Drug News
藥 物 情 報

Issue Number 87

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

UK: Class 4 Caution in Use : Mirena 20 micrograms / 24 hours intrauterine delivery system

On 5 January 2017, the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom (UK) announced that Bayer plc has informed MHRA that they have received two complaints globally concerning inserters of Mirena 20 micrograms / 24 hours intrauterine delivery system with an insertion tube which is mounted inversely to the handle. This has resulted in inversion of the insertion depth scale, which may lead to incorrect insertion depth and the possibility of a reduced efficacy or adverse events.

A very small number of Mirena inserters may potentially be affected by this issue. An investigation has shown that both complaints involve one batch of inserters and Mirena batch TU01BPE has been manufactured using inserters from the same batch.

In Hong Kong, Mirena Intrauterine System 52mg (HK-41251) is a pharmaceutical product registered by Bayer Healthcare Ltd (Bayer HK), and is a prescription only medicine. On 19 December 2016, Bayer HK has notified the Department of Health (DH) the above incident. As confirmed with Bayer HK, one of the potentially affected batches (i.e. Batch TU01BST) has been distributed to private doctors and hospitals, and hospitals under Hospital Authority, while the batch (batch number: TU01BPE) mentioned in the MHRA announcement has not been imported into Hong Kong. As on 24 February 2017, DH has not received any adverse drug reaction (ADR) report related to defect of the inserters of the product. As precautionary measures, Bayer HK has quarantined the remaining stock of the affected batch for inspection, and also issued a "Dear Healthcare Professional" letter to the doctors and hospitals receiving the affected batch. DH will continue to remain vigilant on the incident.

Canada: New safety information on injectable gadolinium-based contrast agents used in MRI scans

On 6 January 2017, Health Canada announced that it has conducted a safety review of gadolinium-based contrast agents (GBCAs) due to growing scientific evidence that gadolinium may accumulate in the brain following multiple contrast -enhanced magnetic resonance imaging (MRI) scans.

Although no health consequences have been identified with gadolinium accumulation in the brain, Health Canada will be working with Canadian manufacturers to update the labelling of GBCAs in Canada to include this new information.

Gadolinium is a chemical element and a component of dyes used to enhance contrast and improve radiology images. GBCAs are administered by injection and used for MRI scans when needed.

After injection, gadolinium is eliminated through the kidneys (in urine) and for some of the agents also through the liver, but small amounts may stay in different parts of the body, including the brain. Gadolinium accumulation in the brain has been found in patients both with and without kidney disease.

As on 6 January 2017, Health Canada has not

received any adverse event reports related to gadolinium accumulation in the brain.

Patients and caregivers should talk to their health care professionals if they have questions about the use of GBCAs with MRIs for their individual health circumstances.

Health professionals are advised to:

- limit the use of GBCAs to situations where the contrast agent is considered necessary,
- use the lowest effective dose, and
- assess the benefits and any potential risks to individual patients before administering repeated doses of GBCAs.

Health Canada is also advising health care professionals that the available scientific evidence suggests that gadolinium accumulation in the brain is higher with the use of linear agents than with the use of macrocyclic agents, but it has occurred with both types.

Health Canada is continuing its monitoring and evaluation of the risk of gadolinium accumulation in the brain associated with the use of GBCAs and will inform Canadians again as required.

In Hong Kong, there are nine registered pharmaceutical products which are gadolinium contrast agents, and are prescription only medicines, including Magnevist Inj (HK-32608) containing meglumine gadopentetate, Omniscan Inj 0.5mmol/ml (HK-43493) containing gadodiamide, Gadovist Inj 1mmol/ml (HK-51750) and Gadovist Inj 1mmol/ml (Pre-filled Syringe) (HK-57330) containing gadobutrol, Primovist Pre-filled Syringe Inj 0.25mmol/ml (HK-54116) containing sodium gadoxetate, Dotarem Inj 377mg/ml (Vial) (HK-41578) and Dotarem Prefilled Syringes 377mg/ml (HK-41579) containing meglumine gadoterate, and MultiHance Inj 334mg (China) (HK-55495) and MultiHance Inj 334mg (HK-57789) containing gadobenic acid (as meglumine gadobenate).

Related news was previously issued by the United States (US) Food and Drug Administration (FDA), Taiwan Food and Drug Administration (TFDA) and European Medicines Agency (EMA), and was reported in the Drug News Issue No. 69. As on 24 February 2017, DH has received seven cases of ADR in connection with GBCAs: two cases on Omniscan, three cases on Dotarem, and two cases on Gadovist. These reported ADR cases were not related to brain deposits.

As the US FDA will study the risk of brain deposits further to consider if change to product label is needed, and the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) will carry out an in-depth review of the risk of brain deposits, DH will remain vigilant on the conclusion of these reviews and any safety updates from other overseas drug regulatory authorities.

Canada: Health Canada advises that the drug hCG is not authorized or proven effective for weight loss

On 19 January 2017, Health Canada advised Canadians that hCG (human chorionic gonadotropin) is not authorized or proven as a weight loss aid in Canada, and could pose serious health risks.

hCG is a prescription drug authorized in Canada as an injectable for the treatment of hormone-related conditions such as infertility. It should be used only under the supervision of a healthcare professional.

Health Canada has received several complaints that clinics across Canada are advertising hCG for weight loss, which is an unauthorized use. In these cases, products were often promoted as part of a severe calorie-reduced weight loss plan. Health Canada is not aware of any substantial scientific evidence that hCG is effective for weight loss, that it redistributes fat, or that it reduces appetite or the hunger and discomfort associated with calorie-restricted diets.

Risks associated with hCG—whether used for authorized indications or weight loss—include: blood clots; depression; hyper-stimulation of the ovaries (which can lead to severely enlarged and painful cysts and abdominal distension, difficulty breathing and life-threatening imbalances in blood volume), multiple pregnancy (two or more babies in the uterus) and false pregnancy tests in women; and fluid retention and gynecomastia (breast enlargement) in men.

Health Canada has taken action to address the complaints and will take action if identify any

further non-compliance with the Food and Drugs Act and/or its Regulations. Health Canada has also issued a letter to the provincial and territorial colleges of physicians and surgeons, naturopaths and pharmacy associations, to reinforce the federal regulatory requirements related to the advertising of hCG.

Consumers are advised to talk to their health care professional or a dietitian if they are considering starting a special diet, and learn how to minimize risks when considering health products for weight management.

In Hong Kong, there are eight registered pharmaceutical products containing chorionic gonadotropin, and are prescription only medicines. None of the products are indicated for weight loss. As on 24 February 2017, DH has not received any ADR report related to chorionic gonadotropin. DH will remain vigilant on the safety update of the drug.

UK: Apremilast (Otezla ▼): risk of suicidal thoughts and behaviour

On 19 January 2017, MHRA advised that there is an increased risk that some patients may experience psychiatric symptoms with apremilast, including depression and suicidal thoughts. Treatment should be stopped if patients have new psychiatric symptoms or if existing symptoms worsen.

Apremilast (Otezla) is a phosphodiesterase-type-4 inhibitor indicated for the treatment of moderate to severe chronic plaque psoriasis or active psoriatic arthritis in adults who have not responded to other systemic treatments in Canada.

Depression, suicidal thoughts, and suicidal behaviours are more common in patients with psoriasis or psoriatic arthritis than in the general population. Clinical trials and postmarketing experience (including reports to the Yellow Card scheme) have recorded serious psychiatric symptoms, including depression, suicidal thoughts, and suicidal behaviours. Suicidal thoughts and behaviours have been reported in patients with no previous history of depression.

A review of the evidence from clinical trials and postmarketing cases has suggested a causal association between apremilast and suicidal thoughts and suicidal behaviour. These events are reported to occur uncommonly, with an estimated frequency of between 1 in 1000 to 10 in 1000 patients taking apremilast.

MHRA advised healthcare professionals of the following:

- apremilast is associated with an increased risk of psychiatric symptoms, including depression, suicidal thoughts, and suicidal behaviours
- suicidal thoughts and behaviour, including completed suicide, have been reported in patients with or without a history of depression
- carefully assess the benefits and risks of starting or continuing treatment in patients with a history of psychiatric symptoms, or in those who are taking other medicines likely to cause psychiatric symptoms
- stop treatment if patients experience new psychiatric symptoms or if existing symptoms get worse
- advise patients to inform a healthcare professional if they notice changes in their mood

In Hong Kong, Otezla Tablets 30mg (HK-64859) and Otezla Tablets Starter Pack (HK-64860) are pharmaceutical products registered by Celgene Limited, and are prescription only medicines. As on 24 February 2017, DH has not received any ADR report related to apremilast. In view of the above MHRA announcement, DH issued a letter to inform local healthcare professionals to draw their attention on 20 January 2017, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board (the Registration Committee).

UK: Intravenous N-acetylcysteine (NAC) for paracetamol overdose: reminder of authorised dose regimen; possible need for continued treatment with NAC

On 19 January 2017, MHRA advised that the authorised dose regimen in UK for N-acetylcysteine (NAC) in paracetamol overdose is 3 consecutive bags given intravenously over 21 hours. Prescribing information is being updated in

UK to advise that continued treatment with NAC may be necessary depending on clinical evaluation of the individual patient.

Intravenous NAC is the antidote to treat paracetamol overdose and is virtually 100% effective in preventing liver damage when given within 8 hours of the overdose. After this time efficacy falls substantially, affording only a very limited window of time in which to successfully prevent serious hepatotoxicity.

Simplified guidance on the treatment of paracetamol overdose with NAC was implemented in UK in September 2012, after an evidence-based review by the Commission on Human Medicines (CHM). Since 2012, data for an off-label shortened 2-bag regimen for NAC to treat paracetamol overdose have been published from the Scottish and Newcastle Antiemetic Pre-treatment for paracetamol poisoning (SNAP) study. CHM have reviewed these findings and, as part of their review, also looked at the safety profile of NAC since the 2012 guidance was implemented. CHM concluded that there was insufficient evidence of efficacy to add information about the off-label shortened 2-bag dose regimen used in the SNAP study to the product information for NAC.

The pattern of potential ADR associated with NAC is well established, and no new safety issues have been identified since the 2012 guidance. The authorised NAC product information in UK reflects the safety profile. CHM concluded that the benefits of the authorised 3-bag dose regimen continue to outweigh the risks.

As a result of the review, in line with current clinical guidance, prescribing information for NAC is being updated in UK to advise that continued treatment with NAC beyond 21 hours may be necessary depending on the clinical evaluation of the individual patient.

MHRA advised healthcare professionals of the following:

- the authorised posology for intravenous NAC in the treatment of paracetamol overdose is 3 consecutive intravenous infusions
  - ◊ first infusion: initial loading dose of 150 mg/kg bodyweight over 1 hour
  - ◊ second infusion: 50 mg/kg over the next 4 hours
  - ◊ third infusion: 100 mg/kg over the next 16 hours
- the patient should receive a total dose of 300 mg/kg bodyweight over a 21-hour period. A ceiling weight of 110 kg should be used when calculating the dose for obese patients
- continued treatment with NAC (given at the dose and rate as used in the third infusion) may be necessary depending on the clinical evaluation of the individual patient

In Hong Kong, there are nine registered pharmaceutical products which are solution for infusion containing acetylcysteine. As on 24 February 2017, DH has not received any ADR report related to acetylcysteine. In view of the above MHRA announcement with update of prescribing information, DH issued a letter to inform local healthcare professionals to draw their attention on 20 January 2017, and the matter will be discussed by the Registration Committee.

UK: Direct-acting antivirals to treat chronic hepatitis C: risk of interaction with vitamin K antagonists and changes in INR

On 19 January 2017, MHRA advised that INR should be monitored closely during treatment of chronic hepatitis C with direct-acting antivirals in patients also receiving vitamin K antagonists (eg, warfarin), because of possible changes in liver function during treatment.

In UK, direct-acting antivirals for the treatment of chronic hepatitis C infection include: boceprevir (Victrelis); daclatasvir (Daklinza ▼); dasabuvir (Exviera ▼); ombitasvir, paritaprevir, ritonavir (Viekirax ▼); sofosbuvir (Sovaldi ▼); ledipasvir with sofosbuvir (Harvoni ▼); and simeprevir (Olysio ▼). Vitamin K antagonists are used as anticoagulant medicines, and include warfarin and acenocoumarol.

A Europe-wide review of the use of concomitant vitamin K antagonists and direct-acting antivirals for chronic hepatitis C has identified that changes in INR occur during treatment. Changes in liver function secondary to hepatitis C treatment are thought to affect the efficacy of vitamin K

antagonists.

The benefits of treatment with direct-acting antivirals for chronic hepatitis C continue to outweigh the risks of an interaction with vitamin K antagonists. However, INR values should be monitored closely in patients receiving this concomitant treatment because changes in liver function may affect INR values and necessitate adjustment of anticoagulant therapy.

MHRA advised healthcare professionals of the following:

- changes in liver function due to treatment with direct-acting antivirals for chronic hepatitis C infection may result in fluctuations of INR values in patients taking vitamin K antagonists
- in these patients, INR should be monitored closely and, if necessary, anticoagulant therapy adjusted

MHRA advised professionals to give the following advice to patients:

- patients should be advised to inform their doctor or pharmacist that they are taking warfarin or other similar medicines called vitamin K antagonists used to thin the blood if they are prescribed direct-acting antivirals
- patients who are receiving vitamin K antagonists should be advised that during treatment with direct-acting antivirals for chronic hepatitis C, they may have more-regular blood tests to check how well their blood can clot

In Hong Kong, there are seven registered pharmaceutical products which are direct-acting antivirals, namely Harvoni Tablets containing the combination of sofosbuvir and ledipasvir (HK-63886), and Sovaldi Tablets 400mg containing sofosbuvir (HK-63501) which are registered by Gilead Sciences Hong Kong Limited, Viekira Pak Tablets containing the combination of ombitasvir, paritaprevir, ritonavir and dasabuvir (HK-63695) which is registered by Abbvie Limited, Daklinza Tablets 60mg containing daclatasvir (HK-64505) and Sunvepra Capsules 100mg containing asunaprevir (HK-64506) which are registered by Bristol-Myers Squibb Pharma (HK) Ltd, Olysio Capsules 150mg containing simeprevir (HK-64765) which is registered by Johnson & Johnson (Hong Kong) Ltd, and Victrelis Cap 200mg containing boceprevir (HK-61806) which is registered by Merck Sharp & Dohme (Asia) Ltd. There are 15 registered pharmaceutical products containing warfarin. All these products are prescription only medicines. There is no registered product containing acenocoumarol.

As on 24 February 2017, DH has not received any ADR report arising from interaction of direct-acting antivirals with vitamin K antagonists. In view of the above MHRA announcement, DH issued a letter to inform local healthcare professionals to draw their attention on 20 January 2017, and the matter will be discussed by the Registration Committee.

Canada: FLUOROQUINOLONES - Risk of disabling and persistent serious adverse reactions

On 23 January 2017, Health Canada advised that Canadian and international cases of disabling and persistent serious adverse reactions including tendinopathy, peripheral neuropathy, and central nervous system disorders have been reported in patients treated with oral and injectable fluoroquinolones. These included fluoroquinolones (ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin and ofloxacin), in oral and injectable dosage forms.

Fluoroquinolones are a class of antibacterial drugs used in the treatment of various gram-negative and gram-positive bacterial infections, including respiratory and urinary tract infections.

Health Canada conducted an assessment to examine the safety of systemic fluoroquinolones. This was prompted by the findings of the US FDA benefit/risk assessment on systemic fluoroquinolones and the occurrence of disabling and persistent adverse reactions.

Health Canada's safety review focused on already known and labelled adverse reactions associated with the use of fluoroquinolones that resulted in persistent disability. Health Canada has received reports of a small number of these cases over time. The reported adverse reactions in Canada associated with persistent disability mostly involved the musculoskeletal system (e.g., tendonitis and Achilles tendon rupture), peripheral

neuropathy and central nervous system disorders (e.g., depression, anxiety, dizziness and confusion).

Health Canada's assessment concluded that fluoroquinolones are associated with rare cases of disabling and persistent serious adverse reactions such as tendinopathy, peripheral neuropathy, and central nervous system disorders. Health Canada consulted the Scientific Advisory Panel on Anti-Infective Therapies (SAP-AIT) on the use of fluoroquinolones for treating certain infections, considering their potential association with disabling and persistent events. The SAP-AIT recommended labelling updates to all systemic fluoroquinolones to include information on the severity and persistence of these adverse reactions in Canada.

Consumers are advised that fluoroquinolones are generally well tolerated but they have been associated with rare serious side effects that were disabling and persistent, including tendon damage, nerve damage in the hands and feet, and central nervous system disorders. These side effects can occur hours to weeks after exposure to fluoroquinolone treatment. Patients should inform their healthcare professional if they think they have previously experienced a side effect related to fluoroquinolone use. Patients should immediately consult a healthcare professional if they experience serious side effects, such as joint and muscle pain, swelling or rupture of a tendon, tingling, numbness, weakness, or other alterations of sensation, tremors, restlessness, anxiety, lightheadedness, confusion, hallucinations, paranoia, depression, nightmares, insomnia, suicidal thoughts.

Health Canada advised healthcare professionals of the following:

- It is recommended that the potential for disabling and persistent serious adverse events be considered when choosing to prescribe a fluoroquinolone.
- Fluoroquinolones should not be prescribed to patients who have experienced serious adverse reactions during or after prior treatments.
- Stop systemic fluoroquinolone treatment if a patient reports a serious adverse reaction. The patient's treatment should be switched to an alternative treatment with a non-fluoroquinolone antibacterial drug if needed to complete the treatment course.
- Some adverse reactions associated with the use of fluoroquinolones can occur within hours to weeks after exposure to the treatment.

In Hong Kong, there are 250 registered pharmaceutical products containing fluoroquinolones, including 106 ciprofloxacin, 67 levofloxacin, 54 ofloxacin, 8 moxifloxacin, 11 norfloxacin, 2 lomefloxacin, 1 prulifloxacin and 1 sparfloxacin products. All these products are prescription only medicines.

Related news was previously issued by the US FDA on peripheral neuropathy, and was reported in the Drug News Issue No. 46, and on disabling and potentially permanent side effects of the tendons, muscles, joints, nerves, and central nervous system and was reported in the Drug News Issue No. 79 and 81. DH issued a letter to inform local healthcare professionals to draw their attention on 16 August 2013 and 13 May 2016. The Registration Committee discussed the matters on peripheral neuropathy with fluoroquinolones in the meeting held in December 2013, and decided that the relevant warnings should be included in the sales packs and/or package inserts of the products. In September 2016, the Registration Committee further discussed the matters on disabling and potentially permanent side effects of the tendons, muscles, joints, nerves, and central nervous system with fluoroquinolones, and subsequently decided to remain vigilant on any updates by other overseas drug regulatory authorities.

As on 24 February 2017, DH has received two cases of ADR with levofloxacin, which were not related to the adverse effects mentioned in the above Health Canada announcement, and no ADR report has been received for the remaining fluoroquinolones. In view of the above Health Canada announcement, the matter will be further discussed by the Registration Committee.

DH endorsed recall of five batches of Singulair Chewable Tab 4mg (HK-47118)

On 9 January 2017, DH endorsed a licensed drug wholesaler Merck Sharp & Dohme (Asia) Ltd (MSD) to recall five batches (66628008, 66628014, 66628017, 66628018 and 66628027) of Singulair Chewable Tab 4mg (HK-47118) from the market due to printing error.

DH was notified by MSD on 9 January 2017 that one Chinese character printed on the package of the product was incorrect on five batches of product. As incorrect printing of the label may render the product unregistered, MSD voluntarily recalls the above affected batches from the market.

Singulair Chewable Tab 4mg containing montelukast is a Prescription Only Medicine indicated for the treatment of asthma. According to MSD, about 15,200 boxes from the affected batches have been supplied to the Hospital Authority, private hospitals, private doctors and local pharmacies.

A notice was posted on the Drug Office website on 9 January 2017 to alert the public of the product recall.

DH endorsed recall of three batches of Methenin Lotion (HK-42181)

On 16 January 2017, DH endorsed a licensed drug wholesaler Lanway Ltd (Lanway) to recall three batches (5174, 5178 and 5181) of Methenin Lotion (HK-42181) from the market due to a potential quality issue.

DH received information via its surveillance system that the product's manufacturer has recalled the above affected batches of Methenin Lotion because samples from one of these batches of product have failed the on-going stability tests. As a precautionary measure, the manufacturer recalled these batches.

Methenin Lotion, containing Potassium iodide, Iodine, Camphor, Phenol and Salicylic acid, is an over-the-counter product indicated for the external treatment of fungal infection. According to Lanway, the affected product has been supplied to the local pharmacies and medicine stores.

Related news was previously issued by the TFDA, and was reported in the Drug News Issue No. 85. A notice was posted on the Drug Office website on 16 January 2017 to alert the public of the product recall.

DH endorsed batch recall of APO-SERTRALINE Capsules 50mg (HK-49970)

On 16 January 2017, DH endorsed a licensed drug wholesaler, Hind Wing Co Ltd (Hind Wing), to recall a batch (batch number: MV1007) of APO-SERTRALINE Capsules 50mg (HK-49970) from the market as the pharmaceutical product may actually contain APO-SERTRALINE Capsules 25mg, which are of lesser strength.

DH received notification from Hind Wing that the 50mg product's manufacturer in Canada was recalling the above batch as it may contain the 25mg product. According to the manufacturer, the causes of the issue are still under investigation but only one batch was affected.

The 50mg product, containing sertraline, is a prescription medicine used for depression. According to Hind Wing, 95 bottles from the affected batch have been supplied to government (not yet dispensed), private doctors and local pharmacies.

People prescribed with the two products should check the capsule before consumption. The capsule of the 50mg product is yellow-white and printed with "APO" and "50", while that of the 25mg product is entirely yellow and printed with "APO" and "25". Members of the public should consult healthcare professionals if in doubt.

As on 24 February 2017, DH has not received any ADR report in connection with the affected product. A notice was posted on the Drug Office website on 16 January 2017 to alert the public of the product recall.

DH endorsed recall of three batches of Gaster Capsules 20mg (HK-52562) (Each box contains 28 capsules)

On 17 January 2017, DH endorsed a licenced pharmaceutical secondary packaging manufacturer,

Sources (U.S.A.) Medicines Ltd (Sources), to recall three batches (batch number: A0501, A0504 and A0603) of Gaster Capsules 20mg (HK-52562) (Each box contained 28 capsules) from the market because the outer box of the product does not match with the registered one.

During DH routine inspection, it was found that the outer box of the above product was not labeled with "Drug under Supervised Sales" in accordance with the legal requirement and thus different from the registered label. This renders the product unregistered. Since the supply of unregistered pharmaceutical product contravenes the Pharmacy and Poisons Regulations (Cap. 138A), Sources voluntarily recalls the product from the market.

The above product, containing Part 1 poison omeprazole, is used for treatment of gastric ulcer and gastro-oesophageal reflux syndrome. According to Sources, the product has been supplied to local pharmacies.

As on 24 February 2017, DH has not received any ADR report in connection with the affected product. A notice was posted on the Drug Office website on 17 January 2017 to alert the public of the product recall.

DH endorsed batch recall of CP-PYRIDINE TAB 100MG S.C. (HK-47841)

On 26 January 2017, DH endorsed a licenced drug wholesaler, Christo Pharm Ltd (Christo), to recall one batch (batch number: S151203) of CP-PYRIDINE TAB 100MG S.C. (HK-47841) from the market because of the potential quality issue.

DH received notification from Christo that they have received a complaint about the sugar coating on the product was slightly melted. According to Christo, one batch of the product (batch number: S151203) was found to be affected. Hence, Christo decided to recall the affected batch from the market.

The above product, containing phenazopyridine, is an over-the-counter medicine used for the relief of symptoms caused by irritation of the urinary tract. According to Christo, about 327 boxes containing 500 tablets per box of the affected product has been supplied to Hospital Authority (HA), pharmacies, private doctors and private hospitals. According to HA, the affected batch has not been dispensed to patient.

As on 24 February 2017, DH has not received any ADR report in connection with the affected product. A notice was posted on the Drug Office website on 26 January 2017 to alert the public of the product recall.

Drug Incident

Public urged not to buy or consume unlabelled slimming products with controlled ingredients

On 6 January 2017, DH appealed to members of the public not to buy or consume unlabelled slimming products that may contain controlled medicine ingredients.

Upon a public complaint, a local Internet seller was found offering for sale various unlabelled slimming products claimed to be obtained from overseas. Upon analysis, some of these products were found to contain various Part 1 poisons including hydrochlorothiazide, fluoxetine and omeprazole.

During a joint operation with the Police conducted at 5 January 2017 night, a 19-year-old woman was arrested by the Police for illegal sale of Part 1 poisons and unregistered pharmaceutical products.

Hydrochlorothiazide is used for the treatment of hypertension and its side effects include low blood pressure and electrolytes imbalance. Fluoxetine is used for treatment of mood disorder and may cause hallucination and insomnia. Omeprazole is used for managing gastric and duodenal diseases and may cause nausea, vomiting, abdominal pain and diarrhoea. Medicines containing these ingredients should only be supplied by pharmacies under the supervision of a registered pharmacist.

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 notice was posted on the Drug Office website on 6 January 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.

Useful Contact

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Adverse Drug Reaction (ADR) Reporting:

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

Post: ***Pharmacovigilance Unit,***
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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.