

Drug News

藥物情報

Issue Number 202

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in August 2026 with relevant information update before publish. For the latest news and information, please refer to public announcements or the website of the Drug Office of the Department of Health (<http://www.drugoffice.gov.hk>).

Safety Update

Singapore: CellCept® (mycophenolate mofetil): Update to post-treatment contraception period for women of childbearing potential (extension from 6 weeks to 6 months)

On 13 August 2026, Health Sciences Authority (HSA) announced that a Dear Healthcare Professional Letter has been issued by Roche Singapore Pte Ltd to update healthcare professionals that the recommended duration of post-treatment contraception with Cellcept® for women of childbearing potential has been extended from 6 weeks to 6 months.

This update follows a review of current regulatory guidance and scientific best practices, with the 6-month duration determined in accordance with updated European Medicines Agency's recommendations for medicinal products with genotoxic potential. The recommendation takes into account both drug elimination and the maturation cycle of human oocytes to minimise the potential risk of embryo-fetal exposure. Healthcare professionals are advised to ensure that women of childbearing potential are counselled on the increased risk of pregnancy loss and congenital malformations before starting treatment, and that they use two reliable forms of contraception simultaneously before, during, and for 6 months after discontinuation of treatment. This information will be updated in the product information and in associated risk minimisation materials.

Cellcept is indicated for prophylaxis of acute organ rejection and treatment of refractory organ rejection in patients receiving allogeneic renal transplants;

prophylaxis of acute organ rejection and increased graft and patient survival in patients receiving allogeneic cardiac transplants; and prophylaxis of acute organ rejection in patients receiving allogeneic hepatic transplants.

In Hong Kong, there are 34 registered pharmaceutical products containing mycophenolate mofetil or mycophenolic acid. All products are prescription-only medicines. Related news on the teratogenic risk and contraception advice was issued by various drug regulatory authorities, and was reported in the Drug News since Issue No.72, with the latest update reported in the Drug News Issue No. 98. The Department of Health (DH) issued letters to inform local healthcare professionals to draw their attention on 26 October 2015. In December 2016, the Registration Committee of the Pharmacy and Poisons Board of Hong Kong (the Registration Committee) discussed the teratogenic risk of mycophenolate mofetil and related drugs, and decided that the sales pack and/or package insert of the products should include the relevant safety information.

As of the end of August 2026, the Department of Health (DH) had received 98 cases of adverse drug reaction with regard to mycophenolate mofetil or mycophenolic acid, of which one case was reported as missed abortion after taking the drug. In light of the above HSA's announcement on the update of post-treatment contraception period from 6 weeks to 6 months, the DH issued letters to inform local healthcare professionals to draw their attention on 14 August 2026, and the matter will be discussed by the Registration Committee.

Drug Recall

Recall of six batches of three products “Carbimazole 5 Tab 5mg (Remedica), Remycin 100 Cap 100mg and Methyldopa 250 Tab 250mg (Remedica)”

On 14 August 2026, the Department of Health (DH) endorsed a licensed drug wholesaler, Healthcare Pharmascience Limited (HCPS), to recall six batches of three products, namely (i) Carbimazole 5 Tab 5mg (Remedica) (Hong Kong Registration number: HK-52760; batch numbers: 113195, 120776 and 120809); (ii) Remycin 100 Cap 100mg (Hong Kong Registration number: HK-44279; batch number: 117542); and (iii) Methyldopa 250 Tab 250mg (Remedica) (Hong Kong Registration number: HK-43458; batch numbers: 105371 and 113216) from the market due to potential quality issue.

The DH received notification from HCPS that the overseas manufacturer of the above products is voluntarily recalling the affected batches because ongoing stability testing results in those batches did not meet the quality specifications. As a precautionary measure, HCPS is voluntarily recalling the affected batches from the market.

The above three products contain carbimazole, doxycycline and methyldopa respectively. All three are prescription medicines: carbimazole is used to reduce the formation of thyroid hormones in patients with an overactive thyroid gland, doxycycline to treat bacterial infections, and methyldopa to treat high blood pressure. According to HCPS, the affected batches had been imported into Hong Kong and supplied to private doctors, private hospitals and pharmacies.

As of the end of August 2026, the DH had not received any adverse reaction reports in connection

with the products. A notice was posted in the Drug Office website on 14 August 2026 to alert the public of the product recall. The DH continues to monitor the recall.

Batch Recall of Tykerb Tablets 250mg

On 28 August 2026, the Department of Health (DH) endorsed a licensed drug wholesaler, namely Zuellig Pharma Limited (Zuellig), the distributor appointed by the holder of certificate of drug registration, Novartis Pharmaceuticals (HK) Limited (Novartis), to voluntarily recall one batch (batch number: RD0944) of registered pharmaceutical product, namely Tykerb Tablets 250mg (Hong Kong Registration number: HK-67443) from the market due to quality issue.

The DH received notification from Novartis that the overseas manufacturer of the product is recalling the above batch due to out of specification of dissolution test in the affected batch. Therefore, Novartis voluntarily recalls the affected batch from the market.

The above product, containing lapatinib, is a prescription medicine indicated for the treatment of breast cancer. According to Novartis, the above product was imported into Hong Kong and distributed by Zuellig and has been supplied to the Hospital Authority, local private doctors and pharmacies.

As of the end of August 2026, the DH had not received any adverse reaction reports in connection with the above batch of product. A notice was posted in the Drug Office website on 28 August 2026 to alert the public of the product recall. The DH continues to monitor the recall.

Drug Incident

The Department of Health cracks down on illegal sale or possession of unregistered medicine

On 5 August 2026, the Department of Health (DH) conducted operations across multiple districts in Hong Kong to crack down on the illegal sale or possession of unregistered medicine, seizing approximately 100 boxes of suspected unregistered medicine claimed to have pain-relieving effects. Most of the products were labelled in Japanese. Additionally, a man was arrested on suspicion of violating the Pharmacy and Poisons Ordinance (Chapter 138) (the Ordinance).

The DH received a report that pain relief medicine classified as Part 1 poisons under the Ordinance were being sold or possessed on the market. However, the products were labelled in Japanese and were suspected of not being registered in Hong Kong. Hence, the DH officers conducted unannounced inspections in various districts, including Tsim Sha Tsui, Causeway Bay, Sheung Shui and Yuen Long on 5 August 2026.

DH officers seized approximately 100 boxes of suspected unregistered medicine claimed to have pain-relieving effects at an Authorized Seller of Poisons (ASP), commonly known as a pharmacy, a Listed Seller of Poisons (LSP) commonly known as a medicine company, and two retail outlets. Most of the products were labelled in Japanese and did not bear a Hong Kong pharmaceutical product Registration Number. They are suspected to be medicine containing "Ibuprofen" and "dihydrocodeine". A 38-year-old man was arrested by the police on suspicion of contravention of drug-related offences, including, illegal possession of unregistered pharmaceutical products and Part 1 Poisons.

The DH will continue to investigate and follow-up on the case, and will prosecute other individuals involved in the case when sufficient evidence is available.

Ibuprofen is a non-steroidal anti-inflammatory pain killer and its side effects include nausea, gastrointestinal discomfort and peptic ulcers. Dihydrocodeine is an opioid analgesic used as a cough suppressant and for pain relief, and its side effects include nausea, vomiting, constipation and drowsiness. Medicines containing Ibuprofen and dihydrocodeine are Part 1 poisons and should only be supplied by a pharmacy under the supervision of

a registered pharmacist or upon the advice of a medical practitioner.

A press release was posted in the Drug Office website on 5 August 2026 to alert the public of the drug incident.

The Department of Health continues crackdown on illegal sale or possession of unregistered medicine

On 6 August 2026, the Department of Health (DH) continued to conduct operations across multiple districts in Hong Kong to crack down on the illegal sale or possession of unregistered medicine, seizing more than 140 boxes of suspected unregistered medicine claimed to have pain-relieving effects. Most of the products were labelled in Japanese. Additionally, two men were arrested on suspicion of violating the Pharmacy and Poisons Ordinance (Chapter 138) (the Ordinance).

Following the unannounced inspections in various districts, including Tsim Sha Tsui, Causeway Bay, Sheung Shui and Yuen Long on 5 August 2026, DH officers conducted enforcement operations in Tsim Sha Tsui and Mong Kok on 6 August 2026. At three retail outlets, DH officers seized more than 140 boxes of suspected unregistered medicine claimed to have pain-relieving effects. Most of the products were labelled in Japanese and did not bear a Hong Kong pharmaceutical product registration number. They are suspected to be medicine containing Ibuprofen and dihydrocodeine. Two men aged 36 and 40 were arrested by the Police on suspicion of contravention of drug-related offences, including illegal possession of unregistered pharmaceutical products and Part 1 Poisons etc.

The DH will continue to investigate and follow up on the case, and will prosecute other individuals involved in the case when sufficient evidence is available.

Ibuprofen is a non-steroidal anti-inflammatory pain killer and its side effects include nausea, gastrointestinal discomfort and peptic ulcers. Dihydrocodeine is an opioid analgesic used as a cough suppressant and for pain relief, and its side effects include nausea, vomiting, constipation and drowsiness. Medicines containing Ibuprofen and dihydrocodeine are Part 1 poisons and should only be supplied by a pharmacy under the supervision of a registered pharmacist or upon the advice of a medical practitioner.

Drug Incident

A press release was posted in the Drug Office website on 6 August 2026 to alert the public of the

drug incident.

Others

Establishment of the Expert Group on Pharmacovigilance and Annual Summaries of Adverse Drug Reaction Reports in 2024 and 2025

In view of the upcoming enhancement of the local drug registration regime, in particular the phased implementation of primary evaluation approach in Hong Kong, the Expert Group on Pharmacovigilance (EGPV) has been established under the Pharmacy and Poisons Board on 1 August 2026 to strengthen the local pharmacovigilance and drug safety monitoring framework. Membership of the EGPV is composed of medical practitioner, pharmacist, pharmacologist and academia, and the Terms of Reference of the EGPV are found below:

- (i) To review the benefit-risk profile of drugs available in Hong Kong and assess the impact of emerging drug safety information including the notifications and reports provided by the pharmaceutical industry, and advise the appropriate risk minimizing measures to allow safe use of the concerned drugs for consideration by the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee (“the Registration Committee”) and the Pharmacy and Poisons (Certification of Clinical Trial/ Medicinal Test) Committee (“the CT Committee”) of the Pharmacy and Poisons Board;
- (ii) To review and assess adverse drug reaction (ADR)/adverse event following immunisation (AEFI) reports of drugs and vaccines received and processed by the Department of Health

(DH), with particular focus on selected serious or complicated cases, and advise/endorse the causality assessment and recommend any necessary regulatory or other follow up actions for consideration by the Registration Committee or the CT Committee;

- (iii) To advise and support the implementation of target post-approval interventions or studies for the continuous monitoring of drug safety when there is an impact to public health for consideration by the Registration Committee or the CT Committee;
- (iv) To advocate the DH drug safety monitoring system and promote ADR/AEFI reporting of drugs and vaccines by healthcare professionals and the pharmaceutical industry; and
- (v) To advise, contribute and serve as editorial board for publications on drug safety or promotion of pharmacovigilance practice in Hong Kong.

For further details, please visit the website of the Pharmacy and Poisons Board at:

https://www.ppbhk.org.hk/eng/organization/expert_group_Pharmacovigilance.html

Annual summaries of ADR reports received from healthcare professionals and the pharmaceutical industry in 2024 and 2025 are provided in “*Newsletter on Adverse Drug Reaction*” and included as Special Supplement to Drug News Issue No. 202 (August 2026).

A product containing any western drug ingredient must be registered under the Pharmacy and Poisons Ordinance before it can be sold in Hong Kong. Part 1 poisons should be sold at registered pharmacies under the supervision of registered pharmacists. Illegal sale or possession of Part 1 poisons and unregistered pharmaceutical products are offences under the Pharmacy and Poisons Ordinance (Cap. 138). The maximum penalty is a fine of \$100,000 and two years' imprisonment for each offence. Antibiotics can only be supplied at registered pharmacies by registered pharmacists or under their supervision and upon a doctor's prescription. They should only be used under the advice of a doctor. Illegal sale or possession of antibiotics are offences under the Antibiotics Ordinance (Cap. 137) and the maximum penalty is a \$50,000 fine and one year's imprisonment for each offence.

Under the Import and Export Ordinance (Cap. 60), pharmaceutical products must be imported or exported under and in accordance with an import or export licence issued under the Import and Export Ordinance. Illegal import or export of pharmaceutical products are offences under the Import and Export Ordinance (Cap. 60) and the maximum penalty is a fine of \$500,000 and 2 years' imprisonment.

All registered pharmaceutical products should carry a Hong Kong registration number on the package in the format of "HK-XXXXX". The products mentioned in the above incidents were not registered pharmaceutical products under the Ordinance in Hong Kong. Their safety, quality and efficacy cannot be guaranteed. Members of the public were exhorted not to use products of unknown or doubtful composition. They should stop using the aforementioned products immediately if they had them in their possession and to consult healthcare professionals if they felt unwell after taking the products. The products should be destroyed or disposed properly, or submitted to the Department's Drug Office during office hours.

Update on Drug Office's website: You can now search the newly registered medicines in the past year at http://www.drugoffice.gov.hk/eps/drug/newsNRM60/en/healthcare_providers?pageNoRequested=1.

Details of ALL registered pharmaceutical products can still be found in the Drug Office website at http://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/news_informations/

Useful Contact

Drug Complaint:

Tel: 2572 2068

Fax: 3904 1224

E-mail: pharmgeneral@dh.gov.hk

Adverse Drug Reaction (ADR) Reporting:

Tel: 2319 2920

Fax: 2319 6319

E-mail: adr@dh.gov.hk

Link: <http://www.drugoffice.gov.hk/adr.html>

***Post: Clinical Trials and Pharmacovigilance Unit,
Drug Office, Department of Health,
Suite 2002-05, 20/F, AIA Kowloon Tower, Landmark East,
100 How Ming Street,
Kwun Tong, Kowloon***

The purpose of Drug News is to provide healthcare professionals with a summary of local and overseas drug safety news released. Healthcare professionals are advised to keep update with the information and provide corresponding advice or therapeutic measure to patients and public.

NEWSLETTER ON ADVERSE DRUG REACTION

Special Supplement to Drug News Issue No. 202

Background

The Adverse Drug Reaction Reporting System was initially set up under Adverse Drug Reaction Monitoring Unit of the Pharmaceutical Service, Department of Health, in year 2005 (trial run in year 2004). With the establishment of Drug Office (DO) in year 2011 and reorganized 2019, Adverse Drug Reaction Unit is currently operated under the Drug Evaluation and Pharmacovigilance Division of Drug Office, Department of Health to receive local adverse drug reaction reports from healthcare professionals and the pharmaceutical industry.

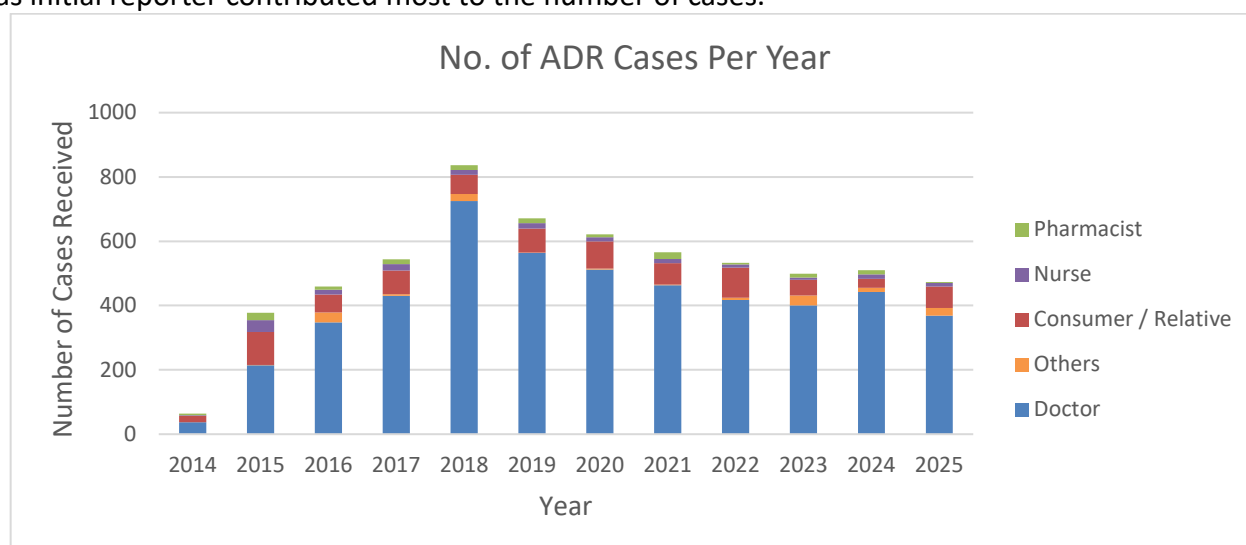
The document “Guidance for Pharmaceutical Industry – Adverse Drug Reaction Reporting Requirements” issued by Drug Office sets out the requirements on reporting adverse drug reactions of pharmaceutical products in Hong Kong by the pharmaceutical industry. The pharmaceutical industry should comply with the Guidance and report serious adverse drug reactions of their products occurring in Hong Kong to Drug Office, Department of Health as soon as possible and no later than 15 calendar days of receipt of information. A serious adverse drug reaction is any untoward medical occurrence that at any dose:

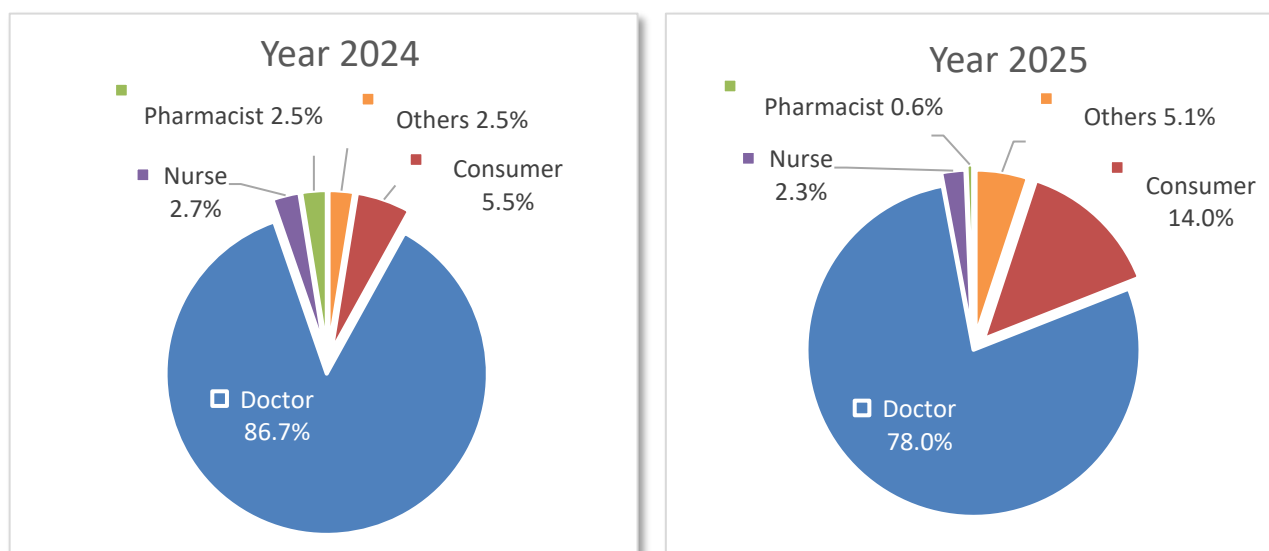
- results in death;
- is life threatening;
- requires inpatient hospitalization or results in prolongation of existing hospitalization;
- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect; or
- is a medically important event or reaction.

Analysis of Reports in 2024 and 2025

Number and source of adverse drug reaction (ADR) cases

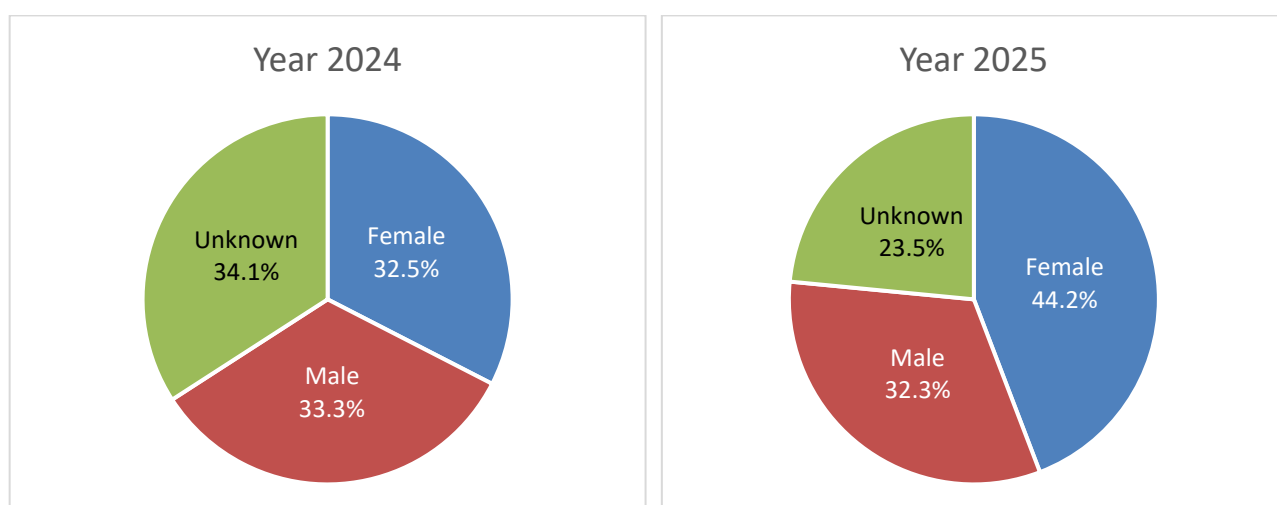
Drug Office received a total of 510 and 473 ADR cases in year 2024 and 2025 respectively. From year 2014 to 2025, Drug Office had received over 6,500 ADR cases. Among the ADR cases received, Doctor as initial reporter contributed most to the number of cases.





A. Demographics (Gender and Age Group)

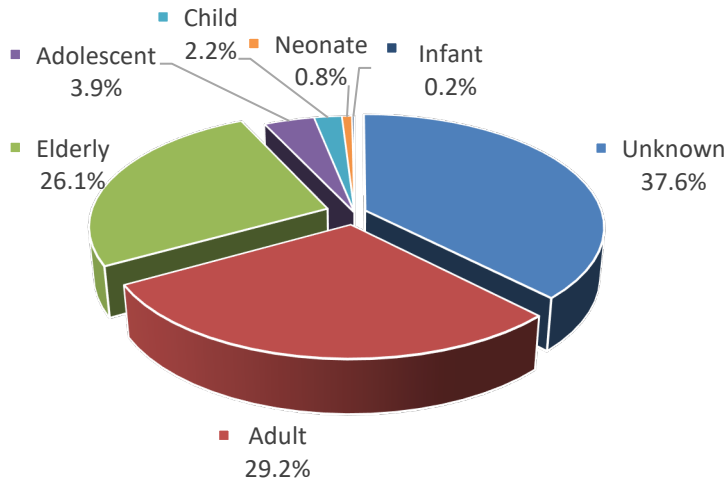
For the ADR cases received in year 2024, there was no significant difference between the genders. Among the ADR cases received in 2025, the gender female was reported in over 44% of the cases. Regarding the age group, around 29% and 35% of the cases were adults in year 2024 and 2025 respectively. No age information was provided in around 38% and 34% of the cases in year 2024 and 2025 respectively.



Gender:

- Female
- Male
- Unknown (or not provided)

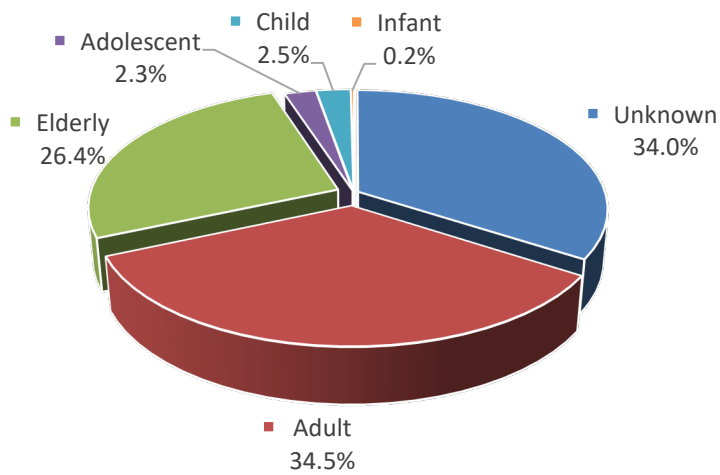
Year 2024



Age Group Classification:

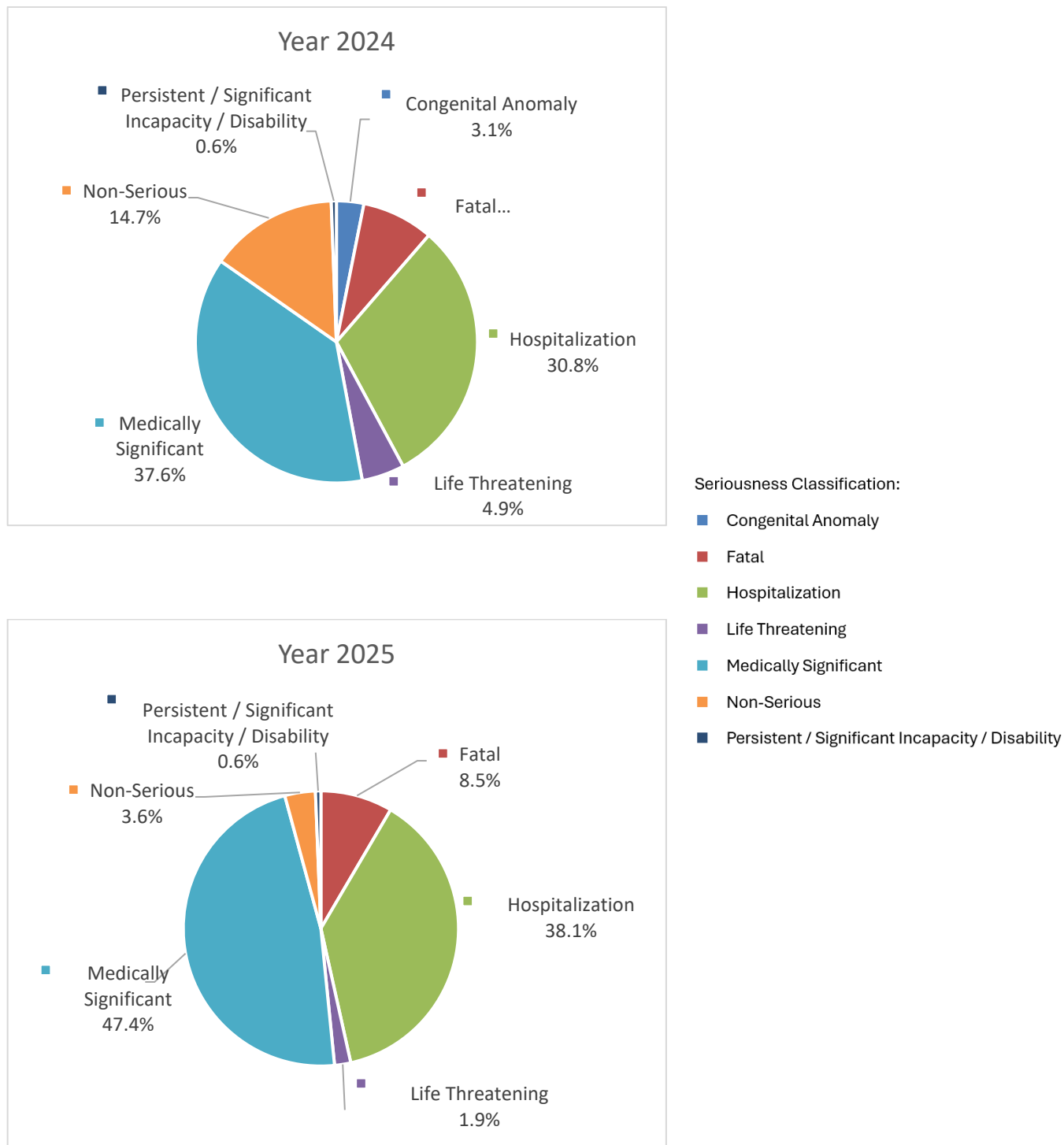
- Elderly (≥65 years old)
- Adult (≥18 years & <65years old)
- Adolescent (≥11 years & <18 years old)
- Child (≥1 years & <11 years old)
- Infant (>28 days & <1 years old)
- Neonate (0-28 days)
- Foetus (Before birth)
- Unknown

Year 2025



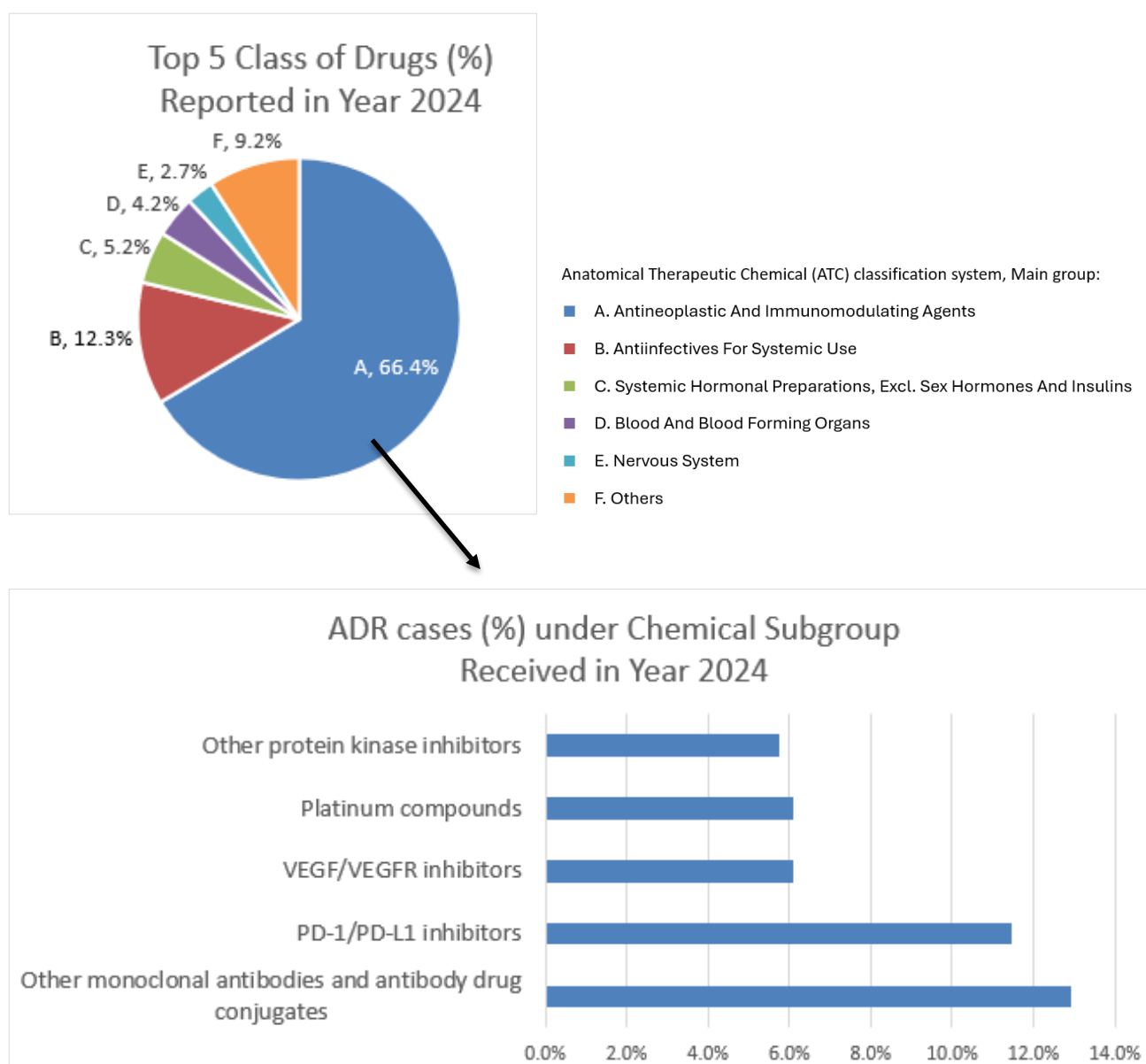
B. Seriousness

Most cases reported to Drug Office were serious as the pharmaceutical industry is obliged to report serious ADR cases.

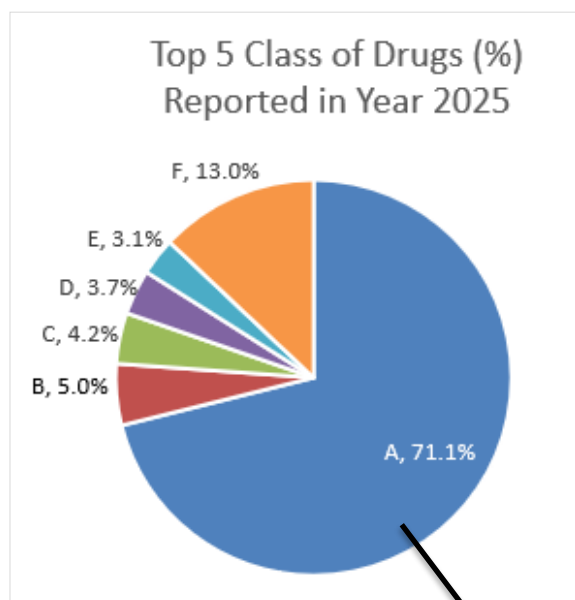


C. Suspected Drugs*

In both years 2024 and 2025, the top class of suspected drugs in the ADR cases received by Drug Office was Antineoplastic and Immunomodulating Agents. Under the aforesaid class of suspected drugs, the top 5 types of drugs reported in year 2024 were other monoclonal antibodies and antibody drug conjugates, PD-1/PD-L1 (Programmed cell death protein 1/death ligand 1) inhibitors, VEGF/VEGFR (Vascular Endothelial Growth Factor / -Receptor) inhibitors, platinum compounds and other protein kinase inhibitors, while the top 6 types of drugs reported in year 2025 were PD-1/PD-L1 (Programmed cell death protein 1/death ligand 1) inhibitors, other monoclonal antibodies and antibody drug conjugates, platinum compounds, nitrogen mustard analogues, taxanes and pyrimidine analogues.

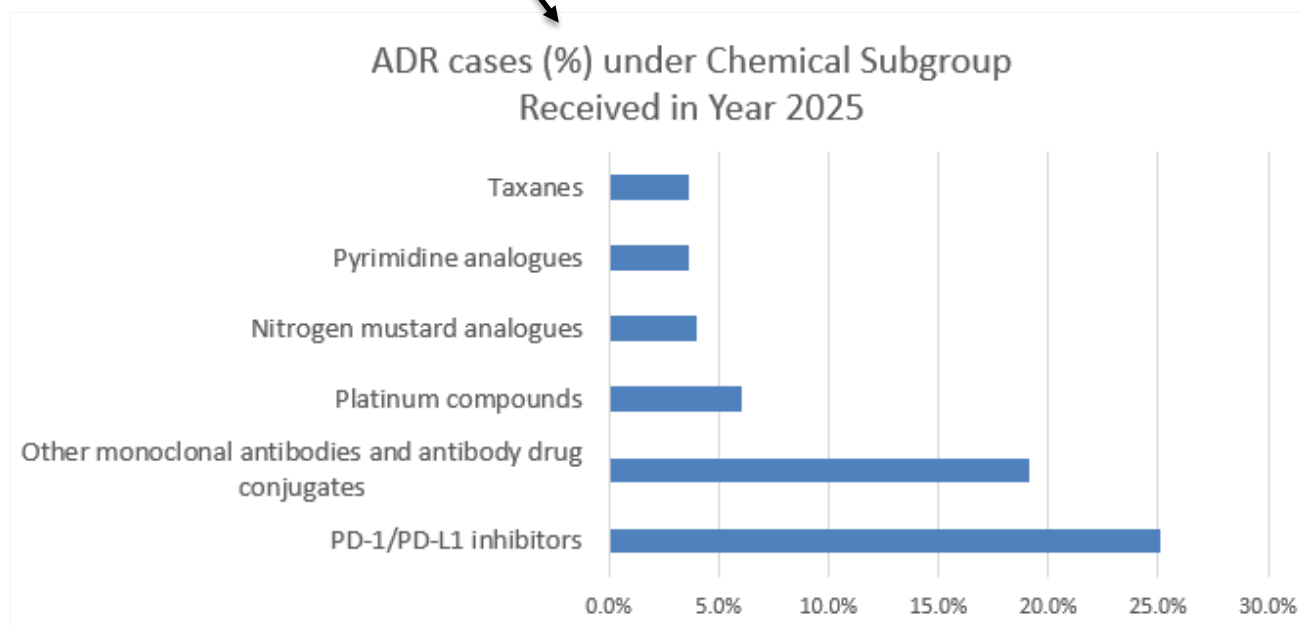


* Suspected drugs were classified according to The Anatomical Therapeutic Chemical (ATC) classification system developed by World Health Organization (WHO)



Anatomical Therapeutic Chemical (ATC) classification system, Main group:

- A. Antineoplastic And Immunomodulating Agents
- B. Musculo-Skeletal System
- C. Nervous System
- D. Antiinfectives For Systemic Use
- E. Blood And Blood Forming Organs
- F. Others



* Suspected drugs were classified according to The Anatomical Therapeutic Chemical (ATC) classification system developed by World Health Organization (WHO)

D. ADR by System Organ Class

In both years 2024 and 2025, the top System Organ Class (SOC[^]) reported were General disorders and administration site conditions, as shown in the tables below.

Ranking	System Organ Class	ADR cases (%)
		in 2024
1	General disorders and administration site conditions (e.g. Pyrexia, Disease Progression, Mucosal inflammation)	16.3%
2	Infections and infestations (e.g. Pneumonia, Lower respiratory tract infection)	13.3%
3	Injury, poisoning and procedural complications (e.g. Foetal exposure during pregnancy)	7.9%

Ranking	System Organ Class	ADR cases (%)
		in 2025
1	General disorders and administration site conditions (e.g. Pyrexia, Disease Progression, Fatigue)	10.0%
2	Injury, poisoning and procedural complications (e.g. Inappropriate schedule of product administration, overdose)	9.4%
3	Infections and infestations (e.g. Pneumonia, Sepsis)	8.9%

[^]The System Organ Class (SOC) refers to the medical terminology by MedDRA (Medical Dictionary for Regulatory Authorities)

Useful Contact

Drug Complaint:

Tel: 2572 2068 Fax: 3904 1224

E-mail: pharmgeneral@dh.gov.hk

Adverse Drug Reaction (ADR) Reporting:

Tel: 2319 2920 Fax: 2319 6319

E-mail: adr@dh.gov.hk Link: <http://www.drugoffice.gov.hk/adr.html>

Post: Drug Evaluation and Pharmacovigilance Division, Clinical Trials and Pharmacovigilance Unit,
Drug Office, Department of Health,
Suites 2002-05, 20/F, AIA Kowloon Tower, Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon

Disclaimers:

Information on suspected ADR should not be interpreted as meaning that the pharmaceutical product in question, or the active substance(s), generally causes the observed effect or is unsafe to use. Any robust conclusion with regard to benefits and risks of a specific pharmaceutical product always requires detailed evaluation and scientific assessment of all available data. The balance between benefit and risk of a specific pharmaceutical product also varies between individual patients. The information in these reports cannot be used to estimate the incidence (occurrence rates) of the reactions reported. If you think that you may be experiencing a side-effect from a pharmaceutical product, please seek advice from a health professional as soon as possible. Never stop or change the dose for prescription medicines without consulting your physician.