



D r u g  
藥 物

N e w s  
情 報

Issue Number 61

*This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in November 2014 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: PRAC recommends measures to reduce risk of heart problems with Corlentor/Procoralan (ivabradine)**

On 7 November 2014, the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) has completed a review of Corlentor/Procoralan (ivabradine) and has made recommendations aimed at reducing the risk of heart problems, including heart attack and bradycardia, in patients taking the medicine. Corlentor/Procoralan is used to treat symptoms of angina and to treat heart failure.

The PRAC made recommendations about the resting heart rate of patients before starting treatment or when the dose is adjusted, recommendations on when treatment should be stopped and recommendations regarding use with other medicines. Because patients treated with Corlentor/Procoralan are at an increased risk of developing atrial fibrillation, the PRAC recommended monitoring for this condition in patients treated with Corlentor/Procoralan. In addition, the PRAC recommended that, when used for angina, Corlentor/Procoralan should only be used to alleviate symptoms as the available data do not indicate that the medicine provides benefits on outcomes such as reducing heart attack or cardiovascular death.

These recommendations follow a review of the final data from the SIGNIFY study, which evaluated whether treatment with Corlentor/Procoralan in patients with coronary heart disease without heart failure reduces the rate of events such as heart attacks when compared with placebo. The study showed that in a subgroup of patients who had symptomatic angina (Canadian Cardiovascular

Society class II - IV) there was a small but significant increase in the combined risk of cardiovascular death or non-fatal heart attack with Corlentor/Procoralan compared with placebo (3.4% vs 2.9% yearly incidence rates). The data also indicated a higher risk of bradycardia with Corlentor/Procoralan compared with placebo (17.9% vs. 2.1%).

The PRAC noted that patients in the SIGNIFY study were started on a higher than recommended dose of Corlentor/Procoralan and received up to 10 mg twice a day, which is higher than the currently authorised maximum daily dose (7.5 mg twice a day). The PRAC considered that the higher dose used in the study did not fully explain the findings. However, the Committee reiterated that the starting dose for angina should not exceed 5 mg twice a day and that the maximum dose should not exceed 7.5 mg twice a day.

On 21 November 2014, EMA has completed the review of Corlentor/Procoralan and has made recommendations aimed at reducing the risk of heart problems when used for angina. Corlentor/Procoralan should only be started if the patient's resting heart rate is at least 70 beats per minute (bpm). Because Corlentor/Procoralan has not been shown to provide benefits such as reducing the risk of heart attack or cardiovascular death, the medicine should only be used to alleviate symptoms of angina. Doctors should consider stopping treatment if there is no improvement in angina symptoms after 3 months, or if the improvement is only limited.

Other recommendations are that doctors must not prescribe Corlentor/Procoralan together with the medicines verapamil or diltiazem that reduce the heart rate, and that they should monitor their

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patients for atrial fibrillation. If atrial fibrillation develops during treatment, the balance of benefits and risks of continued Corlentor/Procoralan treatment should be carefully reconsidered.

The review of Corlentor/Procoralan was first carried out by the EMA's PRAC. The PRAC recommendations have now been endorsed by the Agency's CHMP in its final opinion. The CHMP opinion will be sent to the European Commission, which will issue a legally binding decision valid throughout the EU in due course.

In Hong Kong, there are two registered pharmaceutical products containing ivabradine, namely Coralan Tab 7.5mg (HK-55438) and Coralan Tab 5mg (HK-55439) and both are prescription only medicines registered by Servier Hong Kong Ltd. Related news was released by the EMA and was reported in Drug News Issue No. 55. The Department of Health (DH) will remain vigilant against any new safety updates on the drug and actions taken by overseas regulatory authorities for consideration of any action deemed necessary. The DH remains vigilant on the final decision made by the European Commission and follow up any update on the relevant safety information.

### **EU: PRAC recommends further assessment of risk of developing inhibitors with Kogenate Bayer/Helixate NexGen**

On 7 November 2014, the EMA's PRAC has looked at new evidence from two recently published studies suggesting that previously untreated haemophilia patients may be at greater risk of developing inhibitors (antibodies) if treated with the factor VIII medicine Kogenate Bayer/Helixate NexGen than if treated with other products that contain factor VIII (the blood clotting factor needed by haemophilia patients).

The development of inhibitors is a known risk with products that contain factor VIII. In 2013 the PRAC reviewed the evidence available at the time about the development of inhibitors in these patients and found that it did not support an increased risk in those treated with Kogenate Bayer/Helixate NexGen. In the light of the new data, the PRAC is recommending a further in-depth examination of the available evidence.

In Hong Kong, there are three Kogenate products registered by Bayer Healthcare Ltd, namely, Kogenate FS for Injection 250IU (HK-54068),

500IU (HK-54069) and 1000IU (HK-54067). These products are prescription only medicines indicated for the treatment of classical haemophilia in which there is a demonstrated deficiency of activity of the plasma clotting factor VIII. Helixate NexGen is not a registered pharmaceutical product in Hong Kong. Related news has been released by the EMA and was reported in the Drug News Issue No. 50. The DH remains vigilant against any new safety updates on the drug and actions taken by overseas regulatory authorities for consideration of any action deemed necessary.

### **US / Canada: Long-term antiplatelet therapy - preliminary trial data shows benefits but a higher risk of non-cardiovascular death**

On 16 November 2014, the US Food and Drug Administration (FDA) is evaluating preliminary data from a clinical trial showing that treatment for 30 months with dual antiplatelet blood-thinning therapy decreased the risk of heart attacks and clot formation in stents, but there was an increased overall risk of death compared to 12 months of treatment.

The Dual Antiplatelet Therapy (DAPT) trial was published in the New England Journal of Medicine on 16 November 2014. The DAPT trial is a public-private collaboration to study the optimal duration of antiplatelet therapy after stent placement. The clinical trial compared 30 months versus 12 months of treatment with dual antiplatelet therapy consisting of aspirin plus either clopidogrel (Plavix) or prasugrel (Effient), following implantation of drug-eluting coronary stents. These stents are small, medicine-coated tubes inserted into narrowed arteries in the heart to keep them open and maintain blood flow to the heart. Clopidogrel and prasugrel are important medicines used to prevent heart attacks, strokes, and other clot-related diseases. The risks of stent thrombosis and heart attacks in the group receiving treatment for 30 months was reduced compared to 12 months; however, there was a higher rate of death in the 30-month treatment group. The higher rate of death was largely explained by an increase in deaths from non-cardiovascular causes, primarily cancer and trauma deaths. The increased risk of death with longer treatment was seen in the patients given clopidogrel, but not those given prasugrel. It should be noted that increases in non-cardiovascular death have not been reported in

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previous large trials examining clopidogrel for other cardiovascular diseases.

FDA believes the benefits of clopidogrel (Plavix) and prasugrel (Effient) therapy continue to outweigh their potential risks when used for approved uses. FDA has not reviewed the trial results or reached any conclusions based on the findings from this clinical trial. FDA is communicating this safety information while continues to evaluate the results from this trial and other available data. FDA will communicate their final conclusions and recommendations when their evaluation is complete. Healthcare professionals should not change the way they prescribe these drugs at this time.

On 18 November 2014, Health Canada also notified healthcare professionals and the public about the new evidence on the safety of clopidogrel (Plavix) and prasugrel (Effient). It is important to note that Health Canada has not reached new conclusions or made recommendations regarding clopidogrel or prasugrel safety at this time. The benefits of clopidogrel and prasugrel in protecting against blood clots continue to outweigh their risks when used as directed.

In Hong Kong, there are 34 registered pharmaceutical products containing clopidogrel, 2 containing prasugrel and 30 containing aspirin. In view of FDA's announcement, a letter to inform local healthcare professionals to draw their attention to the issue and urge them to report any adverse drug reaction related to the drug was issued on 17 November 2014. The DH keeps vigilant against any safety updates of the drugs and actions taken by overseas regulatory authorities for consideration of any action deemed necessary.

### **Canada: New safety information regarding the risk of serious skin reactions associated with the use of REMINYL® ER (galantamine hydrobromide)**

On 18 November 2014, Janssen Inc., in consultation with Health Canada, informed healthcare professionals and the public about important new safety information regarding the risk of serious skin reactions associated with the use of REMINYL® ER. This safety information also applies to generic versions of galantamine.

REMINYL® ER is indicated for the symptomatic

treatment of patients with mild to moderate dementia of the Alzheimer's type. REMINYL® ER has not been studied in controlled clinical trials for longer than 6 months. REMINYL® ER should only be prescribed by (or following consultation with) clinicians who are experienced in the diagnosis and management of Alzheimer's disease.

Very rare cases of serious skin reactions including cases of Stevens-Johnson syndrome, acute generalized exanthematous pustulosis, and erythema multiforme have been reported in patients receiving REMINYL® ER. The WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS and CONSUMER INFORMATION sections of the REMINYL® ER Product Monograph have been updated to include this new safety information. Healthcare professionals should inform patients/caregivers about the signs of these serious skin reactions, and discontinue REMINYL® ER at the first appearance of skin rash.

On 8 December 2014, consumers and health professionals are advised that Janssen-Cilag, in consultation with the Australia's Therapeutic Goods Administration (TGA), has updated the Product Information (PI) for galantamine (marketed under the brand name Reminyl, as well as a number of generic brands). Similar to Health Canada, the PI update has added a new precaution for serious skin reactions, including Stevens-Johnson syndrome and acute generalised exanthematous pustulosis.

In Hong Kong, there are five registered pharmaceutical products containing galantamine hydrobromide, namely Reminyl Oral Solution 4mg/ml (HK-49407), Reminyl Prolonged Release Cap 24mg (HK-55292), Reminyl Prolonged Release Cap 8mg (HK-55293), Reminyl Prolonged Release Cap 16mg (HK-55294), HC Galanthamine Hydrobromide Dispersible Tablets 4mg (HK-62303). All of the products are prescription only medicines. Related news had been released by Singapore Health Sciences Authority and was reported in Drug News No. 58. A letter to inform local healthcare professionals to draw their attention to the issue and urge them to report any adverse drug reaction related to the drug was issued on 7 August 2014. The matter was discussed in the meeting of the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certificate of Clinical Trial/Medicine Test)

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Committee (the Registration Committee) of the Pharmacy and Poisons Board in December 2014. The Committee decided that the sales pack labels and/or package inserts of products containing galantamine should include the following new safety information:

Under "Warnings and Precautions":

### *Serious skin reactions*

*Serious skin reactions (Stevens Johnson syndrome and acute generalized exanthematous pustulosis) have been reported in patients receiving galantamine hydrobromide. It is recommended that patients be informed about the signs of serious skin reactions, and that use of galantamine hydrobromide be discontinued at the first appearance of skin rash.*

### **Canada: New dosage recommendations for IMOVANE (zopiclone) to minimize the risk of next-day impairment**

On 19 November 2014, Sanofi-aventis Canada Inc., in collaboration with Health Canada, informed healthcare professionals and the public about important new dosing information which has been added to the local Product Monograph for IMOVANE (zopiclone) related to the risk of next-day impairment.

Like other sedative/hypnotic drugs, IMOVANE has Central Nervous System (CNS)-depressant effects and can cause next-day impairment of activities requiring alertness, including driving a car. The impairment can be present despite the patient feeling fully awake. Even if IMOVANE is taken as instructed, some patients may still have zopiclone blood levels high enough to produce impairment.

- The recommended starting dose has been reduced to 3.75 mg (one-half of the 7.5 mg tablet). IMOVANE should be taken once per night at bedtime. The lowest effective dose for each patient should be used.
- The prescribed dose should not exceed 5 mg in elderly patients, in patients with hepatic or renal impairment or those currently treated with potent CYP3A4 inhibitors. Dose adjustment may be required with concomitant use with other CNS-depressant drugs.

- Patients should be instructed to wait for at least 12 hours after dosing before driving or engaging in other activities requiring full mental alertness, especially for elderly patients and for patients who take the 7.5 mg dose.

The changes in dosage recommendations are supported by data available for zopiclone 7.5 mg showing increased risk of driving impairment when evaluated up to 11 hours after an evening dose. The risks are higher in the elderly and other special populations with increased residual blood levels (hepatic and renal impairment). For some patients taking lower doses, zopiclone blood levels in the morning may be high enough to produce impairment. Therefore, all patients who use IMOVANE should be cautioned about the risks of next-day impairment.

Treatment with IMOVANE should usually not exceed 7-10 consecutive days. Use for more than 2-3 consecutive weeks requires complete re-evaluation of the patient.

In Hong Kong, there are 32 registered pharmaceutical products containing zopiclone and they are prescription only medicines. So far, the DH has not received any adverse drug reaction report in relation to the drug. In view of the Health Canada's announcement, a letter to inform local healthcare professionals to draw their attention to the issue and urge them to report any adverse drug reaction related to the drug was issued on 20 November 2014, and the matter will be discussed in the meeting of the Registration Committee. The DH keeps vigilant on safety updates of the drug.

### **EU: CMDh agrees to strengthen warnings on the use of valproate medicines in women and girls**

On 21 November 2014, the CMDh has agreed to strengthen warnings on the use of valproate medicines in women and girls due to the risk of malformations and developmental problems in babies who are exposed to valproate in the womb. The warnings aim to ensure that patients are aware of the risks and that they take valproate only when clearly necessary.

Doctors in the EU are now advised not to prescribe valproate for epilepsy or bipolar disorder in pregnant women, in women who can become



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pregnant or in girls unless other treatments are ineffective or not tolerated. Those for whom valproate is the only option for epilepsy or bipolar disorder should be advised on the use of effective contraception and treatment should be started and supervised by a doctor experienced in treating these conditions.

Women and girls who have been prescribed valproate should not stop taking their medicines without consulting their doctor as doing so could result in harm to themselves or to an unborn child.

In countries where valproate medicines are also authorised for the prevention of migraine, valproate must not be used for this purpose in pregnant women, and doctors should exclude pregnancy before starting preventive treatment for migraine. Doctors must not prescribe valproate for migraine prevention for women who are not on effective contraception.

Doctors should ensure that their patients are adequately informed of the risks of taking valproate during pregnancy, and should regularly review the need for treatment in female patients who can have children. Doctors should also re-assess the balance of the benefits and risks of valproate medicines for any female patient who becomes or plans to become pregnant and for girls reaching puberty.

In Hong Kong, there are 10 registered pharmaceutical products containing valproate / valproic acid and they are prescription only medicines. News regarding the increased risk of impaired cognitive development in children born to pregnant women treated with valproate or related products were issued by the US FDA and Health Canada previously, and were reported in the Drug News Issue No. 21. A letter to inform local healthcare professionals on the above safety warnings, and urge them to report adverse drug reactions related to the drugs was issued on 4 July 2011. The Registration Committee had discussed the issue and decided that the package inserts or sales packs of the affected products should be updated to include the above mentioned new safety warnings. Besides, warnings regarding valproate / valproic acid products that they should not be used during pregnancy and in women of child-bearing potential were also released by the US FDA, and was reported in the Drug News Issue No. 43. Meanwhile, the EMA and Medicines and Healthcare Products Regulatory Agency have

released recommendations on strengthening the restrictions on the use of valproate in women and girls, which was posted in the Drug News Issue No. 60, and a letter to inform local healthcare professionals on the update regarding safe use of the drugs was issued on 13 October 2014. So far, the DH has not received any adverse drug reaction in connection to the drugs. In view of latest information published by the overseas authorities, the issue had been discussed in the meeting of the Registration Committee in December 2014. The Committee decided that the sales pack labels and/or package inserts of products containing valproate / valproic acid should include the following new safety information:

If the product is authorized for treatment of epilepsy and bipolar disorder in female patients who can have children, under “Warnings and Precautions”:

*i. Valproate medicines can cause malformations and problems with early development of children if they are exposed to these medicines in the womb.*

*ii. Valproate medicines should not be used to treat epilepsy and bipolar disorder in girls, in women who can become pregnant or in pregnant women unless clearly necessary (i.e. in situations where other treatments are ineffective or not tolerated). Those for whom valproate is the only option after trying other treatments, should use effective contraception during treatment; and treatment should be started and supervised by a doctor experienced in treating these conditions.*

*iii. Doctors should consider alternative treatments if a female patient becomes or plans to become pregnant during valproate treatment; and should regularly review the need for treatment and re-assess the balance of the benefits and risks for female patients taking [product name] and for girls reaching puberty. Doctors should also ensure that their patients are adequately informed of the risks of taking [product name] during pregnancy.*

If the product is authorized for migraine prevention, under “Warnings and Precautions”:

*i. Doctors should not prescribe valproate for female patients who can have children if they are not using effective methods of contraception or if they are already pregnant - such use is now contraindicated.*

*ii. Doctors should exclude pregnancy before starting a female patient on valproate treatment for migraine.*

iii. Doctors should stop valproate treatment in the event of pregnancy or if pregnancy is planned; ensure that female patients who can become pregnant are aware that they must keep to their contraception throughout treatment; and inform patients of the risks of taking valproate during pregnancy.

### **Canada: Risk of exfoliative dermatitis and erythrodermic psoriasis with STELARA (ustekinumab)**

On 21 November 2014, Janssen Inc., in consultation with Health Canada, informed healthcare professionals and the public about important new safety information regarding the risk of exfoliative dermatitis and erythrodermic psoriasis associated with the use of Stelara. Stelara is approved for the treatment of moderate to severe plaque psoriasis and active psoriatic arthritis in adult patients.

Cases of exfoliative dermatitis and erythrodermic psoriasis have been reported rarely in psoriasis patients receiving Stelara. These skin conditions can occur within a few days of the patient receiving Stelara. They can be severe and lead to hospitalization.

The Product Monograph for Stelara will be updated to include the adverse events of exfoliative dermatitis and erythrodermic psoriasis. The symptoms of exfoliative dermatitis may be indistinguishable from erythrodermic psoriasis. Patients are advised to watch for and report these symptoms. In case of occurrence of these symptoms, appropriate therapy should be initiated. Treatment with Stelara should be discontinued if a drug reaction is suspected.

There have been rare ( $\geq 1/10,000$  to  $< 1/1,000$ ) reports of exfoliative dermatitis and erythrodermic psoriasis in psoriasis patients receiving ustekinumab. Patients with plaque psoriasis may develop erythrodermic psoriasis, with symptoms that may be clinically indistinguishable from exfoliative dermatitis, as part of the natural course of their disease. Physicians should be alert for symptoms of exfoliative dermatitis. These can appear as redness and shedding of the skin over almost the entire area of the body, which may be itchy and/or painful.

In Hong Kong, Stelara Solution for Injection in Pre-filled syringe 90mg/ml (HK-60837), 45mg/0.5ml

(HK-60838), 45mg/0.5ml (Switzerland) (HK-62386), and 90mg/ml (Switzerland) (HK-62387) are pharmaceutical products registered by Johnson & Johnson (HK) Ltd, and are prescription only medicines. In view of the Health Canada's announcement, a letter to inform local healthcare professionals to draw their attention to the issue and urge them to report any adverse drug reaction related to the drug was issued on 24 November 2014. The issue had been discussed in the meeting of the Registration Committee in December 2014. The Committee decided that the sales pack labels and/or package inserts of products containing ustekinumab should include the following new safety information:

Under "Warnings and Precautions":

i. *There have been rare ( $\geq 1/10,000$  to  $< 1/1,000$ ) reports of exfoliative dermatitis and erythrodermic psoriasis in psoriasis patients receiving ustekinumab. Patients with plaque psoriasis may develop erythrodermic psoriasis, with symptoms that may be clinically indistinguishable from exfoliative dermatitis, as part of the natural course of their disease. These skin conditions can occur within a few days of the patient receiving ustekinumab. They can be severe and lead to hospitalization.*

ii. *Physicians should be alert for symptoms of exfoliative dermatitis. These can appear as redness and shedding of the skin over almost the entire area of the body, which may be itchy and/or painful. In case of occurrence of these symptoms, appropriate therapy should be initiated. Treatment with ustekinumab should be discontinued if a drug reaction is suspected.*

iii. *Shedding of skin – increase in redness and shedding of skin over a larger area of the body may be symptoms of erythrodermic psoriasis or exfoliative dermatitis, which are serious skin conditions. You should contact your doctor straight away if you notice any of these signs.*

### **EU: Investigation into reports of serious adverse events following use of Flud**

On 28 November 2014, the EMA is working with the Italian medicines agency (AIFA) and other EU medicines regulatory authorities to investigate the cause of serious adverse events, including deaths, in a small number of elderly patients who had received Flud flu vaccine. There is so far no

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evidence to suggest a causal link between the vaccine and the reported adverse events. The suspension is a precautionary measure.

AIFA has suspended the use of two batches of the flu vaccine produced by Novartis. Testing of the batches is underway, as well as a detailed analysis of the case reports from Italy. This includes examining all available information on the affected patients' age, health condition and medication regime.

On 3 December 2014, the PRAC of the EMA has concluded that there is no evidence that Fluvad, a flu vaccine manufactured by Novartis, has caused serious events including deaths in Italy. After the review of the cases reported, the PRAC concluded that there was no evidence for a causal relation between the reported fatal events and the administration of Fluvad.

The assessment of the PRAC is reassuring as Member States across the EU continue with their annual flu vaccination campaigns. Influenza can

cause severe illness or death especially in the elderly and in people with long-term conditions. The World Health Organization (WHO) estimates that annual influenza epidemics result in about 3 to 5 million cases of severe illness worldwide and 250,000 to 500,000 deaths. Influenza vaccines are the most effective way to prevent the disease and the serious complications it can cause.

In Hong Kong, Fluvad Vaccine Pre-filled Syr Inj (HK-50982) is registered by Novartis Pharmaceuticals (HK) Ltd. (Novartis), and is a prescription only medicine. According to Novartis, the affected two batches of Fluvad vaccine suspended by the Italy health authority have not been imported into HK. The DH has not received any local adverse drug reaction reports related to Fluvad vaccine. The DH keeps close contact with Novartis for updating any safety issue of the product and remains vigilant on new announcements by other overseas health authorities.

## Drug Recall

### **Recall of Altazac Capsules 20mg (HK-47392)**

On 27 November 2014, the DH instructed a licensed drug manufacturer, Europharm Laboratoires Co. Ltd. (Europharm), to recall all batches of Altazac Capsules 20mg (Altazac Capsules) from the healthcare sector because the sales pack label of the product differs from the registered one. Altazac Capsules contains fluoxetine and is a prescription only medicine indicated for the treatment of depression. It should only be used under the advice of a medical doctor and could only be sold at pharmacies under the supervision of a registered pharmacist upon a doctor's prescription. Side effects include nausea, vomiting, anorexia, excessive sweating, rashes, photosensitivity and hypersensitivity.

Through DH surveillance programme, it was found that the sales pack label of the product was not affixed with an approved cautionary label, which rendered the product unregistered.

During the investigation, it was found that Europharm had been distributing Altazac Capsules to local doctors and pharmacies. The DH will closely monitor the recall. As on 27 November 2014, the DH had not received any adverse reaction report related to the use of the product. A notice was released on the Drug Office's website on the same day to alert the public of the recall.

People should consult healthcare professionals for advice if feeling unwell or in doubt after consumption of the product.

# Drug Incident

## Public urged not to buy or consume slimming product with undeclared Western medicine ingredients

On 4 November 2014, the DH appealed to members of the public not to buy or consume a slimming product called Mezo as it was found to contain undeclared Western medicine ingredients.

During the DH's market surveillance, Mezo was found to be offered for sale over the Internet. A sample was purchased for analysis. Test results from the Government Laboratory revealed that the product contains orlistat and lorcaserin.

Orlistat and lorcaserin are used for the treatment of obesity. Orlistat is a Part I poison and its side effects include faecal urgency, fatty stool, increased

defaecation, faecal incontinence, headache and abdominal pain. Severe liver injuries may also develop in rare cases. Side effects of lorcaserin include headache, dizziness, depression and suicidal ideation.

Products containing orlistat and lorcaserin are pharmaceutical products and must be registered with the Pharmacy and Poisons Board of Hong Kong (the Board) before they can be legally sold in the market.

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.

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.

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.

## News in Brief

### To Use Antibiotics Responsibly:

Don't wait, pledge today! Use antibiotics responsibly

It is indisputable that Antimicrobial resistance (AMR) is a global public health concern. This year, the World Health Organization (WHO) reported that AMR is happening right now in every region of the world with the potential affecting anyone, of any age. A concerted effort to safeguard effective antibiotics is required urgently. WHO Western Pacific Regional Office (WPRO) has recently initiated a campaign to solicit healthcare professionals to pledge on judicious use of antibiotics.

Hong Kong Special Administrative Region

(HKSAR) commits to support WHO's global initiative in combatting AMR: No Action today, no cure tomorrow. Since 2012, Antibiotic Awareness Day has been marked annually on 18 November in Hong Kong as a public health initiative to raise awareness about AMR threat and prudent antibiotic use.

The Department of Health is pleased to launch our locally adapted "I Pledge" Campaign on Antibiotic Awareness Day 2014.

### Ways to fight against AMR

The misuse of antibiotics is creating resistant "superbugs" that may leave your patients without effective treatment the next time antibiotics are needed.



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You can make a difference by committing to some simple actions for using antibiotics responsibly:

- Support judicious use of antibiotics.
- Educate patients:
  - ◆ Take antibiotics as prescribed by healthcare provider only and always complete the full course of medication;
  - ◆ Take antibiotics at the same fixed time every day as far as possible.
  - ◆ Take the missed dose as soon as possible unless it is almost time for the next scheduled dose. In that case, skip the missed dose and take the next dose as directed. Do not take double doses.
  - ◆ Do not drink alcohol as it may affect the effectiveness or increase the risk of side effects of antibiotics.
- Use good hygiene practices to prevent the spread of germs and to limit the need for antibiotics. E.g., wash hands frequently, eat or

drink only thoroughly cooked or boiled items, disinfect and cover all wounds.

- Encourage colleagues, friends and family to use antibiotics responsibly.

Overall, you can do it

- To support WHO's global initiative in combatting AMR: No action today, no cure tomorrow
- To promote the importance of "I pledge to use antibiotics responsibly"
- To highlight international experience in AMR control and Hong Kong's priorities in control of AMR
- To share AMR control in local public hospital and private hospitals

Please refer to the following link to learn more about antibiotics resistance:

[http://www.chp.gov.hk/files/pdf/reducing\\_bacterial\\_resistance\\_with\\_impact.pdf](http://www.chp.gov.hk/files/pdf/reducing_bacterial_resistance_with_impact.pdf)

### *Useful Contact*

#### Drug Complaint:

Tel: 2572 2068

Fax: 3904 1224

E-mail: [pharmgeneral@dh.gov.hk](mailto:pharmgeneral@dh.gov.hk)

#### Adverse Drug Reaction (ADR) Reporting:

Tel: 2319 2920

Fax: 2186 9845

E-mail: [adr@dh.gov.hk](mailto: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.***