



Drug

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News

情報

Issue Number 59

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

UK: Domperidone to be available only as a prescription medicine

The UK Medicines and Healthcare products Regulatory Agency (MHRA) announced that from 4 September 2014, people taking domperidone to treat nausea and vomiting would only be able to get this medicine on prescription from their doctor. It would no longer be available from pharmacies without a prescription. This follows advice previously issued by the MHRA in April 2014 about new information on effects on the heart and that domperidone should no longer be used for heartburn, bloating or relief of stomach discomfort.

The European Medicines Agency (EMA) recently reviewed the safety and efficacy of domperidone and found that people who take them may have a small increased risk of potentially life-threatening effects on the heart. Therefore the indications for these medicines were restricted to nausea and vomiting. Following this, the Commission on Human Medicines (CHM), the independent advisory body to the MHRA, advised that whilst pharmacists were able to manage the majority of risks identified with this medicine, they would not routinely have access to a patient's full medical history and would not quickly and accurately be able to assess which patients were at risk of cardiac side effects.

On the same day, Johnson & Johnson Ltd., on behalf of the Marketing Authorisation Holder McNeil Products Ltd, initiated a recall of all unexpired stock of Motilium 10 10mg Tablets and Motilium Instants 10mg Orodispersible Tablets. Products containing domperidone no longer meet the requirements for supply with legal status 'P' (i.e. in a pharmacy without prescription, under the supervision of a pharmacist). Domperidone

products with legal status prescription-only medicine (POM) are not included in the scope of this recall.

Pharmacists are advised that domperidone containing products must not be sold to anyone without a prescription. This medicine is associated with a small increased risk of serious cardiac effects, hence patients need to have a medical assessment before taking domperidone to determine whether it is suitable for them.

In Hong Kong, there are 50 registered domperidone products including oral and suppository dose-forms. They can be sold without prescriptions at licensed drug stores. Related safety alert has been released by the EMA and was reported in Drug News Issue No. 53. The issue 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 May and July 2014. The Committee decided that the sales pack labels and/or package inserts of products containing domperidone should include the following new safety information:

The sales packs or package insert should include the following safety information in line with that recommended by the European Medicines Agency:

- (a) *Domperidone may continue to be used for the management of the symptoms of nausea and vomiting (indication restricted to management of symptoms of nausea and vomiting only), but that the recommended dose should be reduced to 10mg up to three times daily by mouth for adults and adolescents weighing 35kg or more (for oral*

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products). These patients may also be given the medicine as suppositories of 30mg twice daily (for rectal products).

- (b) *For children and adolescents weighing less than 35kg, domperidone should be given by mouth at a dose of 0.25mg per kg bodyweight up to three times daily. Measuring devices should be included with liquid formulations to allow accurate dosing by bodyweight.*
- (c) *Domperidone should not normally be used for longer than 1 week.*
- (d) *Domperidone should no longer be used to treat other conditions such as bloating or heartburn.*
- (e) *Domperidone must not be given to patients with moderate or severe impairment of liver function, or in those who have existing abnormalities of electrical activity in the heart or heart rhythm, or who are at increased risk of such effect.*
- (f) *Domperidone must not be used with other medicines that have similar effects on the heart or reduce the breakdown of domperidone in the body.*

In addition, the Committee also decided to deregister rectal suppository containing domperidone 10mg with effect from 1 October 2014 because of its small increased risk of potentially life-threatening effects on the heart while data supporting the effectiveness were limited. Apart from this, the Committee decided to strengthen the sales control of the remaining domperidone products so that they could be sold only by prescriptions at pharmacies under the supervision of pharmacists. The legislative amendments are undergoing. The Department of Health (DH) had already issued press statements to the public and letters to healthcare professionals on the Committee's decision to deregister domperidone suppository products on 9 July and 24 September 2014. The DH will remain vigilant on any safety updates and regulatory actions taken by other overseas health authorities on domperidone.

Singapore: New recommendations for simvastatin use in Asians based on findings from the HPS2-THRIVE study

It was noted from the website of HSA on 5 September 2014 that it was recommending for the

local package inserts of simvastatin-containing products to be updated to provide new recommendations for the use of simvastatin in Asians. These recommendations are based mainly on findings from the Heart Protection Study 2 – Treatment of HDL to Reduce the Incidence of Vascular Events (HPS2-THRIVE), which showed a higher rate of myopathy in the Chinese population.

The HPS2-THRIVE study recruited over 25,000 patients with pre-existing cardiovascular disease from the UK, Scandinavia and China. It was designed to assess cardiovascular outcomes following addition of extended-release niacin/laropirant 2g/40mg or placebo to simvastatin (with or without ezetimibe). No other statins were investigated in this study. Failure to achieve the study's primary endpoint of reducing cardiovascular events, coupled with a statistically significant increased risk of non-fatal serious adverse events, led to the worldwide withdrawal of niacin/laropirant in January 2013.

A subsequent review of the study data revealed important observations about the use of simvastatin in Chinese patients, who formed 40% of the study population. This led to new precautions advising caution when prescribing simvastatin to Asian patients and that the lowest dose necessary should be employed.

The benefit-risk profile of simvastatin remains positive when used for its licensed indications. Healthcare professionals are advised to prescribe simvastatin with caution to Asian patients and to use the lowest dose necessary. In addition, co-administration of simvastatin with lipid modifying doses (>1g/day) of niacin is not recommended in Asian patients. As the data supporting these new recommendations arose from the HPS2-THRIVE study that did not investigate other statins, it is not known at this point if these findings can be extrapolated to other statins. In the meantime, HSA is working with the companies to update the new recommendations in the local package inserts of all simvastatin-containing products.

In Hong Kong, there are 118 registered pharmaceutical products containing simvastatin and they are all prescription only medicines indicated for the treatment of hypercholesterolemia. In view of HSA's new recommendations for simvastatin use in Asians based on findings from the HPS2-THRIVE study, a letter to inform healthcare professionals to draw their attention and urge them

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to report any adverse drug reactions related to the drug was issued on 5 September 2014. The DH remains vigilant on any safety updates related to the drug and actions taken by other overseas regulatory authorities.

Singapore: Change in storage condition of Cetrotide® Injection 0.25mg (Cetrorelix acetate)

It was noted from the website of HSA on 10 September 2014 that Merck Pte Ltd has issued a “Dear Healthcare Professional Letter” to inform healthcare professionals that the storage condition of Cetrotide® Injection 0.25mg will be changed from “at or below 25°C” to “2 - 8°C”, to improve product stability. This revision in the storage conditions aims to improve the long term stability of Cetrotide® Injection 0.25mg in Climatic Zone III/IV countries (30°C/75%RH).

In Hong Kong, Cetrotide for Injection 0.25mg (HK-46953) is registered by Merck Pharmaceutical (HK) Ltd and is a prescription only medicine. As confirmed with Merck, the company has the plan to submit the application for changing the storage condition of the product by the end of this year.

Canada: Health Canada requests quarantine of products from IPCA Laboratories following falsification and manipulation of data issues

On 17 September 2014, Health Canada has taken the precautionary step of asking IPCA Laboratories in India to voluntarily stop shipment of products to Canada based on a review of a recent good manufacturing practices (GMP) inspection report by the United States (US) Food and Drug Administration (FDA) where they identified falsification and manipulation of data issues at the company. IPCA has not disputed the FDA findings with Health Canada. The FDA has not issued a recall of any of the affected products.

Health Canada estimates that this affects approximately 21 active pharmaceutical ingredients (APIs). The Department has also asked Canadian companies that import product containing APIs from the IPCA facilities to temporarily quarantine these products.

To date, there has been no indication that the issues identified during the FDA inspection pose a risk to

health. Therefore, like the FDA, Health Canada is not requesting a recall of products already on the market. If the situation changes, the Department would take immediate action and inform Canadians.

The information being sought includes any additional testing being done, the medical necessity of the products involved, their market share, and risk assessments. This process would likely take a few weeks to complete given the complexity of efforts. At this time, Health Canada do not expect that there will be an immediate impact on the availability of these products. Health Canada would work with the provinces and territories to monitor the supply situation and, if necessary, develop mitigation strategies.

Health Canada has requested that the voluntary quarantine continue until the Department is satisfied that adequate measures are in place to confirm the quality of the products from these facilities and protect the health and safety of Canadians. The Department would continue to keep Canadians informed as information becomes available.

In Hong Kong, there are 12 registered pharmaceutical products which are manufactured by IPCA Laboratories in India, including 1 active pharmaceutical ingredient registered by Sunrise Trading Co. (Sunrise) namely Famotidine (IPCA Laboratories) (HK-46044); 3 products registered by U.S. Summit Co. Ltd. (U.S. Summit), and 8 products registered by Swedish Trading Co. Ltd. (Swedish Trading). According to U.S. Summit, all their 3 products are not marketed in Hong Kong; and according to Swedish Trading, only 3 products namely Xtor-10 Tablets 10mg (HK-61658), Xtor-20 Tablets 20mg (HK-61919) and Azibact-250 Tablets 250mg (HK-62320) are marketed in Hong Kong, but their active ingredients are not manufactured by IPCA Laboratories in India. In light of Health Canada’s announcement, the DH has requested Sunrise to quarantine the active pharmaceutical ingredient from IPCS Laboratories in India. The DH has contacted Health Canada to inquire further details related to the incident and continues the investigation on local situation, and will keep vigilant on any further action taken against the products by Health Canada, FDA and other overseas regulatory authorities.

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Australia: TGA Safety advisory regarding the risk of serotonin syndrome associated with serotonin-blocking medicines used to treat nausea and vomiting

On 22 September 2014, the Therapeutic Goods Administration (TGA) advised health professionals that serotonin syndrome is a newly identified issue associated with products containing the serotonin-blocking medicines classed as 5-HT₃ receptor antagonists. Serotonin syndrome has been seen in patients using 5-HT₃ receptor antagonists at the same time as other serotonergic medicines. The 5-HT₃ receptor antagonists available in Australia are: granisetron (Sancuso and Kytril), dolasetron (Anzemet), tropisetron (Navoban), ondansetron (Zofran) and palonosetron (Aloxi).

Serotonin syndrome occurs when serotonin accumulates to high levels in the body, as can happen when medicines block the chemical from entering cells. The syndrome is characterised by:

1. altered mental state, e.g. confusion, agitation, restlessness and excitement;
2. autonomic dysfunction, e.g. tachycardia, sweating, shivering, hypertension and hyperthermia;
3. neuromuscular excitation, e.g. hyperreflexia, tremor. In some cases serotonin syndrome can lead to loss of consciousness, coma and death.

Health professionals are advised to be alert to this issue. The TGA is working with the sponsors of the different 5-HT₃ receptor antagonists to update their Product Information (PI) regarding the risk of serotonin syndrome. Some sponsors already include this information in their PI. The updated PI contains a new precaution and information on drug interactions advising that serotonin syndrome has been described following the use of 5-HT₃ receptor antagonists when used concomitantly with other serotonergic drugs, including selective serotonin reuptake inhibitors (SSRIs) and serotonin noradrenaline reuptake inhibitors (SNRIs). If concomitant treatment with a 5-HT₃ receptor antagonist and other serotonergic drugs is clinically warranted, it is advised that the patient and caregivers are advised of this issue and that appropriate observation is undertaken.

In Hong Kong, there are currently 36 registered pharmaceutical products of serotonin blocking drugs, including 12 granisetron products; 20 ondansetron products; 3 palonosetron products; 1 tropisetron product and there is nil registered pharmaceutical product containing dolasetron. All of them are prescription only medicines. Related news has been released by the Health Canada and was reported in Drug News Issue No. 55. A letter to inform healthcare professionals to draw their attention on the issue and urge them to report any adverse drug reactions related to the drugs was issued on 15 May 2014. The matter was discussed by the Registration Committee of the Pharmacy and Poisons Board (the Committee) on 15 September 2014. The Committee decided that the sales pack labels and/or package inserts of registered pharmaceutical products of serotonin-blocking drugs should include new safety information as follow:

(For iv products only) DOSAGE

For geriatrics:

- In patients ≥ 75 years of age, the initial IV dose must not exceed 8 mg.
- In patients < 75 years of age, the initial IV dose must not exceed 16 mg.
- Subsequent IV doses must not exceed 8 mg and may be give 4 and 8 hours after the initial dose.
- All IV doses must be diluted in 50–100 mL of saline or other compatible fluid.
- All IV doses must be infused over no less than 15 minutes.

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Cases of life-threatening serotonin syndrome have been reported with 5-HT₃ receptor antagonist antiemetics, particularly when given in combination with other serotonergic and/or neuroleptic drugs. Treatment should be discontinued if such events occur and supportive symptomatic treatment should be initiated. If concomitant treatment of [PRODUCT NAME] with a drug affecting the serotonergic neurotransmitter system is clinically warranted, careful observations of the patient is advised, particularly during treatment initiation and dose increases.

The Mainland: Alert on propylthiouracil and the association of severe adverse reactions

On 23 September 2014, the China Food and Drug Administration (CFDA) of the Mainland alerted on the risk of severe adverse reactions which are associated with propylthiouracil. These adverse reactions include liver function abnormalities, liver damage, hepatitis, bilirubin, leukopenia, agranulocytosis.

Propylthiouracil is a thioamide drug which can inhibit thyroid peroxidase, thereby blocking the thyroid hormone production. It is used mainly for the treatment of adults with hyperthyroidism.

Recently, the National Centre for ADR Monitoring of the Mainland, and the results of analysis from the relevant literature data indicate that in patients with long-term use of propylthiouracil may appear antineutrophil cytoplasmic antibody (ANCA) associated vasculitis, may involve multiple body organs and systems, such as the kidneys, lungs and joints. Severe adverse reactions involving the kidneys are hematuria, proteinuria, renal insufficiency or renal failure; involving the lungs are cough, hemoptysis and lung shadows; involving the joint can be expressed as joint pain, swelling.

The CFDA recommends:

- medical personnel shall promptly inform the adverse reactions may occur in patients. They need to regularly check the blood results of the urine, liver and renal function and biochemical indicators when patients are taking propylthiouracil. They should seek immediate medical attention if adverse reactions occur,
- the drug manufacturers should strengthen the monitoring of adverse drug reactions, update the package insert and precautions of the product insert. They should promptly inform the medical staff and patients, and to take effective measures to maximize the protection of the patient's medication safety.

In Hong Kong, there are currently five registered pharmaceutical products containing propylthiouracil and they are prescription only medicines. In April 2010, the US FDA had released the safety information regarding severe hepatic

reactions associated with propylthiouracil, and a letter to healthcare professionals to draw their attention and urge them to report any adverse drug reactions related to the drug was issued on 22 April 2010. The matter was discussed by the Registration Committee in June 2010 and the Committee decided that the sales pack labels and/or package inserts of products containing propylthiouracil should include the relevant safety information. So far, the DH has not received any adverse drug reaction report in relation to propylthiouracil. In view of the CFDA's announcement on propylthiouracil may be associated with adverse reactions on circulatory system, the matter will be brought to the Registration Committee for discussion. The DH will keep vigilance on any safety updates of the drug and actions taken by other overseas regulatory authorities.

EU: European Medicines Agency confirms positive benefit-risk for antidepressant Valdoxan/Thymanax (agomelatine) and takes measures to improve monitoring of liver function during treatment

On 26 September 2014, the EMA has completed a review of the anti-depressant medicine Valdoxan/Thymanax and concluded that its benefits continue to outweigh the risks. However, the Agency has recommended that further measures should be put in place to minimise the risk of liver toxicity. Valdoxan and Thymanax are two identical medicines used to treat major depression in adults.

Warnings in the product information will also be strengthened to emphasis that liver function tests should be performed in patients both before starting the medicine and regularly during treatment. If tests suggest liver injury (i.e. increase of certain liver enzymes called transaminases in the blood to more than 3 times the upper limit of normal) doctors should not start their patients on Valdoxan/Thymanax or stop treatment of those who are already taking the medicine.

The new recommendations follow the most recent benefit-risk assessment of Valdoxan/Thymanax from the Agency's PRAC. As part of its recommendations, the PRAC had even considered that the use of Valdoxan/Thymanax should be contraindicated in patients aged 75 years or above since these patients might be at an increased risk of

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severe side effects on the liver and beneficial effects have not been documented in this population. The current product information for Valdoxan/Thymanax includes a warning that the medicine should not be used in patients aged 75 years or over. The Committee for Medicinal Products for Human Use (CHMP) considered that upgrading this warning to a contraindication in this population was not justified by the available data.

The CHMP opinion will be sent to the European Commission, which will issue a legally binding decision.

In Hong Kong, there is one registered pharmaceutical product containing agomelatine, namely Valdoxan Tab 25mg (HK-46233). It is a prescription only medicine and is registered by Servier HK Ltd. The package insert of the product has included the relevant safety information. The DH will keep vigilant on any safety updates of the drug.

US: Xolair (omalizumab) and slightly elevated risk of cardiovascular and cerebrovascular serious adverse events

On 26 September 2014, an FDA review of safety studies suggests a slightly increased risk of problems involving the heart and blood vessels supplying the brain among patients being treated with the asthma drug Xolair (omalizumab) than in those who were not treated with Xolair. As a result, FDA has added information about these

potential risks to the drug label. Xolair is an injectable medicine for patients 12 years of age and older with moderate to severe persistent allergic asthma whose asthma symptoms are not controlled by asthma medicines called inhaled corticosteroids

The review found no difference in the rates of cancer between those patients being treated with Xolair and those who were not being treated with Xolair. However, due to limitations in the 5-year study, FDA cannot rule out a potential risk of cancer with Xolair, so this information was added to the Warnings and Precautions section of the drug label.

FDA recommended that patients taking Xolair should continue to take the medication as prescribed and discuss any questions or concerns with their healthcare professionals.

In Hong Kong, there is one registered pharmaceutical product containing omalizumab, namely Xolair for Inj with Solvent 150mg (HK-54330). It is a prescription only medicine and is registered by Novartis Pharmaceuticals (HK) Ltd (Novartis). In view of the announcement by the US FDA, a letter to healthcare professionals to draw their attention and urge them to report any adverse drug reactions related to the drug was issued on 29 September 2014. The DH is following up with Novartis on the above mentioned safety concern and remains vigilant on any safety updates of the drug announced by other drug regulatory authorities.

Drug Recall

Recall of Maxrin Cap 0.4mg (HK-59215)

On 5 September 2014, the DH instructed a licensed drug wholesaler, Champion Healthcare Ltd (Champion), to recall all batches of Maxrin Cap 0.4mg from the market because the product had been released based on specifications different from the registered specifications. Maxrin Cap 0.4mg, containing Tamsulosin, is a prescription medicine used for the treatment of benign prostatic hyperplasia. It can only be sold at pharmacies under the supervision of a registered pharmacist upon a doctor's prescription.

During DH's market surveillance, samples of the product were collected for evaluation and it was found that the manufacturer of the product has revised the release specifications without notifying

Champion. Change in product specifications without prior approval from the Pharmacy and Poisons Board would render the product unregistered under the Pharmacy and Poisons Ordinance (Cap 138).

According to Champion, the product has been supplied to private doctors and local pharmacies. The DH will closely monitor the recall. As on 5 September 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.

Members of the public should consult their healthcare professionals for advice if in doubt.

Drug Incident

Public urged not to buy or consume slimming product with undeclared and banned drug ingredient

On 15 September 2014, the DH appealed to members of the public not to buy or consume a slimming product, namely Slim Perfect Legs, as it contains an undeclared and banned drug substance.

Following the DH operation against two slimming products known as Slim Perfect Arm and Slim Perfect Legs, both found to contain sibutramine, on 14 July, it was found that Slim Perfect Legs was being offered for sale in another channel via mobile phone application. Sample of the product, with different packing design from the previous one, was purchased for analysis. Result from the Government Laboratory revealed that the slimming product contained sibutramine, a banned drug ingredient.

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

Members of the public who have purchased the above product should stop consuming it immediately. They should consult healthcare professionals for advice if feeling unwell or in doubt after use. 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.

Retail shop raided for suspected illegal sale and possession of unregistered pharmaceutical product with controlled drug ingredient

On 16 September 2014, a joint operation was conducted by the DH and the Police against a retail shop in Kwai Chung resulting in the arrest of a 28-year-old woman for suspected illegal sale and possession of an unregistered pharmaceutical product and Part I poison. The unregistered pharmaceutical product was called "SW by Fern".

Acting upon a public complaint, a sample of the above product was previously purchased from the retail shop for analysis. Analytical results from the Government Laboratory revealed that the product contained a Part I poison, oestradiol.

Products containing oestradiol are prescription drugs used for hormone replacement therapy. Side effects include nausea, vomiting, headache, abdominal cramps and bloating. They should only be supplied at pharmacies under the supervision of a registered pharmacist upon a doctor's prescription.

Members of the public who have purchased the above product should stop taking it immediately and consult healthcare professionals for advice if they are in doubt or feeling unwell after using it.

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.

Updated recommendations for Xgeva (denosumab) regarding calcium monitoring related to the risk of severe symptomatic hypocalcemia

On 16 September 2014, GlaxoSmithKline Ltd (GSK), a licensed drug wholesaler, informed the DH about updated recommendations for Xgeva (denosumab) regarding calcium monitoring related to the risk of severe symptomatic hypocalcemia (SSH). Xgeva is indicated for the prevention of skeletal related events in adults with bone metastases from solid tumors and it is not indicated for the prevention of skeletal-related events in patients with multiple myeloma. The Xgeva prescribing information communicates the risk of severe symptomatic hypocalcemia including reports of fatal cases in the post-marketing setting. The ongoing pharmacovigilance program further characterizes the onset of hypocalcemia and the clinical manifestations, allowing GSK to provide updated recommendations for risk mitigation.

In the post-marketing experience, clinical manifestations of SSH associated with Xgeva have included QTc interval prolongation, tetany, seizures, and altered mental status (including coma). The majority of the SSH cases occurred within the first 30 days after first dose of Xgeva. Fatal cases of SSH have been reported. In clinical trials in patients with bone metastasis, severe hypocalcemia (laboratory values for corrected serum calcium <7mg/dL or <1.75 mmol/L) occurred in 3.1% of patients receiving treatment

with Xgeva, 1.4% of patients receiving Xgeva had hypocalcemia reported as a serious adverse event.

GSK advised Healthcare providers to monitor calcium levels in all patients at baseline and throughout the duration of treatment especially in the first few weeks. Other recommendations related to management of hypocalcemia related to Xgeva treatment include:

1. Pre-existing hypocalcemia must be corrected prior to initiating therapy with Xgeva.
2. Supplementation of calcium and vitamin D is required in all patients, unless hypercalcemia is present.
3. If hypocalcemia occurs, additional short-term calcium supplementation may be necessary.
4. Patients with severe renal impairment or receiving dialysis are at a higher risk of hypocalcemia.

In Hong Kong, Xgeva Solution for Injection 120mg (HK-61163) is registered by GSK and is a prescription only medicine. Regarding this issue, GSK informed DH that they had already issued a "Dear Healthcare Professional Letter" to inform local healthcare professionals, and submitted the application to change the package insert by including the relevant safety information. So far, the DH has not received any relevant adverse drug reaction in connection with Xgeva and will keep vigilant on any safety updates of the drug.

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.