Drug News
藥 物 情 報

Issue Number 60

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

Canada: Health Canada takes action to stop import of products from three sites in India: Apotex Pharmachem India Pvt Ltd (APIPL), Apotex Research Private Ltd (ARPL) and IPCA Laboratories

It was noted from the website of Health Canada on 3 October 2014 that the Department took action to stop the import of health products from the following sites in India: Apotex Pharmachem India Pvt Ltd (APIPL), Apotex Research Private Ltd (ARPL) and IPCA Laboratories. The action applies to finished products from ARPL, as well as active pharmaceutical ingredients (APIs) and products made with APIs from APIPL and IPCA. Certain medically necessary products may be excluded from the action on the condition they are tested by an independent third party before being released for use or sale. Independent testing against specifications will provide confidence that these products meet Canadian quality standards, and will allow consumers to have continued access to medically necessary and safe products.

When data integrity issues were first identified at each of these sites by the U.S. Food and Drug Administration (FDA), Health Canada took action to protect the health and safety of Canadians. There is currently a voluntary quarantine on products from ARPL and IPCA. Products from APIPL have been undergoing additional testing, as required by Health Canada before being allowed on the Canadian market.

Health Canada continues to gather information about the situation at these three sites from trusted regulatory partners, including the FDA. Based on recent information, the Department has significant concerns with the manner in which data are collected and reported, raising serious doubts about the quality and safety of finished products and APIs produced at these sites. Until Health Canada can be satisfied that the production processes used at these three sites meet internationally recognized good manufacturing practices (GMP), it is taking this additional precautionary step to keep these products off the Canadian market.

Consumers should be aware that no specific safety issues have been identified with products currently on the market from the list. Neither the FDA nor Health Canada has requested a recall of these products. Health Canada has stopped imports as a temporary precautionary measure until it is satisfied of the processes followed at these sites. Consumers should not make any change to their medication without first consulting with a healthcare professional.

On 17 October 2014, Health Canada was providing an update on measures it is taking so that Canadians can have access to affected medically necessary products.

Health Canada remains in regular contact with its provincial and territorial counterparts to monitor the impact of the import restrictions. The list of medically necessary products may change over time as new information becomes available.

The licences of companies that import products from these three facilities have all been amended with terms and conditions to require independent third party testing against the approved Canadian specifications prior to release of any medically necessary products to the Canadian market. Independent testing will provide confidence that these products meet Canadian quality standards, and will allow consumers to have continued access

to medically necessary products that are safe and of good quality. Products from these three sites that are not on the medically necessary list will not be imported or released on to the Canadian market until Health Canada is satisfied that the data integrity issues at the plants have been addressed.

Although the new licence conditions are effective, companies have already begun taking appropriate steps to comply with the terms and conditions and are working to put in place, or have already arranged, the required testing.

In Hong Kong, the Department of Health (DH) has noted relevant news announced by the Health Canada which was reported in Drug News Issue No. 59. According to the updated list of affected products from Health Canada, there are a total of 64 registered pharmaceutical products involved or matched with registered product's name in Hong Kong. Among these 64 products, 22 products are not marketed in Hong Kong, the rest of 42 products are registered by Takeda Pharm (HK) Ltd, AstraZeneca HK Ltd, Trenton-Boma Ltd and Hind Wing Co Ltd. The DH has instructed the certificate holders to provide investigation reports and requested them to quarantine the active pharmaceutical ingredients from the respective manufacturers in India. The DH noted that from the announcement that there is no specific safety issues have been identified with the products and neither the US FDA nor Health Canada has requested a recall of these products, and shall remain vigilant on any further action taken against the products by the US FDA, Health Canada and other overseas regulatory authorities.

Canada / Australia: Safety updates on Diclofenac and other NSAIDs

On 6 October 2014, Novartis Pharma Canada Inc. ("Novartis Canada") and Pfizer Canada Inc. ("Pfizer Canada"), in collaboration with Health Canada, informed the public and healthcare professionals of revisions made to the Product Monographs for all diclofenac-containing systemic medicines (tablets and suppositories) including VOLTAREN/VOLTAREN SR (diclofenac sodium), VOLTAREN RAPIDE (diclofenac potassium), ARTHROTEC (diclofenac sodium/misoprostol). This safety update does not refer to topical formulations of diclofenac, such as gel or eye drops.

Health Canada is currently updating the labelling of all systemic formulations of diclofenac-containing medicines as follows:

a. Diclofenac (tablets and suppositories), particularly at higher doses (150 mg per day), is associated with an increased risk of serious cardiovascular adverse events (such as myocardial infarction, stroke or thrombotic events which can be fatal) that is comparable to COX-2 inhibitors. Evidence suggests that the risk may increase with the dose and duration of use.

b. The maximum recommended daily dose of systemic diclofenac has been reduced from 150 mg per day to 100 mg per day for all indications, excluding VOLTAREN RAPIDE which allows for a 200 mg dose only on the first day of treatment for dysmenorrhea. To minimize the potential risk for an adverse cardiovascular event, the lowest effective dose should be used for the shortest possible duration.

c. Treatment with diclofenac is not recommended in patients with pre-existing cardiovascular disease (CVD) or cerebrovascular disease, or presenting risk factors for CVD. For these patients, treatment options other than non-steroidal anti-inflammatory drugs (NSAIDs), particularly COX-2 inhibitors and diclofenac, should be considered first.

On 7 October 2014, the Therapeutic Goods Administration (TGA) has completed a review of the cardiovascular risks associated with the use of the NSAIDs diclofenac, naproxen, ibuprofen, celecoxib, etoricoxib, indomethacin, meloxicam and piroxicam. In addition to this review, the TGA has also completed a full safety review of diclofenac. In summary:

a. While use of NSAIDs at prescription only dosages was already known to increase the risk of high blood pressure, heart failure, heart attack and stroke, the TGA NSAIDs review found that these risks also applied to OTC forms of diclofenac, naproxen and ibuprofen.

b. Similarly, the risk of hepatotoxicity (commonly known as liver damage) in relation to use of prescription diclofenac was known, but the TGA's safety review of that medicine found that OTC diclofenac products also carried this risk.

The TGA reviews found that there is a need to raise awareness among consumers and health professionals of the cardiovascular risks associated with NSAIDs and the additional hepatotoxicity risks for diclofenac, including OTC versions of these medicines. The TGA reviews have found that use of OTC NSAIDs is safe when they are used according to the recommended doses for short durations, as instructed on the label. However, inappropriate use or overuse of these medicines can pose a significant health risk. The product labelling for OTC diclofenac, naproxen and ibuprofen does not carry adequate warnings regarding the risks of adverse cardiovascular events or, in the case of diclofenac, hepatotoxicity.

In Hong Kong, there are 603 registered pharmaceutical products containing NSAIDs, including 247 diclofenac, and 356 other NSAIDs products of ibuprofen, naproxen, indomethacin, mefenamic acid, piroxicam, celecoxib, parecoxib and etoricoxib. Safety alerts regarding diclofenac and other NSAIDs associated with cardiovascular risks had been issued by various health authorities and were reported in Drug News Issues Numbers 24, 36, 43, 53 and 54. Letters to inform healthcare professionals to draw their attention on the safety of NSAIDs associated with cardiovascular risks, and new warnings on the use of high dose diclofenac for more than four weeks in selected patients were issued on 30 September 2011 and 3 March 2014 respectively. The above two safety issues had been discussed in the meetings of the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certificate of Clinical Trial/Medicine Test) Committee (the Registration Committee) of the Pharmacy and Poisons Board in February 2013 and May 2014 respectively. In February 2013, the Committee decided that NSAIDs-containing products other than external preparations should include new warnings on cardiovascular risks. In May 2014, the Committee further discussed the safety with high dose of diclofenac and concluded that the DH would remain vigilant on new announcements related to diclofenac by other health authorities. Both decisions were outlined in Drug News Issues Numbers 43 and 54 respectively. So far, the DH has received 10 local adverse drug reactions reports concerning NSAIDs, but none of them was related to cardiovascular or hepatotoxicity adverse events. In view of the latest recommendations by Health Canada and the TGA, a letter to inform local healthcare professionals to draw their attention and urge them to report any adverse drug reactions related to the drug was issued on 7 October 2014, and the safety with hepatotoxicity and high dose of diclofenac will be further discussed by the Registration Committee.

EU / UK: PRAC recommends strengthening the restrictions on the use of valproate in women and girls

On 10 October 2014, the European Medicines Agency (EMA)'s Pharmacovigilance and Risk Assessment Committee (PRAC) has recommended strengthening the restrictions on the use of valproate medicines due to the risk of malformations and developmental problems in children exposed to valproate in the womb.

Valproate should not be used to treat epilepsy or bipolar disorder in girls and in women who are pregnant or who can become pregnant unless other treatments are ineffective or not tolerated. Women for whom valproate is the only option after trying other treatments, should use effective contraception and treatment should be started and supervised by a doctor experienced in treating these conditions. Women who have been prescribed valproate should not stop taking their medicine without first consulting their doctor.

In countries where valproate medicines are authorised for the prevention of migraine, women must not use valproate for preventing migraine when they are pregnant. Pregnancy should be excluded before starting treatment for migraine, and women should use effective contraception.

The recommendations of the PRAC follow a review of available data on the effects of valproate exposure during pregnancy. During the review the PRAC also consulted representatives of patients and families who have been affected as well as a group of experts and specialists. While valproate remains an option for patients where other treatments have failed or are not tolerated, the Committee concluded that women and healthcare professionals need to be better informed about the risks of valproate exposure in the womb and of the need for effective contraception.

Data show that children exposed to valproate in the womb are at an approximately 11% risk of malformations at birth (such as neural tube defects

and cleft palate) compared to a 2 to 3% risk for children in the general population. Available data also show that children exposed to valproate in the womb are at increased risk of autistic spectrum disorder (around 3 times higher than in the general population) and childhood autism (5 times higher than in the general population). There are also limited data suggesting that children exposed to valproate in the womb may be more likely to develop symptoms of attention deficit hyperactivity disorder (ADHD). The EU product information for healthcare professionals and patients is to be updated with the latest information and recommendations.

The recommendations of the PRAC will be sent the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. In the meantime, women currently taking valproate who have any questions about their treatment should speak with their doctor.

On the same day, the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK announced also that the PRAC of the EMA has recommended strengthening the restrictions on the use of valproate medicines due to an increased risk of birth defects and developmental problems in children exposed to valproate in the womb.

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 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 previously, and was reported in the Drug News Issue No. 43. So far, the DH has not received any adverse drug reaction in connection to the drugs. In light of the latest EU PRAC recommendations on strengthening the restrictions on the use of valproate in women and girls, a letter to inform local healthcare professionals on the update regarding safe use of the drugs was issued on 13 October 2014. The matter will be further discussed by the Registration Committee, and the DH will continue to keep vigilant on further announcements on the products issued by other overseas health authorities.

EU: PRAC review does not confirm increase in heart problems with testosterone medicines

On 10 October 2014, the EMA's PRAC has completed an EU-wide review of testosterone-containing medicines following concerns over serious side effects on the heart and blood vessels, including heart attack. The PRAC review did not find consistent evidence that the use of testosterone in men who do not produce enough testosterone (a condition known as hypogonadism) increases the risk of heart problems. The Committee considered that the benefits of testosterone continue to outweigh its risks but recommended that testosterone-containing medicines should only be used where lack of testosterone has been confirmed by signs and symptoms as well as laboratory tests.

The evidence about the risks of serious side effects on the heart of these medicines is inconsistent. While some studies including three recently published studies did suggest an increased risk of heart problems in men using testosterone compared with men not taking it, these studies had some limitations and others did not confirm this risk. The PRAC also noted that the lack of testosterone itself could increase the risk of heart problems. The PRAC therefore recommended that testosterone-containing medicines should only be used if the lack of testosterone has been confirmed by signs and symptoms as well as laboratory tests. The EU product information for all testosterone-containing medicines should be updated to include this recommendation as well as warnings against use in men suffering from severe heart, liver or kidney problems. The limited data on safety and effectiveness in patients over 65 years of age as well as the fact that testosterone levels decrease

with age and that age-specific testosterone reference values do not exist will be highlighted in the product information.

The PRAC recommendation will be forwarded to the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) which will adopt a final position.

In Hong Kong, there are eight registered pharmaceutical products containing testosterone and they are prescription only medicines. The DH noted that the US FDA and EMA have started to review the risk of cardiovascular events of testosterone products and the related news was reported in the Drug News Issue No. 52. Related news on the risk of venous thromboembolism was also released by the US FDA and was reported in the Drug News Issue No. 56. Meanwhile, Health Canada has completed a safety review on the possible cardiovascular problems with testosterone products, and is working with their manufacturers to update the Canadian product labels with the safety warnings, and the news was reported in the Drug News Issue No. 57. Letters to inform local healthcare professionals on the above safety warnings, and urged them to report adverse drug reactions related to the drugs were issued on 20 June 2014 and 16 July 2014. So far, the DH has not received any adverse drug reaction report on the drug related to cardiovascular complications. In light of the above announcements by the EU, US and Canada health authorities, a letter to inform local healthcare professionals to draw their attention on safe use of the drugs was issued on 13 October 2014. The matter will be discussed by the Registration Committee, and the DH will continue to keep vigilant on further announcements on the products issued by other overseas health authorities.

Australia: Potential confusion in reading correct dose of Children's Panadol 1-5 Years Colourfree Suspension

On 14 October 2014, the TGA has become aware that some people have expressed confusion over how to use measuring syringes supplied with Children's Panadol 1-5 Years Colourfree Suspension which the manufacturer is GlaxoSmithkline (GSK). Incorrect measurements have the potential to lead to accidental overdoses.

The active ingredient in Children's Panadol 1-5 Years Colourfree Suspension is paracetamol. Paracetamol is safe and effective when taken as directed on the label. However, if taken either in overdose or in amounts that exceed the recommended dose for more than a few days, the unwanted effects can be severe.

The syringe supplied with Children's Panadol 1-5 Years Colourfree Suspension is shaped in such a way that the dose should be measured where the widest side of the plunger meets the barrel of the syringe. This differs from most syringes which measure to the tip of the plunger where the liquid finishes. With the Children's Panadol syringe, the liquid continues past the tip of the plunger and therefore needs be measured to where the widest sides of the plunger meet the barrel of the syringe. If the dose is measured from the point where the liquid touches the end of the plunger closest to the nozzle, the dose is incorrect.

The TGA is working with GSK to address any potential for accidental over use, including whether an update to the packaging of Children's Panadol 1-5 Years Colourfree Suspension to clarify the instructions on how to use the dosing syringe is sufficient or if other actions are also required.

In Hong Kong, a series of Panadol products are registered by GSK. Amongst them, there are seven registered pharmaceutical products containing paracetamol in liquid dose form, namely Panadol Syrup 160mg/5ml (HK-29178), Panadol Infant Drops 100mg/ml (HK-48092), Panadol Infant Drops Colourfree 100mg/ml (HK-48093), Panadol Suspension 250mg/5ml (HK-52665), Panadol Suspension 120mg/5ml (HK-52694), Panadol Infant Drops 100mg/ml (Orange/Vanilla) (HK-52933) and Panadol Children Suspension 120mg/5ml (Australia) (HK-53958). According to GSK, Panadol Suspension 120mg/5ml (HK-52694) is the only product currently marketed in Hong Kong and it contains a measuring cup for dose measurement instead of a syringe. The DH will continue to keep vigilant on further update related to the safe use of the drug.

UK: MHRA statement on misuse of laxatives

On 17 October 2014, following the BBC Watchdog investigation into the availability of stimulant laxatives in the UK, first broadcast on Thursday 16 October the MHRA's statement is below.

An MHRA spokesperson said:

"Most laxative medicines are used by patients safely and in accordance with the instructions for use on the patient information leaflet (PIL), however we do recognise that some patients misuse or abuse them. The Patient and Public Engagement Expert Advisory Group (EAG) which reports to the Commission on Human Medicines (CHM) has recently reviewed the patient information for non-prescription laxatives and has recommended that stronger warnings should be added emphasising that taking laxatives regularly for a long time is harmful and they do not aid weight loss. We are currently working with companies of stimulant laxative products to introduce these updated warnings which should provide consistency across the range of stimulant laxative products available.

We continuously monitor the safety of all medicines in the UK including concerns about misuse and abuse, and where necessary, we will take suitable action to safeguard public health within our regulatory remit. We would remind the public that anyone who self-medicates and buys their medicines from unauthorised internet sites could be in danger of receiving counterfeit or substandard medicines. We will continue to monitor the safety of non-prescription laxatives and will take further action if necessary."

In Hong Kong, there are 112 registered pharmaceutical products containing stimulant laxatives, including bisacodyl, docusate sodium, glycerol, senna (e.g. sennoside, senna leaf powder, etc.), casanthranol and sodium picosulfate. In view of the above announcement, a letter to inform local healthcare professionals and urged them to report adverse drug reactions related to the drugs was issued on 20 October 2014. The DH will keep vigilant on updates of the announcement by the health authorities.

EU: EMA completes review of polymyxin-based medicines

On 24 October 2014, the EMA has reviewed the safety and effectiveness of products containing the antibiotics colistin or colistimethate sodium (known as polymyxins) and recommended changes to their product information to ensure safe use in the treatment of serious infections that are resistant to standard antibiotics.

Polymyxin-based products have been available since the 1960s, but their use quickly decreased due to the availability of antibiotics with fewer potential side effects. Due in part to this limited use, colistimethate sodium has retained activity against a number of bacteria which have become resistant to commonly used antibiotics.

The Agency's Committee for Medicinal Products for Human Use (CHMP) reviewed the available data about the pharmacokinetics, effectiveness and safety of these medicines. The CHMP concluded that injection or infusion (drip) of colistimethate sodium should be reserved for the treatment of serious infections due to susceptible bacteria, in patients whose other treatment options are limited. The medicine should be given with another suitable antibiotic where possible. The Committee recommended that doses should always be expressed in international units (IU) but because doses of colistimethate sodium can be expressed in different ways a conversion table should be included in the product information. Critically ill patients should be given a higher starting dose (loading dose) to provide an effective level of the antibiotic in the body more quickly. Although data were very limited, the Committee recommended doses for use in patients with kidney problems and in children, and provided guidance on dosage in adults when given directly into fluid surrounding the brain or spinal cord (intrathecal or intraventricular injection).

CHMP concluded that colistimethate sodium may also be given by inhalation or in a nebuliser to treat ongoing (chronic) infections with the bacterium Pseudomonas aeruginosa in patients with cystic fibrosis.

The CHMP opinion will be forwarded to the European Commission, which will issue a final decision in due course.

In Hong Kong, there is one registered pharmaceutical product registered for human use, namely Colomycin for Inj 1 Million IU (HK-58514), containing Colistimethate. The product is prescription only medicine. The DH will remain vigilant on the final decision made by the European Commission and follow up any update on the relevant safety information.

Canada: Health Canada takes action to restrict import of products from three Micro Labs facilities in India

On 27 October 2014, Health Canada took action to restrict the import of health products from three

Safety Update

Micro Labs facilities in India (Bangalore, Goa and Hosur) because of data integrity concerns identified in recent inspections by international partners.

The licences of companies that import products from these three facilities will be amended with terms and conditions to require independent third-party testing prior to the release of any products determined to be medically necessary onto the Canadian market. Products from these three sites that are not on the medically necessary list will not be allowed to be imported or released on to the Canadian market until Health Canada is satisfied that the data integrity issues at the plants have been addressed.

Health Canada continues to gather information about the situation at these sites from trusted international partners, including the US FDA, the UK MHRA and the World Health Organization. Based on a review of this information, the Department has significant concerns with the manner in which data are collected and reported, raising uncertainty about the quality and safety of products from these sites. Until Health Canada can be satisfied that the production processes used at these three sites meet internationally recognized GMP, it is taking this additional precautionary step to keep these products off the Canadian market.

Consumers should be aware that no specific safety issues have been identified with products currently on the market from the list. No recall of products from these facilities has been requested by Health Canada or its regulatory partners. Health Canada has stopped imports as a temporary precautionary measure until it is satisfied of the processes followed at these sites. Consumers should not make any change to their medication without first consulting with a healthcare professional.

In Hong Kong, the products mentioned in the announcement of Health Canada are not registered pharmaceutical products. However, there are 24 registered pharmaceutical products which are manufactured by Micro Labs Ltd in India. Among these products, 12 of them are not currently marketed in Hong Kong. The rest of 12 products are registered by LF Asia (HK) Ltd and Sincerity (Asia) Co Ltd. The DH has dictated to the above companies to provide investigation reports from the manufacturer, and to ensure quality of the products prior to release of these products onto the Hong Kong market. The DH also noted that from the announcement that there is no specific safety issues have been identified with the products and no recall of products from these facilities has been requested by Health Canada or its regulatory partners. The DH shall remain vigilant on any further action taken against the products by Health Canada and other overseas regulatory authorities.

Drug Recall

Recall 2 batches of Torisel Inj 25mg/ml (HK-58079)

On 9 October 2014, the DH endorsed a licensed drug wholesaler, Pfizer Corporation HK Ltd (Pfizer), to voluntary recall two batches of Torisel Inj Kit 25mg/ml from the market due to potential quality issue. The affected batches were AIEM/1G and AI3V/1V. Torisel Inj Kit 25mg/ml, containing temsirolimus, is a prescription medicine used for the treatment of advanced renal cells carcinoma.

The DH received notification from Pfizer that the company has received complaints in overseas that particulate matters were observed in some of the diluent of the product. According to Pfizer, preliminary investigation indicated that the particulate matters were impurities of the diluent and only two batches of the product were affected. Since the particulate matters would dissolve in room temperature and filter would be applied during administration of the product, risk posed by the issue is considered to be minimal. Nevertheless, as a precautionary measure, Pfizer decided to recall globally the two affected batches.

According to Pfizer, about 250 sets of the affected batches had been supplied to Hospital Authority, private hospitals, private doctors and pharmacies. The DH will closely monitor the recall. As on 9 October 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.

Drug Recall

Recall of Neo-Polybacin Eye Ointment (HK-53647)

On 14 October 2014, the DH requested a licensed drug wholesaler, Welldone Pharmaceutical Ltd (Welldone), to recall those Neo-polybacin Eye Ointment that bear the wrong Hong Kong registration number from the market. Neo-Polybacin Eye Ointment is a prescription medicine for the treatment of eye infections.

Under the DH's market surveillance, samples of Neo-Polybacin Eye Ointment were collected from the market for analysis. It was found that the outer box of the samples was printed with the wrong registration number "HK-53535", which belongs to another registered product from the same manufacturer. The correct registration number of Neo-Polybacin Eye Ointment should be HK-53647. Preliminary investigation indicated that only some of the product's label contain the wrong registration number. To avoid confusion, Welldone was requested to recall the wrongly-labelled product.

According to Welldone, the product has been supplied to pharmacies. The DH will closely monitor the recall. As on 14 October 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.

Drug Incident

DH raids hair treatment shop for sale of unregistered pharmaceutical product with undeclared drug ingredients

On 29 October 2014, a joint operation was conducted by the DH and the Police against a hair treatment shop in Yau Ma Tei resulting in the arrests of a 41-year-old man and a 24-year-old woman for the suspected sale and possession of an unregistered pharmaceutical product containing undeclared Part I poisons.

Acting on a public complaint, a sample of a hair treatment product, namely Winfa, was purchased from the shop for analysis and was found to contain minoxidil, finasteride and dexamethasone upon testing by the Government Laboratory.

Minoxidil, finasteride and dexamethasone are Part I poisons. Minoxidil is commonly used topically for the treatment of hair loss, with side-effects including scalp irritation and itchiness. Finasteride is generally used orally also for the treatment of hair loss, with side-effects including loss of libido and erectile dysfunction. It should not be used in women who are or may become pregnant. Dexamethasone is a steroid with anti-inflammatory effects, and its side-effects include moon face, high blood pressure, high blood sugar, muscle atrophy, adrenal insufficiency and even osteoporosis.

Products containing a combination of minoxidil, finasteride and dexamethasone are prescription medicines and must be registered with the Pharmacy and Poisons Board of Hong Kong before they can be legally sold in the market. They should be used under medical advice and can only be supplied in pharmacies under the supervision of a registered pharmacist upon a doctor's prescription.

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

Quality Defect of Timentin® (ticarcillin-clavulanate): Cracked vials

On 22 October 2014, GlaxoSmithKline Limited (GSK), a licensed drug wholesaler, informed the DH about a low incidence quality defect of Timentin® (ticarcillin-clavulanate). An investigation at the GSK Worthing UK manufacturing site has identified a low incidence of cracked vials used in multiple finished batch lots of Timentin®. A formal investigation is currently ongoing at the manufacturing site. GSK has informed the UK Medicines and Healthcare Products Regulatory Agency (MHRA), and MHRA have agreed that it is appropriate to alert Healthcare Professionals who administer the antibiotic to this issue. No further market action is required. This product has been on global rationing since late 2011, and as such overall market stocks are low. The stock is being carefully managed by GSK to minimize patient impact of this shortfall in supply.

The cracked vial defect has the potential to breach the integrity of the vial. In the event of the integrity of the vial being breached the antibiotic powder may be subject to discolouration prior to or upon reconstitution. As a precaution, GSK advise healthcare professionals to inspect the integrity of the vial before use. If they observe any damage to the glass that looks like a crack then do not use the vial and return to GSK. Besides, healthcare professionals is advised to administer the product only if it presents as a pale or straw coloured liquid upon reconstitution.

In Hong Kong, Timentin for IV Infusion 3.2G (HK-30366) is registered by GSK and it is a prescription only medicine. Regarding this issue, GSK informed DH that they had issued a "Dear Healthcare Professional Letter" to inform healthcare professionals about the incident on 22 October 2014. The DH will keep vigilant on the above issue.

Useful Contact

Drug Complaint:

Tel: 2572 2068

Fax: 3904 1224

E-mail: pharmgeneral@dh.gov.hk

Adverse Drug Reaction (ADR) Reporting:

Tel: 2319 2920

Fax: 2186 9845

E-mail: adr@dh.gov.hk

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

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

The purpose of Drug News is to provide healthcare professionals with a summary of local and overseas drug safety news released. Healthcare professionals are advised to keep update with the information and provide corresponding advice or therapeutic measure to patients and public.