

NEW DRUGS APPROVED in 2025



Healthcare professionals are encouraged to report all serious and non-serious suspected adverse drug reactions (ADRs) with the use of new drugs. Your active participation in the ADR monitoring programme will provide valuable support to the post-marketing surveillance on drug safety.

HOW TO REPORT

Please report to us as soon as you are made aware of the adverse events. You may do so by reporting online at <https://www.hsa.gov.sg/adverse-events> or download the ADR reporting form and send the completed form to Vigilance and Compliance Branch, HSA either by post or email.

WHERE TO SEND YOUR REPORT

Vigilance and Compliance Branch, Health Products Regulation Group,
Health Sciences Authority

11 Biopolis Way, #11-01, Helios, Singapore 138667

Tel: +65-6866 1111 • Email: HSA_productsafety@hsa.gov.sg

NEW CHEMICAL / BIOLOGICAL ENTITY	PHARMACOTHERAPEUTIC GROUP
Alpha-ketoglutaric acid 0.1461 g/L, Calcium chloride dihydrate 0.0022 g/L, Histidine 27.9289 g/L, Histidine hydrochloride monohydrate 3.7733 g/L, Magnesium chloride hexahydrate 0.8132 g/L, Mannitol 5.4651 g/L, Potassium chloride 0.6710 g/L, Sodium chloride 0.8766 g/L, Tryptophan 0.4085 g/L CUSTODIOL® solution	Blood substitute & perfusion solution (POM)
Belzutifan 40 mg WELIREG® film-coated tablet	Antineoplastic agent (POM)
Datopotamab deruxtecan 100 mg/vial DATROWAY® powder for concentrate for solution for infusion	Antineoplastic agent (POM)
Donanemab 350 mg/20 ml Lormalzi® concentrate for solution for infusion	Antidementia agent (POM)
Efgartigimod alfa 20 mg/ml Vyvgart® concentrate for solution for infusion	Immunosuppressant (POM)
Elafibranor 80 mg IQIRVO® film-coated tablet	Agent for bile & liver therapy (POM)
Eplontersen 45 mg/0.8 ml WAINUA® solution for injection in autoinjector	Agent acting on nervous system (POM)
Fezolinetant 45 mg VEOZA™ film-coated tablet	Gynaecological agent for menopause (POM)
Futibatinib 4 mg LYTGOBI® film-coated tablet	Antineoplastic agent (POM)
Inavolisib 3 mg, 9 mg Itovebi® film-coated tablets	Antineoplastic agent (POM)
Influenza virus (NH) A/Croatia/10136RV/2023 (H3N2)-like virus (A/Perth/722/2024) 7.0 ± 0.5 log ₁₀ FFU/dose, Influenza virus (NH) A/Victoria/4897/2022 (H1N1) pdm09 - like virus (A/Norway/31694/2022) 7.0 ± 0.5 log ₁₀ FFU/dose, Influenza virus (NH) B/Austria/1359417/2021 (B/Victoria lineage) - like virus (B/Austria/1359417/2021) 7.0 ± 0.5 log ₁₀ FFU/dose FluMist® trivalent influenza intranasal vaccine	Viral vaccine (POM)
Iptacopan 200 mg FABHALTA™ capsule	Immunomodulatory agent (POM)
Lazertinib 80 mg, 240 mg LAZCLUZE® film-coated tablets	Antineoplastic agent (POM)
Lebrikizumab 250 mg/2 ml Ebglyss® solution for injection in pre-filled pen	Immunomodulatory agent (POM)
Lecanemab 100 mg/ml LEQEMBI® concentrate for solution for infusion	Antidementia agent (POM)
Lenacapavir 300 mg, 463.5 mg/1.5 ml Sunlenca® film-coated tablet 300 mg Sunlenca® solution for injection 463.5 mg/1.5 ml	Antiviral agent for systemic use (POM)
Maribavir 200 mg LIVTENCITY® film-coated tablet	Antiviral agent for systemic use (POM)
Marstacimab 150 mg/ml HYMPAVZI® solution for injection in single-dose pre-filled pen	Antithrombotic agent (POM)
Meropenem 1 g, Vaborbactam 1 g Vaborem® powder for concentrate for solution for infusion 1 g/1 g	Antibacterial agent for systemic use (POM)
Mirvetuximab soravtansine 100 mg/20 ml ELAHERE® concentrate for solution for infusion	Antineoplastic agent (POM)
Mitomycin 10 mg/vial MITOCIN® powder for solution for injection	Antineoplastic agent (POM)
Mogamulizumab 20 mg/5 ml POTELIGEO® concentrate for solution for infusion	Antineoplastic agent (POM)
Nemolizumab 30 mg Nemluvio® powder & solvent for solution for injection in pre-filled pen Nemluvio® powder & solvent for solution for injection in pre-filled syringe	Immunomodulatory agent (POM)
Pegunigalsidase alfa 2 mg/ml ELFABRIO® concentrate for solution for infusion	Enzyme replacement therapy (POM)
Remimazolam 20 mg Byfavo® powder for solution for injection	Hypnotic & sedative agent (POM)
Sebelipase alfa 2 mg/ml KANUMA® concentrate for solution for infusion	Enzyme replacement therapy (POM)
Sebetralstat 300 mg Ekterly® film-coated tablet	Agent used in hereditary angioedema (POM)
Serplulimab 100 mg/10 ml Zerpidio® concentrate for solution for infusion	Antineoplastic agent (POM)
Somapacitan 5 mg/1.5 ml, 10 mg/1.5 ml, 15 mg/1.5 ml Sogroya® solution for injection in pre-filled pen	Growth hormone replacement therapy (POM)
Tarlatamab 1 mg/vial, 10 mg/vial IMDELLTRA® powder for solution for infusion	Antineoplastic agent (POM)
Toripalimab 240 mg/6 ml LOQTORZI® concentrate for solution for infusion	Antineoplastic agent (POM)
Zolbetuximab 100 mg/vial VYLOY™ powder for concentrate for solution for infusion	Antineoplastic agent (POM)
NEW BIOSIMILAR	PHARMACOTHERAPEUTIC GROUP
Denosumab 60 mg/ml, 120 mg/1.7 ml Stoboclo® solution for injection in pre-filled syringe 60 mg/ml Osenvelt® solution for injection 120 mg/1.7 ml	Agent for treatment of bone diseases (POM)
Omalizumab 75 mg/0.5 ml, 150 mg/1 ml OMLYCLO® solution for injection in pre-filled syringe	Immunomodulatory agent (POM)
Ustekinumab 45 mg/0.5 ml, 90 mg/ml, 130 mg/26 ml STEQEYMA® solution for injection in pre-filled syringe 45 mg/0.5 ml, 90 mg/ml STEQEYMA® concentrate for solution for infusion 130 mg/26 ml	Immunosuppressant (POM)

Continued in the next column

OTHERS*	
*Applies to registered products with new combination, dosage form or recommendation, presentation, formulation, route of administration, patient population etc. For details, please refer to https://go.gov.sg/tp-application-types	
CHEMICAL / BIOLOGICAL ENTITY	PHARMACOTHERAPEUTIC GROUP
A/Croatia/10136RV/2023 (H3N2) - like strain (A/Croatia/10136RV/2023, X-425A) 15 mcg/0.5 ml, A/Victoria/4897/2022 (H1N1) pdm09-like strain (A/Victoria/4897/2022, IVR-238) 15 mcg/0.5 ml, B/Austria/1359417/2021-like strain (B/Michigan/01/2021, wild type) 15 mcg/0.5 ml Vaxigrip® vaccine	Viral vaccine (POM)
Aripiprazole 960 mg/3.2 ml Abilify Asimtufii® prolonged-release suspension for injection in pre-filled syringe	Antipsychotic agent (POM)
Asciminib 100 mg Scemblix® film-coated tablet	Antineoplastic agent (POM)
Beclometasone dipropionate 0.2 mg/actuation, Formoterol fumarate dihydrate 0.006 mg/actuation, Glycopyrronium bromide 0.0125 mg/actuation Trimbow® pressurised inhalation solution 200/6/12.5 µg per actuation	Agent for obstructive airway diseases (POM)
Bilastine 20 mg BILAXTEN® orodispersible tablet	Antihistamine for systemic use (POM)
Brimonidine tartrate 0.1 % w/v ALPHAGAN® P ophthalmic solution	Antiglaucoma preparation & miotic agent (POM)
Brimonidine tartrate 1 mg/ml, Ripasudil 4 mg/ml GLAALPHA® combination ophthalmic solution	Antiglaucoma preparation & miotic agent (POM)
Cefuroxime 50 mg/vial Aprokam® powder for solution for injection	Ophthalmic anti-infective agent (POM)
Cholecalciferol 25,000 IU GP® Cholecalciferol softgel capsule	Vitamin D & analogues (POM)
COVID-19 mRNA encoding LP.8.1 30 mcg/dose COMIRNATY®, dispersion for injection in pre-filled syringe	Viral vaccine (POM)
Dexamethasone (micronized) 0.4 mg DEXTENZA® ophthalmic insert	Ophthalmic anti-inflammatory agent (POM)
Donepezil 5 mg/24 hours, 10 mg/24 hours ADLARITY® transdermal system	Antidementia agent (POM)
Enzalutamide 40 mg, 80 mg Xtandi™ film-coated tablets	Endocrine therapy (POM)
Finasteride 2.275 mg/ml Finjuve® for men cutaneous spray, solution	Dermatological preparation (POM)
(IG 10%) Human normal immunoglobulin 100 mg/ml HyQvia® solution for infusion	Agent used in treatment of immunodeficiencies, autoimmune & inflammatory disorders (POM)
Icosapent ethyl 998 mg VAZKEPA® soft capsule	Lipid modifying agent (POM)
Influenza virus surface antigens (haemagglutinin and neuraminidase) A/Official strain (HxNy)-like (A/HxNy Official strain) 7.5 micrograms HA per 0.5 ml dose AUDENZ® pandemic influenza vaccine suspension for injection in pre-filled syringe	Viral vaccine (POM)
Influenza virus surface antigens (haemagglutinin and neuraminidase) A/turkey/Turkey/1/2005(H5N1)-like strain used (NIBRG-23) 7.5 micrograms HA per 0.5 ml dose CELLDEMIC® pre-pandemic influenza vaccine suspension for injection in pre-filled syringe	Viral vaccine (POM)
Lutetium (177Lu) chloride 51.8 GBq/ml Lutetium (177Lu) chloride radiopharmaceutical precursor solution	Therapeutic radiopharmaceutical agent (POM)
Macitentan, Tadalafil OPSYNVI® film-coated tablets 10 mg/20 mg, 10mg/40mg	Antihypertensive agent (POM)
Macrogol 4000 (Polyethylene glycol 4000) 4 g Forlax® powder for oral solution 4 g/sachet	Agent for constipation (GSL)
Pitavastatin calcium, Ezetimibe LIVAZEBE® film-coated tablets 2 mg/10 mg, 4 mg/10 mg	Lipid modifying agent (POM)
Risperidone 25 mg/vial, 37.5 mg/vial, 50 mg/vial RYKINDO® extended-release injectable suspension	Antipsychotic agent (POM)
Rivastigmine 25.92 mg, 51.84 mg Zeyzef® twice weekly transdermal patch 4.6 mg/24 h, 9.5 mg/24 h	Antidementia agent (POM)
SARS-CoV-2 recombinant spike protein (Omicron JN.1) 5 mcg/0.5 ml Nuvaxovid® dispersion for injection COVID19 vaccine 5 mcg/dose (recombinant, adjuvanted) in pre-filled syringe	Viral vaccine (POM)
Talazoparib 0.1 mg, 0.35 mg, 0.5 mg TALZENNA® capsules	Antineoplastic agent (POM)
Tegoprazan 25 mg K-CAB® film-coated tablet	Agent for peptic ulcer & gastro-oesophageal reflux disease (POM)
Tenecteplase 5,000 units (25 mg)/vial METALYSE® for injection 5,000 U/vial	Antithrombotic agent (POM)
Tirzepatide 2.5 mg/0.6 ml, 5 mg/0.6 ml, 7.5 mg/0.6 ml, 10 mg/0.6 ml, 12.5 mg/0.6 ml, 15 mg/0.6 ml Mounjaro® KwikPen® solution for injection in pre-filled pen	Antidiabetic agent & agent for weight management (POM)
Tirzepatide 2.5 mg/0.5 ml, 5 mg/0.5 ml, 7.5 mg/0.5 ml, 10 mg/0.5 ml, 12.5 mg/0.5 ml, 15 mg/0.5 ml Mounjaro® solution for injection in vial	Antidiabetic agent & agent for weight management (POM)
BIOSIMILAR	PHARMACOTHERAPEUTIC GROUP
Adalimumab 20 mg/0.2 ml, 40 mg/0.4 ml, 80 mg/0.8 ml AMGEVITA® solution for injection in pre-filled syringe 20 mg/0.2 ml AMGEVITA® solution for injection in pre-filled autoinjector 40 mg/0.4 ml YUFLYMA® solution for injection in pre-filled syringe 20 mg/0.2 ml YUFLYMA® solution for injection in pre-filled pen 80 mg/0.8 ml Hyrimoz® solution for injection in pre-filled pen 40 mg/0.4 ml Hyrimoz® solution for injection in pre-filled syringe 20 mg/0.2 ml, 40 mg/0.4 ml	Immunosuppressant (POM)
Denosumab 120 mg/ml XGEVA® solution for injection in pre-filled syringe	Agent for treatment of bone diseases (POM)
Dupilumab 200 mg/1.14 ml, 300 mg/2 ml DUPIXENT® solution for injection in a pre-filled pen	Immunomodulatory agent (POM)
Faricimab 6 mg/0.05 ml Vabysmo® solution for injection in pre-filled syringe	Ophthalmic anti-vascularisation agent (POM)
Guselkumab 200 mg/2 ml, 200 mg/20 ml TREMIFYA® concentrate for solution for infusion 200 mg/20 ml TREMIFYA® PushPen® solution for injection in pre-filled pen 200 mg/2 ml TREMIFYA® solution for injection in pre-filled syringe 200 mg/2 ml	Immunosuppressant (POM)
Ocrelizumab 920 mg/23 ml Ocrevus® solution for injection	Immunosuppressant (POM)
Risankizumab 180 mg/1.2 ml SKYRIZI® solution for injection in pre-filled cartridge with on-body injector	Immunosuppressant (POM)
Trastuzumab 60 mg/vial TRAZHER® (Trastuzumab) powder for concentrate for solution for infusion	Antineoplastic agent (POM)

POM: Prescription-only medicine

P: Pharmacy-only medicine

GSL: General Sale List