | Swiss care; India; Thrive therapeutic Pvt.Ltd                                                                                     |
| 34                          | F20240618CP08831  | Bisoprolol-ACOS                          | Bisoprolol                                       | 5mg; Tablets N30; N50                                                             | JSC Biocom; Russia                                                                                                                |
| 35                          | F20240618CP08832  | Bisoprolol-ACOS                          | Bisoprolol                                       | 10mg; Tablets; N30; N50                                                           | JSC Biocom; Russia                                                                                                                |
| <b>Түргэвчилсэн бүртгэл</b> |                   |                                          |                                                  |                                                                                   |                                                                                                                                   |
| 1                           | FT20240618AP08787 | Focigli® tablet                          | Dapagliflozin                                    | 10mg; Immediate release tablet; N28                                               | Sinil Pharmaceutical Co., Ltd; Republic of Korea                                                                                  |
| 2                           | FT20240618BP08788 | Runaplast®                               | Rivaroxaban                                      | 10mg; Film-coated tablets; N30                                                    | Batch releaser: Salutas Pharma GmbH; Bulk manufacturer: Oman Pharmaceutical Products Co.,LLC; Germany; Sandoz Pharmaceuticals D.D |
| 3                           | FT20240618BP08789 | Runaplast®                               | Rivaroxaban                                      | 15mg; Film-coated tablets; N30                                                    | Batch releaser: Salutas Pharma GmbH; Bulk manufacturer: Oman Pharmaceutical Products Co.,LLC; Germany; Sandoz Pharmaceuticals D.D |

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| 4  | FT20240618BP08790 | Runaplast®                              | Rivaroxaban                                                                                                                                                                                                              | 20mg;<br>Film-coated tablets; N30                                                     | Batch releaser: Salutas Pharma GmbH; Bulk manufacturer: Oman Pharmaceutical Products Co.,LLC; Germany;<br>Sandoz Pharmaceuticals D.D |
| 5  | FT20240618BP08791 | Sodium Chloride Infusion                | Sodium Chloride                                                                                                                                                                                                          | 0.9%-100ml;<br>Solution for injection; N1                                             | Cisen Pharmaceutical Co., Ltd;<br>China;<br>Ningbo Nuobai Pharmaceutical Co Ltd                                                      |
| 6  | FT20240618BP08792 | Sodium Chloride Infusion                | Sodium Chloride                                                                                                                                                                                                          | 0.9%-250ml;<br>Solution for injection; N1                                             | Cisen Pharmaceutical Co., Ltd;<br>China;<br>Ningbo Nuobai Pharmaceutical Co Ltd                                                      |
| 7  | FT20240618BP08793 | Sodium Chloride Infusion                | Sodium Chloride                                                                                                                                                                                                          | 0.9%-500ml;<br>Solution for injection; N1                                             | Cisen Pharmaceutical Co., Ltd;<br>China;<br>Ningbo Nuobai Pharmaceutical Co Ltd                                                      |
| 8  | FT20240618CP08794 | Milrinone Injection                     | Milrinone                                                                                                                                                                                                                | 10mg/10ml; Injection; N5                                                              | Shanghai Xudong Haipu Pharmaceutical Co.,Ltd;<br>China                                                                               |
| 9  | FT20240618CP08795 | Epinephrine hydrochloride Injection     | Epinephrine hydrochloride                                                                                                                                                                                                | 1mg/ml; Injection; N10                                                                | Grand Pharmaceutical (China) Co.,Ltd; China                                                                                          |
| 10 | FT20240618JP08796 | Azimax dry Syrup                        | Azithromycin                                                                                                                                                                                                             | 200mg/5ml;<br>Oral dry Syrup, N1                                                      | GenuPharma Inc.;<br>Republic of Korea;<br>Genuone Sciences Inc                                                                       |
| 11 | FT20240618NP08797 | Dexmedetomidine Hydrochloride injection | Dexmedetomidine Hydrochloride injection                                                                                                                                                                                  | 0.2mg/2ml; Solution for injection; N1                                                 | Cisen Pharmaceutical Co.,Ltd;<br>China                                                                                               |
| 12 | FT20240618NP08798 | Mepivacaine Hydrochloride Injection     | Mepivacaine Hydrochloride                                                                                                                                                                                                | 0.4g/20ml; Solution for injection; N1                                                 | Cisen Pharmaceutical Co.,Ltd;<br>China                                                                                               |
| 13 | FT20240618MP08799 | Vecuronium Bromide for injection        | Vecuronium Bromide                                                                                                                                                                                                       | 4mg/vial; Lyophilized powder for injection; N10                                       | Cisen Pharmaceutical Co.,Ltd;<br>China                                                                                               |
| 14 | FT20240618RP08800 | Alkafen Cough Soft capsule              | Acetaminophen;<br>Dextromethorphan HBr;<br>Doxylamine Succinate;<br>Pseudoephedrine HCl                                                                                                                                  | 250mg+<br>10mg+6.25mg+30mg;<br>Soft Capsule;<br>N10                                   | Korea United Pharm.Inc;<br>Republic of Korea;<br>Duk Young Kang                                                                      |
| 15 | FT20240618RP08801 | Luxat 10mg                              | Montelukast                                                                                                                                                                                                              | 10mg;<br>Film coated Tablet; N28                                                      | Deva Holding A.S;<br>Turkey                                                                                                          |
| 16 | FT20240618JP08802 | Fixef 400 mg Film Coated Tablet         | Cefixime                                                                                                                                                                                                                 | 400mg; Tablet; N10                                                                    | Deva Holding A.S; Turkey                                                                                                             |
| 17 | FT20240618MP08803 | Clodifen 5% Gel                         | Diclofenac Sodium                                                                                                                                                                                                        | 5%-45g; Gel;<br>N1                                                                    | World Medicine Ilac Sanayi ve Ticaret A.S.;<br>Turkey                                                                                |
| 18 | FT20240618CP08804 | Sybrava                                 | Inclisiran                                                                                                                                                                                                               | 284mg;<br>Solution for subcutaneous injection; 1.5ml solution in a pre-filled syringe | Novartis Pharmaceuticals Manufacturing GmbH;<br>Austria<br>Novartis Overseas Investments AG;                                         |
| 19 | FT20240618AP08805 | Zero X Capsule                          | Orlistat                                                                                                                                                                                                                 | 120mg;<br>Hard Capsule; N84                                                           | GENUPharma Inc;<br>Republic of Korea                                                                                                 |
| 20 | FT20240618CP08806 | Eglandin Injection                      | Alprostadil                                                                                                                                                                                                              | 5mcg/ml- 2ml;<br>Solution for injection; N10                                          | Mitsubishi Tanabe Pharma Korea Co.,Ltd;<br>Republic of Korea                                                                         |
| 21 | FT20240618BP08807 | Multipotent 9 Inj.                      | Chromic chloride hydrate + Cupric chloride hydrate + Ferric chloride hydrate + Manganese chloride hydrate + Potassium iodide + Sodium fluoride + Sodium molybdate hydrate + Sodium selenite pentahydrate + Zinc chloride | 5.33mcg+0.34mg+0.54mg +99mcg+16.6mcg+0.21mg +4.85mcg+6.9mcg+1.36mg; Injection; N10    | BCWORLD HARM Co., Ltd;<br>Republic of Korea                                                                                          |
| 22 | FT20240618CP08808 | Trenzamin 500mg Inj                     | Tranexamic Acid                                                                                                                                                                                                          | 500mg/5ml;<br>Solution for injection; N10                                             | Jeil Pharmaceutical Co.,Ltd;<br>Republic of Korea                                                                                    |
| 23 | FT20240618NP08809 | Dexmedetomidine EVER Pharma®            | Dexmedetomidine                                                                                                                                                                                                          | 100mcg/ml- 2ml;<br>Concentrate for solution for infusion; N5                          | EVER Pharma Jena GmbH;<br>Germany;<br>EVER Valinject GmbH                                                                            |

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| 24 | FT20240618JP08810 | ENTECAVIR TABLETS 0.5mg "TOWA"  | Entecavir hydrate                                                                                             | 0.5mg; Tablets; N60                                                    | TOWA Pharmaceutical Co,Ltd; Japan                                                     |
| 25 | FT20240618LP08811 | Paclitaxel-Teva                 | Paclitaxel                                                                                                    | 6mg/ml- 50ml; Concentrate for solution for infusion; N1                | Pharmachemie B.V; The Netherlands; Teva Pharmaceutical Industries Ltd                 |
| 26 | FT20240618NP08812 | Finlepsin® retard               | Carbamazepine                                                                                                 | 400mg; Prolonged release tablets; N50                                  | Teva Operations Poland Sp.z o.o.; Poland; Teva Pharmaceutical Industries Ltd.; Israel |
| 27 | FT20240618NP08813 | Finlepsin® retard               | Carbamazepine                                                                                                 | 200mg; Prolonged release tablets; N50                                  | Teva Operations Poland Sp.z o.o.; Poland Teva Pharmaceutical Industrries Ltd.; Israel |
| 28 | FT20240618LP08814 | Oxaliplatin-Teva                | Oxaliplatin                                                                                                   | 5mg/ml-10ml; 20ml; Concentrate for solution for infusion; N1           | Pharmachemie B.V.; The Netherlands                                                    |
| 29 | FT20240618AP08815 | No-Spa®                         | Drotaverine hydrochloride                                                                                     | 40mg/2ml; Solution for injection; N5                                   | Chinion Pharmaceutical and Chemical Works Private Co.Ltd; Hungary                     |
| 30 | FT20240618LP08816 | Vopazzi 400mg                   | Pazopanib Hydrochloride                                                                                       | 400mg; Film-coated tablet; N60                                         | Deva Holding A.S; Turkey                                                              |
| 31 | FT20240618NP08817 | Fentadur                        | Fentanyl                                                                                                      | 12mcg/h- 1.375mg; 50mcg/h-5.50mg; 100mcg/h- 11mg; TransdemaI patch; N5 | Lavipharm S.A; Greece                                                                 |
| 32 | FT20240618AP08818 | Devit-3 2.000 IU Soft Capsules  | Cholecalciferol                                                                                               | 50mcg; Soft capsule; N60                                               | Deva Holding A.S.; Turkey                                                             |
| 33 | FT20240618BP08819 | Neostreptaza                    | Streptokinasum + Streptodornasum                                                                              | 15000IU+1250IU; Suppository; N6                                        | Farmina sp. z o.o; Poland                                                             |
| 34 | FT20240618CP08820 | Etimib-Denk 10mg                | Ezetimibe                                                                                                     | 10mg; Tablets; N30                                                     | Artesan Pharma GmbH & Co.KG; Germany; Denk Pharma GmbH & Co.KG                        |
| 35 | FT20240618GP08821 | Antilin Tablets 1.5mg           | Levonorgestrel                                                                                                | 1.5mg; Tablet; N1                                                      | Synmosa Biopharma Corporation; Taiwan                                                 |
| 36 | FT20240618MP08822 | Acelex                          | Polmacoxib                                                                                                    | 2mg; Tablets; N30                                                      | Crystal Life Science; Republic of Korea; Crystal Genomics.inc                         |
| 37 | FT20240618RP08823 | Dufanas Nasal Spray             | Azelastine Hydrochloride + Fluticasone Propionate Micronized                                                  | 137mcg+50mcg; nasal spray; N1                                          | Synmosa Biopharma Corporation; Taiwan                                                 |
| 38 | FT20240618BP08824 | Multiple Electrolytes Injection | Sodium Chloride+Sodium Gluconate+Sodium Acetate Trihydrate+ Potassium Chloride+Magnesium Chloride Hexahydrate | 2.63g+2.51g+1.84g+0.185g+0.15g; 500ml; Injection; N1                   | Sichuan Kelun Pharmaceutical Co., Ltd; P.R. China                                     |
| 39 | FT20240618RP08825 | MozinCare                       | Montelukast+ Levocetirizine                                                                                   | 4mg+2.5mg/5ml; 60ml; Syrup; N1                                         | Huazhong Pharmaceutical Co., Ltd; China; Advacare International Limited               |
| 40 | FT20240618JP08826 | AclavCare                       | Amoxicillin Trihydrate+ Clavulanate Potassium                                                                 | 250mg+ 62.5mg; 60ml; Powder for suspension; N1                         | Huazhong Pharmaceutical Co., Ltd; China; Advacare International Limited               |