



Drug

藥物

News

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 2018 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: EMA restricts use of Keytruda and Tecentriq in bladder cancer. Data show lower survival in some patients with low levels of cancer protein PD-L1.

On 1 June 2018, the European Medicines Agency (EMA) of the European Union (EU) announced that early data from two clinical trials show reduced survival with Keytruda (pembrolizumab) and Tecentriq (atezolizumab) when used as first-line treatments for urothelial cancer (cancer of the bladder and urinary tract) in patients with low levels of a protein called programmed death-ligand 1 (PD-L1). The data indicate that Keytruda and Tecentriq may not work as well as chemotherapy medicines in this group of patients.

As a result, EMA has recommended restricting the use of these medicines as first line-treatments for urothelial cancer.

Keytruda and Tecentriq should now only be used for first-line treatment of urothelial cancer in patients with high levels of PD-L1. There are no changes to how these medicines should be used in patients with urothelial cancer who have had chemotherapy or in patients with other cancers for which these medicines are approved.

The two clinical trials are continuing but no new patients with low levels of PD-L1 will be given only Keytruda or Tecentriq. Patients in the trials who have any questions should speak to the doctor treating them.

The review of data on Keytruda and Tecentriq was carried out by EMA's Committee for Medicinal Products for Human Use (CHMP). The CHMP

opinion will be forwarded to the European Commission (EC), which will issue a final legally binding decision applicable in all EU Member States.

In Hong Kong, Keytruda Solution for Injection 100mg/4ml (HK- 64228) and Keytruda Powder for Injection 50mg (HK- 64229) are pharmaceutical products registered by Merck Sharp & Dohme (Asia) Ltd while Tecentriq Concentrate for Solution for Infusion 1200mg/20ml (HK-65567) is a pharmaceutical product registered by Roche Hong Kong Limited. All three products are prescription-only medicines and are indicated for urothelial carcinoma. In view of the EMA announcement on the restriction, the Department of Health (DH) issued a letter to inform local healthcare professionals to draw their attention on 4 June 2018, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board (the Registration Committee).

Canada: BLINCYTO (blinatumomab) and Benzyl Alcohol Toxicity for Pediatric Patients

On 12 June 2018, Health Canada informed healthcare professionals for the serious and fatal adverse reactions including "gasping syndrome" occurring in paediatric patients; particularly in neonates and infants when treated with BLINCYTO containing benzyl alcohol as a preservative.

Benzyl alcohol has the potential to cause serious and fatal adverse reactions when administered intravenously to neonates and infants. Therefore, 0.9% sodium chloride containing 0.9% benzyl

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alcohol is not recommended for use in the preparation of BLINCYTO intended to be administered to neonates, infants, or patients weighing less than 22 kg.

BLINCYTO is indicated for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in Canada. BLINCYTO has also been issued marketing authorization in Canada with conditions, for the treatment of paediatric patients with Philadelphia chromosome-negative relapsed or refractory B cell precursor ALL, pending the results of studies to verify its clinical benefit.

In Canada, BLINCYTO has recently been authorized with an additional option of preparing a 7-day infusion bag containing benzyl alcohol for patients weighing greater than or equal to 22 kg. It is not recommended for use in patients weighing less than 22 kg.

When preparing bags of BLINCYTO solution for infusion in neonates, infants and patients weighing less than 22 kg, healthcare professionals are advised to only utilize preservative-free saline.

In Hong Kong, there is a registered pharmaceutical product containing blinatumomab (i.e. Blincyto Powder for Concentrate and Solution for Solution for Infusion 35mcg/Vial (HK-65074)) registered by Amgen Asia Holding Limited (Amgen), and is a prescription-only medicine. According to the registered information of Blincyto (HK-65074), the product instruction does not include its use in a 7-day infusion bag containing benzyl alcohol.

As on 5 July 2018, DH has received one case of adverse drug reaction (ADR) with blinatumomab; but it was not related to benzyl alcohol. DH shall remain vigilant on any safety updates of the drug issued by other overseas drug regulatory authorities.

UK: Denosumab (Xgeva) for giant cell tumour of bone: risk of clinically significant hypercalcaemia following discontinuation

On 22 June 2018, the Medicines and Healthcare products Regulatory Agency (MHRA) of the

United Kingdom (UK) announced that cases of rebound hypercalcaemia have been reported up to 9 months after cessation of treatment. Healthcare professionals should monitor patients for signs and symptoms of hypercalcaemia after discontinuation of denosumab treatment for giant cell tumour of bone.

Cases of clinically significant hypercalcaemia requiring hospitalisation and complicated by acute renal injury have been reported in a clinical trial of adults and skeletally mature adolescents with giant cell tumour of bone. Cases of rebound hypercalcaemia were reported up to 9 months after discontinuation of denosumab. Cases have also been through some national ADR reporting schemes. No Yellow Cards have been received of this suspected ADR with denosumab in UK, but continued vigilance is recommended.

The Summary of Product Characteristics (SmPC) for Xgeva in UK has been updated to include risk of hypercalcaemia following discontinuation of treatment for giant cell tumour of the bone. This adverse event is thought to occur uncommonly, with an estimated frequency of occurring in fewer than 1 in every 100 patients receiving denosumab. Symptoms of hypercalcaemia include excessive thirst, fatigue, drowsiness, confusion, loss of concentration, depression, nausea, vomiting, constipation, and muscle and/or bone pain.

Clinically significant hypercalcaemia is a known risk after stopping denosumab treatment in patients with growing skeletons; denosumab is not recommended in this patient group.

Healthcare professionals are advised:

- cases of clinically significant hypercalcaemia (rebound hypercalcaemia) have been reported up to 9 months after discontinuation of denosumab treatment for giant cell tumour of bone.
- monitor patients for signs and symptoms of hypercalcaemia after discontinuation, consider periodic assessment of serum calcium, and re-evaluate the patient's calcium and vitamin D supplementation requirements.
- advise patients to report symptoms of hypercalcaemia.
- denosumab is not recommended in patients

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with growing skeletons.

- report any suspected adverse reactions to denosumab or other medicines.

In Hong Kong, Xgeva Solution for Injection 120mg (HK-61163) is a pharmaceutical product registered by Amgen, and is a prescription-only medicine. As on 5 July 2018, DH has received 15 cases of ADR related to denosumab, but these cases were not related to hypercalcaemia.

In June 2018, Amgen submitted an application for update of the product insert to include the safety information on hypercalcaemia following treatment discontinuation in patients with giant cell tumour of bone, and the application is currently being processed. In light of the above MHRA's announcement, DH issued a letter to inform local healthcare professionals to draw their attention on 25 June 2018. DH will remain vigilant on safety update of the product issued by other overseas drug regulatory authorities.

UK: Denosumab (Xgeva) for advanced malignancies involving bone: study data show new primary malignancies reported more frequently compared to zoledronate

On 22 June 2018, MHRA announced that a pooled analysis has shown an increased rate of new primary malignancies in patients given Xgeva (1-year cumulative incidence 1.1%) compared with those given zoledronic acid (0.6%), when used in the indication of the prevention of skeletal-related events with advanced malignancies involving bone. No treatment-related pattern in individual cancers or cancer groupings were apparent.

A recent EU review of Xgeva has added into the product information the risk of new primary malignancy when used for the prevention of skeletal-related events in adults with advanced malignancies involving bone. A letter has been sent to healthcare professionals about this risk.

In a pooled analysis of four phase III studies in patients with advanced malignancies involving bone, new primary malignancy was reported more frequently in patients treated with Xgeva (denosumab 120 mg, once a month) compared to

zoledronic acid (4 mg, once a month) during the primary double-blind treatment phases of these studies. New primary malignancy occurred in 54 (1.5%) of 3,691 patients treated with Xgeva (median exposure of 13.8 months; range: 1.0–51.7 months) and in 33 (0.9%) of 3,688 patients treated with zoledronic acid (median exposure of 12.9 months; range: 1.0–50.8 months). The cumulative incidence at 1 year was 1.1% for denosumab and 0.6% for zoledronic acid. No treatment-related pattern in individual cancers or cancer groupings were apparent.

In Hong Kong, Xgeva Solution for Injection 120mg (HK-61163) is a pharmaceutical product registered by Amgen, and is a prescription-only medicine. As on 5 July 2018, DH has received 15 cases of ADR related to denosumab, of which one case was cancer related to the use of Prolia (another drug containing 60mg of denosumab). In light of the above MHRA's announcement, DH issued a letter to inform local healthcare professionals to draw their attention on 25 June 2018 and the matter will be discussed by the Registration Committee.

US: FDA approves labeling supplement for Celebrex (celecoxib)

On 28 June 2018, the United States (US) Food and Drug Administration (FDA) approved a labeling supplement for Celebrex (celecoxib), a cyclooxygenase-2 (COX-2) selective non-steroidal anti-inflammatory drug (NSAID), to include results from a postmarketing cardiovascular (CV) outcomes trial that found that at the lowest dose, Celebrex was similar to moderate doses of naproxen and ibuprofen with regard to CV safety.

The concerns about the CV thrombotic risk of COX-2 selective NSAIDs emerged in the early 2000's. Following an FDA Advisory Committee meeting held in 2005, in which data from large clinical outcome trials in a wide range of indications and epidemiology studies of several individual NSAIDs were considered, FDA concluded that the risk for CV thrombotic events was present for both COX-2 selective NSAIDs and nonselective NSAIDs.

The "Prospective Randomized Evaluation of Celecoxib Integrated Safety vs Ibuprofen or Naproxen" (PRECISION) trial was conducted to

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address the remaining concerns about the relative CV safety of COX-2 selective NSAIDs and non-selective NSAIDs. PRECISION was a large, randomized, double-blind controlled trial that began in 2006. Ninety percent of the patients enrolled in the trial had osteoarthritis and the remaining 10% had rheumatoid arthritis.

The results of the PRECISION trial demonstrated that celecoxib at the lowest approved dose of 100 mg twice daily, is non-inferior to (or no worse than) ibuprofen dosed in the range of 600 mg - 800 mg three times daily or naproxen dosed in the range of 375 mg - 500 mg twice daily on a composite CV endpoint consisting of CV death, nonfatal myocardial infarction (MI), and nonfatal stroke.

In an ambulatory blood pressure monitoring study that was part of the larger PRECISION trial, celecoxib dosed at 100 mg twice daily showed little effect on average 24-hour systolic blood pressure (SBP), whereas ibuprofen dosed in the range of 600 mg - 800 mg three times daily and naproxen dosed in the range of 375 mg - 500 mg twice daily increased average 24-hour SBP by 3.7 mmHg and 1.6 mmHg, respectively.

Too few patients received higher doses of Celebrex to evaluate the risk of CV events or the effect on blood pressure for doses greater than 100 mg twice daily. The CV risks of the NSAID class are dose-dependent, therefore, the results for celecoxib 100 mg twice daily on the composite CV endpoint and the lack of effect on SBP cannot be extrapolated to dosing regimens using the higher strengths of celecoxib (200 mg or 400 mg). Patients with recent CV events such as acute MI, coronary revascularization, or coronary stent placement were not studied in the PRECISION trial. NSAID class labeling warns against the use of NSAIDs in such patients.

In Hong Kong, there are 36 registered pharmaceutical products containing celecoxib, and are prescription-only medicines. As on 5 July 2018, DH has received 3 cases of ADR related to celecoxib, of which one case was related to ischemic heart disease.

News related to cardiovascular risk of NSAIDs was previously issued by various overseas drug

regulatory authorities, and was reported in the Drug News Issue No. 24, 36, 43, 53, 54, 60, 66, 68 and 84. DH issued letters to inform local healthcare professionals to draw their attention on 30 September 2011, 3 March 2014, 7 October 2014 and 12 June 2015. The matter related to cardiovascular risk of NSAIDs was discussed by the Registration Committee, and the package insert of products containing celecoxib should include a warning on the increased risk of cardiovascular adverse effects. DH will remain vigilant on safety update of the product issued by other overseas drug regulatory authorities.

EU: Hydroxyethyl starch solutions: CMDh introduces new measures to protect patients. Medicines to remain on the market provided that training, controlled access and warnings on the packaging are implemented.

On 29 June 2018, EMA announced that the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) has decided that hydroxyethyl starch (HES) solutions for infusion should remain on the market provided that a combination of additional measures to protect patients is implemented. This follows further reflection, in consultation with EU member states, on whether it would be feasible to introduce new measures that would effectively reduce the risks with these medicines.

HES solutions for infusion are used to replace plasma volume following acute (sudden) blood loss, where treatment with alternative products known as ‘crystalloids’ alone is not considered sufficient.

In January 2018, EMA’s safety committee, the Pharmacovigilance Risk Assessment Committee (PRAC), recommended suspending the marketing authorisations of these medicines because they continued to be used in critically ill patients and patients with sepsis despite restrictions introduced in 2013 due to the risk of kidney injury and death in these patients.

CMDh agreed with the PRAC’s assessment of the serious risks in critically ill patients and patients with sepsis. However, CMDh gave further

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consideration to the place of HES in the clinical practice of some countries, noted that previous risk minimisation measures had some effect, and considered that a combination of new risk minimisation measures would effectively ensure that HES solutions are not used in patients at risk.

The new measures are:

- The implementation of a controlled access programme by the companies holding the marketing authorisations to ensure that only accredited hospitals will be supplied with these medicines. The accreditation would require that relevant healthcare professionals receive training on the safe use of HES solutions for infusion. Further details about the training and the controlled access programme will be provided to hospitals and healthcare professionals in due time.
- Warnings in the medicines' packaging and at the top of SmPCs (Summary of Product Characteristics) reminding healthcare professionals that these medicines must not be used in patients with sepsis or kidney impairment or in critically ill patients.
- Writing directly to healthcare professionals to ensure that they are fully aware of the conditions of use of the medicines and the groups of patients that must not receive them due to an increased risk of kidney injury and death.

CMDh also requested marketing authorisation holders to conduct studies to check that only patients who should be treated with these medicines are receiving them. This is in addition to ongoing studies on the benefits and risks of HES solutions in patients with trauma and those undergoing elective surgery.

CMDh position was adopted by majority vote and the matter will now be sent to EC, which will take an EU-wide legally binding decision.

In Hong Kong, there are 6 registered pharmaceutical products containing hydroxyethyl starch, namely Voluven Infusion 6% (HK-50474) and Volulyte 6% Solution for Infusion (HK-58087) registered by Fresenius Kabi Hong Kong Limited, Tetraspan 6% Solution for Infusion (HK-56978) and Tetraspan 10% Solution for Infusion (HK-

56979) registered by B. Braun Medical (HK) Ltd, and Hestar-200 Inj. 10% (HK-57095) and Hestar-200 Inj. 6% (HK-57096) registered by Unico & Co. All products are prescription-only medicines.

Related news on increased risks of death and kidney injury in critically ill patients was previously issued by various overseas drug regulatory authorities, and was reported in the Drug News Issue No. 44, 48, 50, 99, 102 and 103. DH issued letters to inform local healthcare professionals to draw their attention on the above risks on 17 June 2013 and 15 January 2018.

The Registration Committee first discussed the matter in the meeting on 5 December 2013, and decided that DH will remain vigilant on the final version of the warnings by EU health authority and the final legally binding decision by EC for further consideration. On 23 October 2013, CMDh endorsed the recommendation of PRAC and concluded that HES solutions must no longer be used to treat patients with sepsis or burn injuries or critically ill patients because of an increased risk of kidney injury and mortality. Subsequently, EC endorsed it on 19 December 2013 for the adoption of a final legally binding decision valid throughout EU.

On 12 April 2018, the Registration Committee further discussed the suspension of the marketing authorisations for HES solutions for infusion across EU, and having considered the local situation, decided to keep vigilant on any update on the issue from other regulatory authorities.

As on 5 July 2018, DH has not received any case of ADR related to hydroxyethyl starch. In light of the above EMA's announcement, DH will remain vigilant on the development of this issue and any updates of recommendation of HES solutions issued by other overseas regulatory authorities.

Drug Recall

DH endorsed recall of Enzyplex Tab (HK-06544)

On 21 June 2018, DH is investigating a case of suspected mould contamination of a pharmaceutical product named Enzyplex Tab (HK-06544) following a report from Queen Mary Hospital. Samples of the product were collected immediately from the local supplier Unam Corporation Ltd (Unam), the Hospital Authority (HA) as well as DH clinics for analysis on 21 June 2018 to ascertain whether the product exceeds the pharmacopoeial standards on mould and yeast content. DH has also instructed Unam to ask the manufacturer in Indonesia to conduct an investigation. Initial investigation by the manufacturer indicates that the raw materials used and the production facilities complied with its in-house specifications.

Enzyplex tablet, containing vitamins and digestive enzymes, is an over-the-counter medicine for digestive disorders. According to Unam, about 128 000 bottles of 100 tablets and 46 000 bottles of 30 tablets of the product have been supplied to HA, DH clinics, private hospitals, local private doctors, pharmacies and medicine stores, and also re-exported to Macao. The majority of the product has been supplied to the private market. As a precautionary measure, Unam has asked all its

clients to suspend the supply of the product to patients or customers on 22 June 2018.

On 26 June 2018, the testing results revealed that the bacterial contents of the samples comply with the pharmacopoeial requirements but the level exceeded the in-house specifications set by the Indonesia manufacturer of the product. Due to the quality issue, DH endorsed Unam to recall all batches of Enzyplex tablet from the market on the same day. DH has also instructed Unam to ask the manufacturer to conduct a thorough investigation and submit an investigation report as soon as possible.

The analysis to confirm whether the product exceeds the pharmacopoeial standards on mould and yeast content usually takes five to seven days. On 28 June 2018, DH announced the analysis results, the mould and yeast content of all samples comply with both the pharmacopoeial requirements and the in-house specifications set by the Indonesian manufacturer of the product.

As on 5 July 2018, DH has not received any ADR reports in connection with the product. Notices were posted on the Drug Office website on 21, 22, 26 and 28 June 2018 to alert and update the public of the issue and product recall.

Drug Incident

Woman arrested for suspected illegal sale of slimming product with undeclared banned drug ingredient

On 15 June 2018, a woman aged 19 was arrested in a joint operation by DH and the Police for suspected illegal sale of a slimming product called "MATCHA SURIMU", which is suspected to contain an undeclared banned drug ingredient.

From DH's market surveillance, a sample of the above slimming product was purchased from an Internet seller for analysis. Test results from the Government Laboratory revealed that the sample contains sibutramine, which is a Part 1 poison under the Pharmacy and Poisons Ordinance (Cap. 138). During the operation, the Police arrested the seller for suspected illegal sale of an unregistered

pharmaceutical product and Part 1 poison.

Sibutramine was once used as an appetite suppressant. Since November 2010, products containing sibutramine have been banned in Hong Kong because of increased cardiovascular risk.

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

The public may visit DH Drug Office's pages for health messages on [weight control and slimming products](#) and information on [slimming products with undeclared Western drug ingredients](#).

A notice was released on the website of the Drug

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Office on 15 June 2018 to alert the public of the drug incident.

Public urged not to buy or consume slimming product from unknown sources or of doubtful composition

On 19 June 2018, DH appealed to the public not to buy or consume a slimming product named SPARKLE TWINS as it was found to contain an undeclared and banned drug ingredient that might be dangerous to health.

DH commenced investigation upon receipt of a notification from HA regarding a 29-year-old female patient admitted to hospital for emotional disturbance with a history of consuming the above slimming product.

According to testing results by HA, which were later confirmed by the Government Laboratory, the sample of the product provided by the patient was found to contain the banned substance sibutramine.

Preliminary investigation revealed that the patient purchased the product through a social media network platform.

Sibutramine was once used as an appetite suppressant. Since November 2010, products containing sibutramine have been banned in Hong Kong because of increased cardiovascular risk.

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

The public may visit the website of the Drug Office of DH for [health messages on overweight problem and slimming products](#) and [information on slimming products with undeclared Western drug ingredients](#).

A notice was posted on the website of Drug Office on 19 June 2018 to alert the public of the drug incident.

DH raided retail shop for suspected illegal sale of unregistered pharmaceutical products

On 21 June 2018, DH and the Police conducted a joint operation and raided a retail shop in Sha Tin for suspected illegal sale of unregistered pharmaceutical products, which were found to contain undeclared controlled ingredients.

Acting upon a public complaint, samples of products were purchased from the above shop for analysis. Test results from the Government Laboratory confirmed that the samples of three products contained undeclared Part 1 poisons, which are as follows:

	Product Name	Part 1 Poisons Found
1.	Zang Yao Xuan Du Wang Cao Ben Ru Gao	Clobetasol propionate and miconazole
2.	Miao Jia Du Xuan Gao	Clobetasol propionate, miconazole and ketoconazole
3.	苗药皮癬王噴剂 (no English name)	Miconazole

During the operation, two women aged 31 and 61 were arrested by the Police for suspected illegal sale and possession of Part 1 poisons and unregistered pharmaceutical products.

Clobetasol propionate is a steroid substance used for treating inflammation. Inappropriate or excessive application of steroids could cause skin problems and body-wide side effects like moon face, high blood pressure, high blood sugar, muscle atrophy, adrenal insufficiency and osteoporosis. Products containing clobetasol propionate should be used under a doctor's directions and be supplied in a pharmacy under the supervision of a registered pharmacist upon a doctor's prescription. Miconazole and ketoconazole are used for the treatment of fungal infections with side effects including local irritation and sensitivity reactions.

A notice was released on the website of Drug Office on 21 June 2018 to alert the public of the drug incident.

Drug Incident

Public urged not to buy or consume slimming products from unknown sources or of doubtful composition

On 28 June 2018, DH appealed to the public not to buy or consume a slimming product named MUSE POTENT SLIMMING CAPSULE as it was found to contain an undeclared and banned drug ingredient that might be dangerous to health.

Acting upon intelligence, a sample of the above product was purchased from an Internet seller for analysis. Test results from the Government Laboratory revealed that the sample contains the banned substance sibutramine, which is a Part 1 poison under the Pharmacy and Poisons Ordinance (Cap. 138).

Sibutramine was once used as an appetite suppressant. Since November 2010, products containing sibutramine have been banned in Hong Kong because of increased cardiovascular risk.

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

The public may visit the website of Drug Office of DH for [health messages on overweight problem and slimming products](#) and [information on slimming products with undeclared Western drug ingredients](#).

A notice was posted on the Drug Office website on 28 June 2018 to alert the public of the drug incident.

News in Brief

General Information of Biosimilars

According to the Pharmacy and Poisons Regulations, all pharmaceutical products must satisfy the criteria of safety, quality, and efficacy before they can be registered with the Pharmacy and Poisons Board and be sold in Hong Kong. Pharmaceutical products may include chemical or 'biological' materials as active ingredients or substances.

Biological product

Biological products, as distinguished from other chemical products, according to the World Health Organization, is derived from living organisms and frequently have complex molecular structures. They require special quality consideration because of the biological nature of the starting materials, the manufacturing processes, and/or the test methods needed to characterize batches of the products. The expiration of patents and/or data protection for the originator's biological products lead to the development of copy versions of the originator products. In the context of biological products and having due consideration of the specificities mentioned above, these copy products cannot be considered as identical but merely 'similar' to the originator products because of the inevitable differences in molecular structures and quality

attributes arising from their different manufacturing processes. They will be referred as 'biosimilar' products hereafter.

Biosimilar product

As biosimilar product is similar but not identical to the reference product, approval for registration of a biosimilar product does not imply bioequivalence or clinical equivalence between the biosimilar and reference products. The Pharmacy and Poisons Board has already promulgated the guidelines for registration of biosimilar products (http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/Biosimilar_guidelines_revised_Final_ENG.pdf?v=85s5s) and has come into effect on 1 January 2016.

In Hong Kong, there are some registered biosimilar products including

- products containing infliximab, a chimeric monoclonal antibody to Tumor Necrosis Factor α (TNF- α), for management of rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis.
- products containing filgrastim, a granulocyte colony-stimulating factor (G-CSF), against neutropenia.

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 \$30,000 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/reListRPP_index.html.

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: *Pharmacovigilance Unit,
Drug Office, Department of Health,
Rm 1856, 18/F, Wu Chung House,
213 Queen's Road East,
Wan Chai, Hong Kong***

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.