Drug News
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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 April 2017 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

US: Information on Erythropoiesis-Stimulating Agents (ESA) Epoetin alfa (marketed as Procrit, Epogen), Darbepoetin alfa (marketed as Aranesp)

On 13 April 2017, the United States (US) Food and Drug Administration (FDA) provided postmarket drug safety information regarding Epoetin alfa and darbepoetin alfa. Epoetin alfa and darbepoetin alfa are Erythropoiesis-Stimulating Agents (ESAs), approved for the treatment of anemia (low red blood cells) resulting from chronic kidney disease, chemotherapy, certain treatments for Human Immunodeficiency Virus (HIV), and also to reduce the number of blood transfusions during and after certain major surgeries. ESAs work like the human protein erythropoietin, which stimulates bone marrow to make red blood cells. In US, Epoetin alfa (marketed as Procrit and Epogen) and darbepoetin alfa (marketed as Aranesp), are manufactured by Amgen, Inc.

In 2017, US FDA determined that the ESA Risk Evaluation and Mitigation Strategy (REMS), which was limited to the use of Epogen/Procrit and Aranesp to treat patients with anemia due to associated myelosuppressive chemotherapy is no longer necessary to ensure that the benefits of Epogen/Procrit and Aranesp outweigh its risks of shortened overall survival and/or increased risk of tumor progression or recurrence in patients with cancer. US FDA made this determination based on an evaluation of the results of the REMS Assessments submitted by Amgen, Inc., and additional US FDA analyses to understand the impact of the various regulatory and other actions on the use of ESAs.

The REMS Assessment showed that:

- The results from surveyed prescribers demonstrate acceptable knowledge of the product risks of decreased survival and/or the increased risk of tumor progression or recurrence and the need to counsel patients about these risks.
- The drug utilization data indicates appropriate prescribing of ESAs consistent with the intended use as a treatment alternative to red blood cell (RBC) transfusion for anemia associated with myelosuppressive chemotherapy

US FDA conducted an evaluation of the impact of multiple actions, including the ESA REMS, on the utilization of the ESAs using sponsor-submitted data from outpatient oncology practices between 2006 and 2014. During 2004-2009, US FDA took multiple regulatory actions, including labeling changes. In 2007, the Center for Medicare and Medicaid Services (CMS) made a National Coverage Determination (NCD) to limit coverage of ESAs for non-renal disease indications. These actions coincided with:

- A decrease in the proportion of patients receiving chemotherapy using ESAs
- An increase in the proportion of patients receiving chemotherapy who initiate ESAs at a hemoglobin level <10g/dl, and
- An increase in the proportion of patients who initiate ESAs at a dosage consistent with product prescribing information.

Full implementation of the ESA REMS in 2011 had minimal impact on trends in these three ESA utilization metrics beyond the changes observed

after the CMS coverage determination and multiple other FDA regulatory actions.

This information led US FDA to conclude it is no longer necessary to require the certification of prescribers and hospitals that prescribe and/or dispense ESAs to patients with cancer in order to ensure the benefits outweigh the risks.

US FDA has released the REMS requirements for the ESA products, Epogen/Procrit and Aranesp, and the risks can be communicated by the current product prescribing information. The appropriate use of ESAs is supported by the CMS NCD, the American Society of Clinical Oncology (ASCO) and American Society of Hematology (ASH) clinical guidelines which are evidence-based guidelines intended to provide a basis for the standard of care in clinical oncology.

While the REMS is no longer necessary to ensure the benefits outweigh the risks, the serious risks of shortened overall survival and/or increased risk of tumor progression or recurrence associated with these drugs remain. The prescribing information continues to note an increased risk of tumor progression or recurrence, as well as death, myocardial infarction, stroke, venous thromboembolism, and thrombosis of vascular access. Healthcare providers are encouraged to discuss the risks and benefits of using ESAs with each patient before initiating use.

In Hong Kong, there are 13 pharmaceutical products containing epoetin alfa and 12 pharmaceutical products containing darbepoetin alfa which have been registered with the Pharmacy and Poisons Board since 1995 and 2003 respectively. All these products are prescription only medicines. As on 8 May 2017, the Department of Health (DH) has not received any adverse drug reaction (ADR) report related to epoetin alfa or darbepoetin alfa. In light of the above US FDA announcement that the REMS requirements for ESA products are no longer necessary, DH will continue to remain vigilant on the safety updates on ESA products by other overseas drug regulatory authorities.

Australia: Idelalisib (Zydelig): change to indications and addition of warnings

On 19 April 2017, the Therapeutic Goods Administration (TGA) advised consumers and health professionals that TGA has completed a review of idelalisib (marketed in Australia as Zydelig) and the medicine should no longer be used in combination with rituximab in specific situations outlined in further detail below.

Idelalisib belongs to a group of medicines called antineoplastic agents. It is approved to treat some rare kinds of blood cancer by affecting the growth of cancerous lymphocytes (a type of white blood cell). TGA's review was undertaken following advice from the sponsor, Gilead Sciences, of a potential increased risk of serious adverse events, including death, in patients receiving the medicine in combination with other cancer medicines to treat chronic lymphocytic leukaemia (CLL) and relapsed indolent non-Hodgkin's lymphoma (iNHL). These patients received the medicine as part of phase 3 clinical trials, which were ceased.

TGA's review found that these results, which related to currently unapproved uses for the idelalisib, were also relevant to some of the previously approved uses for the medicine. As a result, there have been changes to the indications for idelalisib and additional information relating to serious infections, including a boxed warning, has been added to its Product Information (PI) in Australia.

Gilead Sciences has written to health professionals providing further information about this issue, including details of the changes to idelalisib's PI in Australia.

The phase 3 clinical trials, through which patients received idelalisib in combination with other cancer medicines to treat CLL and relapsed iNHL, were discontinued early, as more participating patients who received idelalisib died than patients who received a placebo (7.4% vs 3.5%). The deaths often occurred within 180 days of starting treatment and were often due to infection (such as sepsis and pneumonia).

The subsequent TGA review concluded that idelalisib should no longer be indicated in

combination with rituximab as first-line treatment in CLL/small lymphocytic lymphoma (SLL) patients in the presence of 17p deletion or TP53 mutation.

TGA provides further information for healthcare professionals as follows:

- Additional clarifications to the indications:
  - ※ Extension of the indication in CLL/SLL to include use in combination with ofatumumab in adult CLL/SLL patients upon relapse in patients for whom chemoimmunotherapy is not considered suitable.
  - ※ Revision of the indication in follicular lymphoma (FL) to specify that the disease must be refractory to both rituximab and an alkylating agent.

- The revised indications are:
  - ※ Zydelig in combination with rituximab is indicated for the treatment of adult patients with CLL/SLL upon relapse in patients for whom chemo-immunotherapy is not considered suitable.
  - ※ Zydelig in combination with ofatumumab is indicated for the treatment of adult patients with CLL/SLL upon relapse in patients for whom chemo-immunotherapy is not considered suitable.
  - ※ Zydelig is indicated as monotherapy for the treatment of patients with FL which is refractory to at least two prior systemic therapies. The disease must be refractory to both rituximab and an alkylating agent.

- Risk minimisation measures to prevent infection in all indications have been updated in the PI in Australia. A boxed warning has been added to the PI to alert prescribers of the risk of serious infections with specific reference to *Pneumocystis jirovecii pneumonia* (PJP) and cytomegalovirus (CMV) infection and also pneumonitis. Further guidance regarding PJP and CMV infection are provided as follows:
  - ※ All patients should receive prophylaxis for PJP during treatment with Zydelig. This should be continued for up to 2 to 6 months after discontinuation of Zydelig. The duration of post treatment prophylaxis should be based on clinical judgment, taking into account the patient's risk factors such as concomitant corticosteroid treatment and prolonged neutropenia.
  - ※ At least monthly clinical and laboratory monitoring for CMV infection is recommended in patients who are CMV-seropositive at the start of treatment with Zydelig or have other evidence of a history of CMV infection or disease. Patients with CMV viraemia without attributable symptoms or signs should be monitored for evidence of high or rising viral load. For asymptomatic patients with evidence of high or rising viral load, consideration should be given to interruption of Zydelig and commencement of antiviral therapy to prevent invasive disease. For patients with evidence of CMV viraemia and attributable symptoms or signs, initiate antiviral therapy; and strong consideration should be given to interrupting Zydelig until CMV disease has resolved. Zydelig may be restarted if the infection has resolved and if the benefits of resuming Zydelig are judged to outweigh the risks. Consideration should be given to administering pre-emptive CMV therapy.

- The following previously issued guidance is unchanged:
  - ※ Patients should be informed about the risk of potential serious and/or fatal infections during treatment with Zydelig.
  - ※ Zydelig should not be initiated in patients with any evidence of ongoing systemic bacterial, fungal or viral infection.
  - ※ Patients should be monitored for respiratory signs and symptoms throughout treatment with Zydelig and be advised to promptly report new

respiratory symptoms.

※ Absolute neutrophil counts (ANC) should be monitored in all patients at least every two weeks for the first six months of treatment with Zydelig, and at least weekly in patients while ANC is less than $1.0X10^9$/L.

Patients or carers for patients who are taking idelalisib (Zydelig) should talk to their health professional to make sure this medicine is still appropriate for them.

In Hong Kong, there are two registered pharmaceutical products containing idelalisib, namely Zydelig Tablets 100mg (HK-64093) and Zydelig Tablets 150mg (HK-64094). Both products are prescription only medicines and are registered by Gilead Sciences Hong Kong Limited (Gilead). News on the risk of serious adverse effects including deaths in patients receiving idelalisib was previously issued by various overseas drug regulatory authorities, and was reported in the Drug News Issue No. 77 and 81. DH issued a letter to inform local healthcare professionals to draw their attention on the above risk on 14 March 2016. Gilead had also issued letters to inform local healthcare professionals and had submitted application to update the package inserts of the two products on the above risk. As on 8 May 2017, there is one case of ADR of skin reactions after receiving idelalisib, and it is not related to the findings in the above TGA announcement. In view of the additional findings with idelalisib in the above TGA announcement, DH issued a letter to update local healthcare professionals on the latest findings with idelalisib on 20 April 2017, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board (the Registration Committee).

US: FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women

On 20 April 2017, US FDA is restricting the use of codeine and tramadol medicines in children. Codeine is approved to treat pain and cough, and tramadol is approved to treat pain in US. These medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in these children. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults. FDA is also recommending against the use of codeine and tramadol medicines in breastfeeding mothers due to possible harm to their infants.

As a result, FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond the FDA's 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids. FDA is now adding:

- FDA's strongest warning, called a *Contraindication*, to the drug labels of codeine and tramadol alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- A new *Contraindication* to the tramadol label warning against its use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids.
- A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants. These can include excess sleepiness, difficulty breastfeeding, or serious breathing problems that could result in death.

Caregivers and patients should always read the label on prescription bottles to find out if a medicine contains codeine or tramadol. Watch closely for signs of breathing problems in a child of any age who is taking these medicines or in infants exposed to codeine or tramadol through breastmilk. These signs include slow or shallow breathing, difficulty or noisy breathing, confusion, more than

usual sleepiness, trouble breastfeeding, or limpness.

Healthcare professionals should be aware that tramadol and single-ingredient codeine medicines are FDA-approved only for use in adults. Consider recommending over-the-counter (OTC) or other FDA-approved prescription medicines for cough and pain management in children younger than 12 years and in adolescents younger than 18 years, especially those with certain genetic factors, obesity, or obstructive sleep apnea and other breathing problems. Cough is often secondary to infection, not serious, and usually will get better on its own so treatment may not be necessary.

Codeine and tramadol are a type of narcotic medicine called an opioid. Codeine is used to treat mild to moderate pain and also to reduce coughing in US. It is usually combined with other medicines, such as acetaminophen, in prescription pain medicines. It is frequently combined with other drugs in prescription and OTC cough and cold medicines. Tramadol is a prescription medicine approved only for use in adults to treat moderate to moderately severe pain. However, data show it is being used in children and adolescents despite the fact that it is not approved for use in these patients.

In early 2013, FDA added a *Boxed Warning* to the codeine drug label cautioning against prescribing codeine to children of any age to treat pain after surgery to remove tonsils or adenoids. FDA also issued Drug Safety Communications in July 2015 and September 2015 warning about the risk of serious breathing problems in some children who metabolized codeine and tramadol much faster to their active form than usual (called ultra-rapid metabolism), causing potentially dangerously high levels in their bodies too quickly. At that time, FDA said it would continue to evaluate this safety issue. As part of that safety review, the codeine-related safety issues were discussed at an FDA Advisory Committee meeting in December 2015.

FDA reviewed several decades of adverse event reports submitted to FDA from January 1969 to May 2015 identified 64 cases of serious breathing problems, including 24 deaths, with codeine-containing medicines in children younger than 18 years. This includes only reports submitted to FDA, so there may be additional cases about which FDA is unaware. FDA also identified nine cases of serious breathing problems, including three deaths, with the use of tramadol in children younger than 18 years from January 1969 to March 2016. The majority of serious side effects with both codeine and tramadol occurred in children younger than 12 years, and some cases occurred after a single dose of the medicine.

In FDA's review of the medical literature for data regarding codeine use during breastfeeding, numerous cases of excess sleepiness and serious breathing problems in breastfed infants were found, including one death. A review of the available medical literature for data regarding tramadol use during breastfeeding did not reveal any cases of adverse events. However, tramadol and its active form are also present in breast milk, and tramadol has the same risks associated with ultra-rapid metabolism as codeine.

FDA will continue to monitor this safety issue. FDA is considering additional regulatory action for the OTC codeine products that are available in some states. OTC codeine products are available in combination with other medicines for cough and cold symptoms. FDA is also considering an FDA Advisory Committee meeting to discuss the role of prescription opioid cough-and-cold medicines, including codeine, to treat cough in children.

In Hong Kong, there are 312 registered pharmaceutical products containing codeine, including 30 products classified as prescription-only medicines (i.e. containing codeine 0.2% or more) and the remaining products classified as pharmacy-only medicines. News on codeine safety was previously issued by various overseas drug regulatory authorities, and was reported in the Drug News Issue No. 34, 40, 44, 54, 65 and 69. DH issued a letter to inform local healthcare professionals to draw their attention on the risk of respiratory depression on 16 August 2012, and on the restrictions to patients older than 12 years old on 7 June 2013. The previous FDA evaluation on potential risk of serious side effects in children using codeine cough-and-cold medicines was reported in the Drug News Issue No. 69. On 5 July 2013, the Registration Committee decided that the sales packs and/or package inserts of pharmaceutical products containing codeine should be updated to include the latest safety warnings restricting the use of codeine to patients older than

12 years old.

Meanwhile, there are 50 registered pharmaceutical products containing tramadol, and they are prescription-only medicines. The previous FDA evaluation on the risk of tramadol in children aged 17 and younger was reported in the Drug News Issue No. 71.

As on 8 May 2017, DH has received 1 case of ADR after receiving codeine, and 2 cases of ADRs after receiving tramadol, but none of them was related to respiratory depression in adult or infant.

In view of the latest conclusions with new contraindication and warning of codeine and tramadol in the above FDA announcement, DH issued a letter to update local healthcare professionals on the above conclusions on 21 April 2017, and the matter will be further discussed by the Registration Committee.

Singapore: Risk of severe haemorrhage with Cotellic™ (cobimetinib)

On 5 April 2017, Singapore Health Sciences Authority (HSA) announced that Roche would like to inform healthcare professionals of the risk of severe haemorrhage associated with the use of Cotellic™ (cobimetinib).

Haemorrhage is a known adverse drug reaction of Cotellic™. An analysis on post-marketing safety reports and ongoing clinical trials has identified additional severe haemorrhage events in patients receiving Cotellic™, including intracranial and gastrointestinal tract bleeds. In most cases of severe haemorrhage, the patients had additional risk factors for bleeding, such as central nervous system metastasis, pre-existing gastrointestinal disorders, and/or concomitant medications that increase the risk of bleeding, such as antiplatelet or anticoagulant therapy.

Healthcare professionals are advised to take into consideration the above safety information when prescribing Cotellic™, and to discuss the risks that may be associated with Cotellic™ therapy with patients and their caregivers.

In Hong Kong, Cotellic Tablets 20mg (HK-64797) is a pharmaceutical product registered by Roche Hong Kong Limited (Roche HK), and is a prescription only medicine. The news on the above risk was posted on the Drug Office website on 11 January 2017. Subsequently, Roche HK confirmed with DH that a "Dear Healthcare Professional Letter" to local oncologists and pharmacists to draw their attention on the above risk was issued on the same day. As on 8 May 2017, DH has not received any ADR report related to the product. DH will remain vigilant on future safety update of the product by other overseas drug regulatory authorities.

UK: Multiple sclerosis therapies: signal of rebound effect after stopping or switching therapy

On 24 April 2017, the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom (UK) is aware of two recently published articles describing a suspected rebound syndrome (clinical and radiological signs of severe exacerbation beyond what was expected for that patient prior to discontinuation or treatment change) in patients with multiple sclerosis after treatment with fingolimod (Gilenya ▼) was stopped, some of whom were switched to other treatments.

In conjunction with other European national regulatory authorities and the European Medicines Agency (EMA), MHRA is evaluating all available evidence on this safety signal. Further information on the outcome of the review and any relevant new guidance will be issued as soon as it is available.

Healthcare professionals are reminded to be vigilant for such events and report any suspected adverse effects relating to fingolimod or other treatments for multiple sclerosis, including suspected adverse effects occurring after discontinuation.

In Hong Kong, there is one registered pharmaceutical product containing fingolimod, namely Gilenya Hard Capsules 0.5mg (HK-61192) which is registered by Novartis Pharmaceuticals (HK) Limited, and is a prescription only medicine. As on 8 May 2017, DH has received one case of ADR of fingolimod, but it was not related to the adverse effect mentioned in the above MHRA

announcement. As MHRA is still conducting the review of fingolimod, DH will remain vigilant on the outcome of the review and will continue to monitor safety updates of fingolimod issued by other overseas drug regulatory authorities.

UK: Valproate and developmental disorders: new alert asking for patient review and further consideration of risk minimisation measures

On 24 April 2017, MHRA advised that babies born to mothers who take valproate medicines (Epilim ▼, Depakote ▼) during pregnancy have a 30-40% risk of developmental disability and a 10% risk of birth defects. Despite communications to prescribers in January 2015 and February 2016 on the magnitude of this risk and the actions to take, there is evidence that women are still not aware of the risk. Patient Safety Alerts have now been issued asking all organisations to undertake systematic identification of women and girls taking valproate. A new European review is considering whether further regulatory action is necessary and there will be a public hearing at EMA later in 2017.

MHRA's toolkit resources have been disseminated widely. However, evidence suggests as many as 1 in 5 women taking valproate are not aware of any of its risks in pregnancy. Evidence from the Clinical Practice Research Datalink also suggests that, although prescription rates for valproate have been declining gradually in recent years, the measures put in place have not had a significant effect.

On 6 April 2017, National Health Service (NHS) Improvement and MHRA sent a Patient Safety Alert through the NHS Central Alerting System to further highlight risks to the unborn child and support the safety of girls and women taking valproate. Consistent action is being taken in Scotland, Wales, and Northern Ireland. These alerts direct organisations to undertake systematic identification of women and girls taking valproate and to use MHRA resources to support them to make informed choices.

In March 2017, the European Pharmacovigilance Risk Assessment Committee (PRAC) initiated a further review to look at the use of valproate-containing medicines in women and girls of childbearing potential. The committee will consider whether these medicines require further restrictions of use due to their very high risk of causing developmental disorders and congenital malformations to unborn babies and evidence of continued use in pregnancy. The review will also examine the effectiveness of regulatory measures put in place to increase awareness and reduce valproate use in patients at risk.

MHRA advised healthcare professionals of the followings:

- do not prescribe valproate medicines for epilepsy or bipolar disorder in women and girls unless other treatments are ineffective or not tolerated; migraine is not a licensed indication
- ensure women and girls taking valproate medicines understand the 30–40% risk of neurodevelopmental disorders and 10% risk of birth defects and are using effective contraception
- valproate use in women and girls of childbearing potential must be initiated and supervised by specialists in the treatment of epilepsy or bipolar disorder

In Hong Kong, there are 15 registered pharmaceutical products containing valproic acid and/or valproate, and they are prescription only medicines. In December 2014, the Registration Committee discussed the findings of an EMA's previous review on the risks of valproate products in pregnancy and had decided that warnings and precautions on the risks of pregnancy should be included in valporate products. As on 8 May 2017, DH has received six cases of ADR in connection with valproic acid or valproate, but none of them was related to adverse effects in new-born babies whose mothers took valproate for their medical conditions.

As EMA is conducting a new review on whether further regulatory action is necessary for valproate products, DH will remain vigilant on the outcome of the review and will continue to monitor safety updates of valproate issued by other overseas drug regulatory authorities.

Drug Recall

DH endorsed batch recall of Human Albumin 20% "Biotest" Infusion (HK-16685)

On 27 April 2017, DH endorsed a licensed drug wholesaler, Chong Lap (HK) Co Ltd (Chong Lap), to recall 19 batches of Human Albumin 20% "Biotest" Infusion (HK-16685) from the market for a potential quality issue.

The affected batches are: B225065, B225105, B225135, B225654, B234026, B234046, B234306, B234514, B234645, B234784, B234866, B235174, B235364, B235525, B235684, B234926, B225056, B235066 and B235256.

DH received notification from Chong Lap that the pharmaceutical product's manufacturer in Germany was recalling the above batches as they might have been contaminated with the cooling liquid circulating in the production equipment during manufacture. According to the risk assessment conducted by the manufacturer, the potential risk to patients using the product is low and the recall is a precautionary measure.

The above product, containing human albumin, is a prescription medicine used for the treatment of low plasma volume and hypoalbuminaemia (abnormally low blood albumin). According to Chong Lap, about 64 000 bottles of the affected batches have been supplied to private hospitals, private doctors and local pharmacies. DH will closely monitor the recall.

As on 8 May 2017, DH has not received any ADR report in connection with the product. A notice was posted on the Drug Office website on 27 April 2017 to alert the public of the product recall.

Drug Incident

DH urges public not to buy or use cream product with undeclared controlled ingredients clobetasol propionate and ketoconazole

On 7 April 2017, DH appealed to the public not to buy or use a cream product called LANG DU as it was found to contain undeclared controlled ingredients.

Acting upon a public complaint, DH purchased a sample of the above product for analysis. The test results from the Government Laboratory revealed that the sample contained two Part 1 poisons, namely clobetasol propionate and ketoconazole.

Clobetasol propionate is a steroid substance for treating inflammation and 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 supervision of a registered pharmacist upon a doctor's prescription. Ketoconazole is used for the treatment of fungal infection with side effects such as local irritation and sensitivity reactions.

A notice was posted on the Drug Office website on 7 April 2017 to alert the public of the drug incident.

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.

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.

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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.