Drug News
藥 物 情 報

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This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in June 2013 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

EU / UK / Canada: Recommends codeine only be used in patients aged 12 and over for pain management

On 14 June 2013, the European Medicines Agency (EMA)'s Pharmacovigilance Risk Assessment Committee (PRAC) announced a series of recommendations to address the safety concerns with codeine-containing medicines when used for the management of pain in children. The review was initiated at the request of the UK Medicines and Healthcare Products Regulatory Agency (MHRA) in October 2012, with the concern of children developed serious adverse effects (e.g. respiratory depression) or died after taking codeine for pain relief (most of the cases occurred after surgical removal of the tonsils or adenoids for obstructive sleep apnoea). This is also a follow-up of the US Food and Drugs Administration (FDA) news released in August 2012 regarding contraindication on use of codeine in children after tonsillectomy and/or adenoidectomy, and subsequently a new Box Warning had been added in the US labels in February 2013. These news were reported in Drug News Issues No. 34 and No. 40 respectively.

The PRAC recommended the following risk minimisation measures to ensure that only children for whom benefits are greater than the risks are given the medicine for pain relief:

- codeine-containing medicines should only be used to treat acute (short lived) moderate pain in children above 12 years of age, and only if it cannot be relieved by other painkillers such as paracetamol or ibuprofen, because of the risk of respiratory depression associated with codeine use;
- codeine should not be used at all in children (aged below 18 years) who undergo surgery for the removal of the tonsils or adenoids to treat obstructive sleep apnoea, as these patients are more susceptible to respiratory problems; and
- the prescribing information should carry a warning that children with conditions associated with breathing problems should not use codeine.

The above risk minimisation measures were subsequently endorsed by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) and will be implemented directly by all EMA Member States, according to an agreed timetable. The MHRA subsequently confirmed that codeine-containing medicines should only be used in children over 12 years old to treat acute (short lived) moderate pain, and only if it cannot be relieved by other painkillers such as paracetamol or ibuprofen.

On 6 June 2013, Health Canada also announced that prescription pain and cough medications containing codeine are no longer recommended for use in children less than 12 years of age after the review of the safety of these medicines. This recommendation is based on very rare cases of serious side effects and deaths in children that have been attributed to codeine, when given directly to a child, or to babies from breast milk. Non-prescription products containing codeine already indicate that they should not be administered to children. Health Canada was reviewing the drug labels of affected codeine prescription products and will work with manufacturers to update the labels accordingly.

In Hong Kong, there are 360 registered pharmaceutical products containing codeine, which is an ingredient used to relieve pain and cough. In April 2009, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certificate of Clinical Trial/Medicine Test) Committee (the Registration Committee) of the Pharmacy and Poisons Board had decided that pharmaceutical products for the treatment of cough and cold should not be used for children under 6 years of age, and the label of cough and cold products should be revised accordingly. The latest concern of the use of codeine for children had been discussed in the Registration Committee and the Committee decided that the appropriate statements related to the following safety information must be included in the package insert or label for all medicines containing codeine:

(i) Codeine is not recommended for use in children less than 12 years of age.

(ii) Codeine should only be used to treat acute moderate pain in children above 12 years of age, and only if it cannot be relieved by other painkillers such as paracetamol or ibuprofen.

(iii) Codeine should not be used at all in children (aged below 18 years) who undergo surgery for the removal of the tonsils or adenoids to treat obstructive sleep apnoea.

(iv) Codeine should not be used in children with conditions associated with breathing problems.

(v) Codeine should not be used in people of any age who are known to be ultra-rapid metabolisers nor in breastfeeding mothers.

The dosage instructions should be compatible with the following recommendations (given in respect of codeine phosphate):

Adults and children above 12 years: 15 - 30mg three or four times daily

US: New boxed warning for thrombosis related to human immune globulin products

On 10 June 2013, FDA announced to add information on thrombosis to the current boxed warning to all intravenous (IV) human immune globulin products' labels and to add a boxed warning to all subcutaneous (SC) and intramuscular (IM) human immune globulin products' labels, so as to highlight the risk of thrombosis. This is a follow-up of the risks of thrombosis and haemolysis released by FDA in November 2012 and reported in Drug News Issue No. 37. A retrospective analysis of data from a large health claims-related database, as well as continued postmarketing adverse event reports of thrombosis have strengthened the evidence for an association between the use of IV, SC, and IM human immune globulin products and the risk of thrombosis. Although all human immune globulin products already contain some information related to the risk of thrombosis in the current WARNINGS and PRECAUTIONS sections of their labels, FDA recognized that the communication of this risk and its mitigation are not standardized. FDA proposes that for thrombosis a more prominent placement of risk information and a uniform approach for communicating the risk and its possible mitigation will help to reduce the occurrence of these serious adverse events. The information on thrombosis in the boxed warning states:

1. thrombosis may occur regardless of the route of administration;
2. risk factors include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity and cardiovascular risk factors;
3. thrombosis may occur in the absence of known risk factors;
4. for patients at risk of thrombosis, administer at the minimum concentration available and at the minimum rate of infusion practicable;
5. ensure adequate hydration in patients before administration; and
6. monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

In Hong Kong, there are 30 immunoglobulin-containing products registered and all are prescription only medicines. They are indicated in disorders such as primary and secondary antibody deficiencies and passive immunisations. The matter was discussed by the Registration

Committee in April 2013, and the Committee decided that the sales pack labels and/or package inserts of products containing human immunoglobulin should include the appropriate safety information, such as examples given as below:

Thrombosis:
- Care should be used when normal immunoglobulin products are given to individuals determined to be at increased risk of thrombosis.
- Patients at increased risk of thrombosis include those with acquired or hereditary hypercoagulable states, prolonged immobilization, in-dwelling vascular catheters, advanced age, estrogen use, a history of venous or arterial thrombosis, cardiovascular risk factor (including history of atherosclerosis and/or impaired cardiac output), and hyperviscosity (including cryoglobuins, fasting chylomicronemia and/or high triglyceride levels, and monoclonal gammopathies).
- Patients at risk for thrombosis should receive normal immunoglobulin products at the slowest infusion rate practicable, and these individuals should be monitored for thrombotic complications.
- Consideration should also be given to measurement of baseline blood viscosity in individuals at risk of hyperviscosity.

Hemolysis:
- Heightened awareness of the potential for hemolysis is recommended in individuals receiving normal immunoglobulin products, particularly those who are determined to be at increased risk.
- Patients at increased risk for hemolysis following treatment with normal immunoglobulin include those with non-O blood group types, those who have underlying associated inflammatory conditions, and those receiving high cumulative doses of normal immunoglobulin over the course of several days.
- Patients receiving normal immunoglobulin products should be monitored for hemolysis, particularly those at increased risk.
- Clinical symptoms and signs of hemolysis include fever, chills and dark urine. If these occur, appropriate laboratory testing should be obtained.

EU / US / Canada / UK: Updates on infusion solutions containing hydroxyethyl-starch

On 14 June 2013, the EMA's PRAC concluded that the benefits of infusion solutions containing hydroxyethyl-starch (HES) no longer outweigh their risks and therefore recommended that the marketing authorisations for these medicines be suspended. The review of infusion solutions containing HES was triggered by the German Medicines Agency, the Federal Institute for Drugs and Medical Devices, following three recent studies that compared HES with other products used for volume replacement called crystalloids in critically ill patients. The studies showed that patients with severe sepsis treated with HES were at a greater risk of kidney injury requiring dialysis. Two of the studies also showed that there was a greater risk of mortality in patients treated with HES. The PRAC considered that the available data only showed a limited benefit of HES in hypovolaemia, which did not justify its use considering the known risks. The PRAC therefore concluded that the marketing authorisations for these medicines be suspended. The suspension should remain in place unless the marketing authorisation holder can provide convincing data to identify a group of patients in whom the benefits of the medicines outweigh their risks.

On 24 June 2013, FDA concluded that HES solutions should not be used in critically ill adult patients, including patients with sepsis and those admitted to the ICU, and a Boxed Warning to include the risk of mortality and severe renal injury is warranted. FDA analyzed recent data that indicated an increased risk of (i) mortality and renal injury requiring renal replacement therapy in critically ill adult patients, including patients with sepsis and those admitted to the Intensive Care Unit (ICU); and (ii) excess bleeding particularly in patients undergoing open heart surgery in association with cardiopulmonary bypass. FDA also reviewed a meta-analysis of studies conducted in patients undergoing open heart surgery in association with cardiopulmonary bypass and determined that an additional warning about excessive bleeding is needed in the Warnings and Precautions Section of the package insert for these products.

Health Canada also annnounced that HES solutions are now contraindicated in patients with sepsis, with severe liver disease, and in certain types of patients with impaired kidney function. Health Canada worked with the manufacturers and the Product Monographs of the products concerned have been modified to include the above contraindications.

MHRA followed the recommendation of EMA's PRAC and announced that the use of HES drips to treat critically ill patients and those undergoing surgery was to be suspended in the UK because their benefits no longer outweigh the risk of using them. All the unexpired stock of related products is being recalled to pharmacy, clinic and wholesaler level irrespective of batch number and expiry date., i.e., Tetraspan 10% solution for infusion (500ml), 6% (500ml) and Venofundin 60mg/ml solution for infusion (500ml); Voluven 10% solution for infusion (500ml), 6% (500ml) and Volulyte 6% solution for infusion (500ml) were recalled.

In Hong Kong, there are 6 registered pharmaceutical products containing HES, namely Voluven Infusion 6% (HK-50474), Volulyte 6% Solution for Infusion (HK-58087), Tetraspan 6% Solution for Infusion (HK-56978) and 10% (HK-56979), Hestar-200 Inj. 10% (HK-57095) and 6% (HK-57096). Only 2 products, Voluven Infusion 6% and Volulyte 6% Solution for Infusion which are registered by Fresenius Kabi HK Ltd., are marketed in Hong Kong. They are indicated for the therapy and prophylaxis of hypovolaemia. A letter to healthcare professionals was issued on 17 June 2013. The Registration Committee discussed the matter at its latest meeting and, based on the available evidences, concluded that DH will remain vigilant on any further new safety updates of HES released by overseas regulatory authorities for future consideration by the Registration Committee when necessary.

Singapore: Antibody-Mediated Pure Red Cell Aplasia (PRCA) case cluster observed with subcutaneous administration of erythropoietin (EPO) Eprex® at a Singapore Institution

It was noted from Health Sciences Authority (HSA) website on 22 June 2013 that Janssen, a division of Johnson & Johnson Pte Ltd ("Janssen"), informed healthcare professionals of an increase in the number of EPO antibody-mediated PRCA cases with onset in 2012 and 2013 observed from one institution in Singapore. These cases comprise a cluster of 6 Eprex® reports and were reported in patients who had received subcutaneous administration of Eprex® at some point during their treatment. Janssen wishes to reinforce the vigilance for, and identification of, EPO antibody-mediated PRCA and the appropriate storage and handling of Eprex® that is described in the Singapore prescribing information.

In Hong Kong, there are nine pharmaceutical products containing epoetin alfa (a type of erythropoietin) registered under the brand name of Eprex. Eprex are prescription only medicines registered by Johnson & Johnson (HK) Ltd. and are indicated for the treatment of symptomatic anaemia associated with chronic renal failure in adult and paediatric patients. DH will keep vigilant against any safety updates of the drug and actions taken by overseas regulatory authorities for consideration of any action deemed necessary.

EU: New recommendations to manage risk of allergic reactions with intravenous iron-containing medicines

On 28 June 2013, the EMA's Committee for Medicinal Products for Human Use (CHMP) completed its review of IV iron-containing medicines used to treat iron deficiency and anaemia associated with low iron levels. The CHMP concluded that the benefits of these medicines are greater than their risks, provided that adequate measures are being taken to minimise the risk of allergic reactions. All IV iron medicines have a small risk of causing allergic reactions which can be life-threatening if not treated promptly. The CHMP therefore concluded that measures should be put in place to ensure the early detection and effective management of allergic reactions that may occur. Iron preparations should only be given in an environment where resuscitation facilities are available, so that patients who develop an allergic reaction can be treated immediately. In addition, the CHMP considered that the current practice of first giving the patient a small test dose is not a reliable way to predict how the patient will respond when the full dose is given. A test dose is therefore no longer be recommended but instead caution is warranted with every dose of IV iron that is given, even if previous administrations have been well tolerated.

The CHMP also considered that, during pregnancy, allergic reactions are of particular concern as they can put both the mother and unborn child at risk. IV iron medicines should therefore not be used during pregnancy unless clearly necessary. Treatment should be confined to the second or third trimester, provided the benefits of treatment clearly outweigh the risks to the unborn baby.

In Hong Kong, there are 6 registered IV iron-containing pharmaceutical products indicated to treat iron deficiency or anaemia associated with low iron levels. In view of the findings by EMA, a letter to healthcare professionals was issued on 2 July 2013, and the matter will be discussed in the meeting of the Registration Committee.

EU: New restrictions on use of medicines containing ergot derivatives

On 28 June 2013, the EMA's CHMP recommended restricting the use of medicines containing ergot derivatives. These medicines should no longer be used to treat several conditions involving blood circulation problems or problems with memory and sensation, or to prevent migraine headaches, since the risks are greater than the benefits in these indications. This is based on a review of data showing an increased risk of fibrosis (formation of excess connective tissue) and ergotism (symptoms of ergot poisoning, such as spasms and obstructed blood circulation) in patients taking these medicines. Ergot derivatives that are only indicated for these conditions will have their marketing authorisations suspended across the EU. In some EU Member States, ergot derivatives are also authorised for other indications such as treatment of dementia, including Alzheimer's disease, and treatment of acute migraine headache. They will remain authorised for use by patients in those indications.

Fibrosis can be a serious, sometimes fatal disease, which is often difficult to diagnose because of delayed symptoms and may be irreversible. The CHMP noted that there is a plausible mechanism by which ergot-derivatives could cause fibrosis and ergotism. Given that the evidence for these medicines' benefits in these indications was very limited, the CHMP concluded that the benefits in the concerned indications did not outweigh the risk of fibrosis and ergotism.

In Hong Kong, there are 16 registered pharmaceutical products containing ergot derivatives, of ingredients nicergoline, codergocrine (dihydroergotoxine) or dihydroergocryptin. They are indicated for blood circulations problems or problems with memory and sensation, or to prevent migraine headaches. In view of the findings by EMA, a letter to healthcare professionals was issued on 2 July 2013, and the matter will be discussed in the meeting of the Registration Committee.

Drug Recall

Batch recall of APO-K Slow-Release tablet 600mg (HK-36868)

On 4 June 2013, DH endorsed a licensed drug wholesaler, Hind Wing Co. Ltd. (Hind Wing), to recall from shelves two batches of APO-K Slow-Release tablet 600mg (batch numbers JP0380 and JP0385) due to potential quality issue. APO-K Slow-Release 600 mg tablet, containing potassium chloride, is an over-the-counter pharmaceutical product used for the prevention of diuretic-induced hypokalaemia.

DH received notification from Hind Wing that the product's manufacturer in Canada, Apotex Inc., found the tablet coating solution used for the manufacture of three batches of the APO-K Slow Release tablet may have contained metal particles. Investigation by the manufacturer revealed that the metal particles were confirmed to be stainless steel which came from a piece of mixing equipment used for the preparation of the coating solution. According to the manufacturer, no APO-K Slow-Release tablet was found to have contained any metal particle so far. However, as a precautionary measure, the manufacturer decided to recall the three affected batches globally.

Based on Hind Wing's record, two of the three affected batches under global recall had been imported into Hong Kong for distribution in 2010. The affected batches were supplied to private doctors, local pharmacies and private hospitals. DH had closely monitored the recall. As of 4 June 2013, DH had not received any adverse drug reaction reports in connection with the product. A press statement was released on the same day to alert the public of the recall.

Drug Recall

Batch recall of Ambisome for Injection 50mg (HK-43591)

On 18 June 2013, DH endorsed a licensed drug wholesaler, LF Asia (HK) Ltd. - Healthcare Division (LF Asia), to recall from market four batches (batch numbers: 042265AD, 042270AD, 042270AD1 and 042270AD2) of Ambisome for Injection 50mg due to potential quality issue. Ambisome for Injection 50mg, containing amphotericin B, is an antifungal agent used for the treatment of severe fungal infections. It is a prescription medicine and can only be used under medical advice.

DH received notification from LF Asia that the product's manufacturer in Ireland, Gilead Sciences Ltd., detected contamination at the manufacturing facility during its routine process sterility testing. Although so far none of the Ambisome injection was found to be contaminated, the manufacturer initiated a worldwide recall of all 20 affected batches manufactured since July 2012 as a precautionary measure.

According to LF Asia, four affected batches of Ambisome for Injection 50mg were imported into Hong Kong since January 2013. About 3,000 affected bottles were supplied to the Hospital Authority (HA) and private hospitals, local pharmacies and private doctors. DH had closely monitored the recall. As of 18 June 2013, DH had not received any adverse drug reaction reports in connection with the product. A press statement was released on the same day to alert the public of the recall.

Members of the public who are in doubt should seek advice from their healthcare providers.

Drug Incident

Public urged not to buy or use unregistered pharmaceutical product with controlled drug ingredient

On 5 June 2013, DH appealed to members of the public not to buy or use an injectable product named Human Albumin 25% Zinvie (德國先威人血白蛋白注射液) as it was suspected to be an unregistered pharmaceutical product.

DH was notified by HA about a 20-year-old female patient who was hospitalized for having chills, rigors, nausea, vomiting and diarrhoea. She was diagnosed as septic shock upon admission. Her family described a history of consumption of the above product by the patient.

The Human Albumin 25% Zinvie was labeled as containing albumin, but Hong Kong pharmaceutical product registration number was not found on the product label. Pharmaceutical products containing albumin are prescription medicine and are used in conditions such as burns and severe acute albumin loss. They should only be used under medical advice and sold at pharmacies under the supervision of a registered pharmacist upon a doctor's prescription.

Members of public are urged not to buy or consume unregistered pharmaceutical products as they have not been evaluated by the Pharmacy and Poisons Board and their safety, quality and efficacy are not guaranteed.

Public urged not to buy or use slimming products with undeclared and/or banned drug ingredients

In June 2013, DH appealed to members of the public not to buy or consume slimming products called "Super Fat Burning Bomb" (博美堂左旋肉碱), "OxyELITE Pro", "4C Cosmoslim" (4C 鑽石瘦身), "LV Shou Reduces Fat" (綠瘦), "Lami Capsules" and seven unlabelled products with names in Thai, as they were found to contain undeclared and/or banned drug ingredients that are dangerous to health.

DH was notified by the HA about the patients feeling unwell after consumption of the products. The details of these cases were summarized as follows:

Patients	Products consumed	Symptoms developed	Drug ingredients detected in laboratory test
A 34-year-old female	"Super Fat Burning Bomb" (博美堂左旋肉碱)	Intra-cranial haemorrhage	Sibutramine and phenolphthalein
A 21-year-old female	"OxyELITE Pro"	Acute hepatitis symptoms	Yohimbine
A 29-year-old female	"4C Cosmoslim" a. (4C 鑽石瘦身) b. "LV Shou Reduces Fat" (綠瘦)	Psychiatric symptoms including persecutory delusion and auditory hallucination	a. Sibutramine and phenolphthalein b. Sibutramine
A 15-year-old female	Lami Capsules	Psychotic symptoms including flights of ideas, insomnia and auditory hallucination	Sibutramine
A 19-year-old female	Seven unlabelled products with product names in Thai	Palpitations	Sibutramine, hydrochlorothiazide, fluoxetine, chlorpheniramine, bisacodyl were found in six products; animal thyroid tissues were found in another product

Sibutramine is a Part I poison and was once used as an appetite suppressant. Since November 2010, all products containing sibutramine have been banned in Hong Kong because of an increased cardiovascular risk. Phenolphthalein was once used for treating constipation but has been banned in Hong Kong for its possible cancer-causing effect.

Yohimbine, a Part I poison, was sometimes used in the treatment of orthostatic hypotension. Its side-effects include increase in heart rate and blood pressure, anxiety, manic reactions and bronchospasm. Products containing yohimbine can only be sold in a pharmacy under the supervision of a registered pharmacist.

Hydrochlorothiazide is a diuretic and is also used for the treatment of hypertension. It may cause hypotension and electrolyte imbalance. Fluoxetine is used for depression and may cause postural hypotension and alopecia. It must be sold with prescriptions at pharmacies under the supervision of pharmacists. Chlorpheniramine is an over-the-counter Western drug commonly used for relieving allergic symptoms. The most well-known side effect is drowsiness. Bisacodyl is a laxative that may cause abdominal pain. As for animal thyroid tissues, they are not an appropriate agent for weight reduction.

Weight control should be achieved through a balanced diet and appropriate exercises. The public should consult healthcare professionals before using any medication for weight control.

This was the second incidence of news relating to "4C Cosmoslim" and the previous case was reported in Drug News Issue No. 43.

Pharmacy raided for suspected illegal sale of antibiotic

On 3 June 2013, a joint operation was conducted by DH and the Police against a registered pharmacy resulting in the arrest of a 56-year-old salesman for suspected illegal sale of an antibiotic.

Through DH's surveillance programme, the pharmacy was found to be selling an antibiotic without a doctor's prescription. The antibiotic concerned is amoxicillin, which is used for the treatment of bacterial infections. The product can only be supplied at pharmacies under the supervision of a registered pharmacist upon the production of a doctor's prescription. It should only be used under the advice of a doctor.

Members of the public should only take antibiotics prescribed by a doctor and follow the health professionals' instructions. Inappropriate and irrational use of antibiotics provides favourable conditions for resistant microorganisms to emerge and spread.

Retail shop raided for suspected illegal possession of controlled medicine

On 6 June 2013, a joint operation was conducted by DH and the Police resulting in the arrest of a 43-year-old man for suspected illegal possession of Part I poisons and antibiotics.

During the DH's market surveillance, a retail shop was found to be in possession of a number of controlled medicines, including Part I poisons (some of which are prescription medicines) and antibiotics. Investigation revealed that the controlled medicines found were all registered pharmaceutical products. However, the retail shop does not have any valid licence issued by the Pharmacy and Poisons Board of Hong Kong to possess the controlled medicines.

Man arrested for suspected illegal sale of unregistered pharmaceutical products on the Internet

On 28 June 2013, a joint operation was conducted by the DH and the Police resulting in the arrest of a 40-year-old man for suspected illegal sale of two unregistered pharmaceutical products, namely “Swanson Cranberry” and “NeoCell super Collagen+C”.

Upon the investigation of a public complaint, DH found that the above products were being offered for sale on the Internet. The products were labelled as containing vitamin C, but Hong Kong pharmaceutical product registration numbers were not found on any of the product labels. Pharmaceutical products containing vitamin C are over-the-counter medicines used as nutritional supplements.

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 I poisons should be sold at registered pharmacies under the supervision of registered pharmacists. Illegal sale or possession of Part I 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 $30,000 fine and one year's imprisonment for each offence.

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.

Useful Contact

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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.