Drug News
藥 物 情 報

Issue Number 122

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in December 2019 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

Singapore: Important safety update on ESBRIET (pirfenidone) and drug-induced liver injury (DILI)

It was noted from the Singapore Health Sciences Authority (HSA) website on 19 December 2019 that F. Hoffmann-La Roche Ltd. would like to inform healthcare professionals of new safety information regarding DILI with Esbriet (pirfenidone).

Clinical manifestations of DILI including cases with fatal outcome (possibly caused by idiosyncratic reactions to Esbriet) have recently been reported in individual patients. Based on these findings, the prescribing information for Esbriet will be updated to adequately describe the risk of clinically relevant DILI and recommend additional monitoring of liver function in the presence of clinical signs or symptoms suggestive of liver injury. Healthcare professionals are advised on the monitoring of hepatic transaminase and bilirubin levels during drug treatment and prompt measurement of liver function tests in patients who report symptoms that may indicate liver injury, including fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice.

In Hong Kong, Esbriet Capsules 267mg (HK-64288) is a registered pharmaceutical product containing pirfenidone. The product is registered by Roche Hong Kong Limited, and is a prescription-only medicine. As on 6 January 2020, the Department of Health (DH) has received one case of adverse drug reaction (ADR) related to pirfenidone, but this case is not related to liver injury. In light of the above HSA's announcement, the DH issued a letter to inform local healthcare professionals to draw their attention on 19 December 2019. The DH will remain vigilant on safety update of the drug issued by other overseas drug regulatory authorities.

US: Update: FDA requires additional testing of ranitidine and nizatidine as part of agency's ongoing effort to help ensure product safety for patients and consumers

On 4 December 2019, the United States (US) Food and Drug Administration (FDA) announced that it has asked manufacturers of ranitidine and nizatidine products to expand their testing for *N*-nitrosodimethylamine (NDMA) to include all lots of the medication before making them available to consumers. If testing shows NDMA above the acceptable daily intake limit (96 nanograms per day or 0.32 parts per million for ranitidine), the manufacturer must inform the agency and should not release the lot for consumer use.

The FDA continues to work with industry and regulatory agencies around the world to determine the reasons for NDMA in these drugs and have developed and posted multiple testing methods to identify NDMA in ranitidine. The FDA's scientists have determined ranitidine does not form NDMA in typical stomach conditions. However, the FDA needs further investigation to fully test how ranitidine and nizatidine behave in the human body and have plans to study this. There is also some evidence that there may be a link between the presence of nitrites and the formation of NDMA in the body if ranitidine or nizatidine is also present. Because of this, consumers who wish to continue taking these drugs should consider limiting their intake of nitrite-containing foods, e.g. processed meats and preservatives like sodium nitrite.

Consumers may also consider alternative treatments that are approved for the same or similar uses as ranitidine and nizatidine. The US FDA's testing has not found NDMA in Pepcid (famotidine), Tagamet

(cimetidine), Nexium (esomeprazole), Prevacid (lansoprazole), or Prilosec (omeprazole).

In Hong Kong, there is no registered pharmaceutical product containing nizatidine.

As on 6 January 2020, there are 67 registered pharmaceutical products containing ranitidine in Hong Kong. These products in the forms of oral preparations and injections are controlled as over-the-counter medicines and prescription-only medicines respectively. As on 6 January 2020, the DH has not received any case of ADR related to ranitidine.

Related news on the detection of NDMA in ranitidine products was previously issued by various overseas drug regulatory authorities. The DH issued a letter to inform local healthcare professionals to draw their attention on 18 September 2019. The DH has contacted the relevant overseas drug regulatory authorities for further information regarding the detection of NDMA in ranitidine products, and continues to remain vigilant on the update findings and investigation result announced by the authorities for consideration of any action deemed necessary.

The DH has contacted the certificate holders of all registered ranitidine products for follow up on the local impact of the issue; and to provide evidence that NDMA in the products are below the acceptable limit, and samples of ranitidine-containing products have been collected from the market for analysis. When any health risks are posed to the public, a press statement will be issued as soon as possible. Please find update information at Drug Office's website (www.drugoffice.gov.hk). The following are the main content of the press statements issued previously:

- On 24 September 2019, the DH endorsed a licensed drug wholesaler, GlaxoSmithKline Ltd, to recall all Zantac products (HK-42792, HK-42793, HK-30459, HK-42045) from the Hong Kong market as a precautionary measure due to the presence of NDMA in the products.
- On 25 September 2019, the DH endorsed licensed drug wholesalers Hind Wing Co Ltd (Hind Wing) and Top Harvest Pharmaceuticals Co Ltd to recall Apo-Ranitidine Tablets (HK-42273, HK-41873) and Zantidon Tablets 150mg (HK-64329) respectively.
- On 27 September 2019, the DH endorsed licensed drug manufacturer APT Pharma Limited and licensed drug wholesaler Eugenpharm International Limited to recall Amratidine Tablets 150mg (HK-53143) and Peptil H 150 Tablets 150mg (HK-65103) respectively.
- On 30 September 2019, the DH endorsed licensed drug wholesaler Vast Resources Pharmaceutical Limited to recall Weidos Tablets 150mg (HK-62210).
- On 11 October 2019, the DH endorsed licensed drug wholesaler Hind Wing to recall Epadoren Solution for Injection 50mg/2ml (HK-61752).
- On 1 November 2019, the DH endorsed licensed drug wholesaler Welldone Pharmaceuticals Limited to recall six ranitidine-containing products: Epirant Tab 150mg (HK-56826), Welldone Ranitidine Tab 150mg (HK-57473), Kin Pak Tab 150mg (HK-56824), Wah Tat Tab 150mg (HK-56823), Super Pro Tab 150mg (HK-56825) and Glo-Tac Tab 150mg (HK-57472).
- On 7 November 2019, the DH endorsed licensed drug wholesalers Healthcare Pharmascience Limited, Julius Chen & Co (HK) Limited and Atlantic Pharmaceutical Limited to recall 5 ranitidine-containing products: Raniplex 150 Tablet 150mg (HK-43456), Tupast Tablet 150mg (HK-50378), Wontac Tablet 150mg (HK-60085), Jecefarma Ranitidine Tablet 150mg (HK-64041) and Ratic Tablet 150mg (HK-61083).
- On 12 November 2019, the DH endorsed registration certificate holder Medreich Far East Limited to recall Ulticer Tab 150mg (HK-53488).
- On 27 November 2019, the DH endorsed drug suppliers Cera Medical Limited and Sincerity (Asia) Company Limited to recall Emtac 150 Tab 150mg (HK-59353) and Ranitid 150 Tab 150mg (HK-59429) respectively.

The above recalls were reported in the Drug News Issue No. 119, 120 and 121. Patients who are taking ranitidine-containing products should not stop taking the medicines, but should seek advice from their healthcare professionals for proper arrangement, e.g. use of alternative medicines with similar uses.

US: Statement from Janet Woodcock, M.D.,

director of FDA's Center for Drug Evaluation and Research, on impurities found in diabetes drugs outside the US

On 5 December 2019, the US FDA announced that it has been investigating the presence of genotoxic impurities, called nitrosamines, in some types of drugs. Over the past year and a half, several drug products including angiotensin II receptor blockers and ranitidine, commonly known as Zantac, have been found to contain small amounts of nitrosamines such as NDMA. During this time, there has been an ongoing investigation into the presence of nitrosamines in other drug products.

The FDA is aware that some metformin diabetes medicines in other countries were reported to have low levels of NDMA. Based on the information the FDA has available, the levels of NDMA seen outside the US are within the range that is naturally occurring in some foods and in water. While the FDA is aware that some regulatory agencies outside the US may be recalling some metformin drugs, there are no metformin recalls affecting the US market at this time. The FDA is investigating whether metformin in the US market contains NDMA, and whether it is above the acceptable daily intake limit of 96 nanograms. The agency will also work with companies to test samples of metformin sold in the US and will recommend recalls as appropriate if high levels of NDMA are found. If as part of the FDA's investigation, metformin drugs are recalled, the FDA will provide timely updates to patients and healthcare professionals.

Metformin is a prescription drug used to control high blood sugar in patients with type 2 diabetes. Patients should continue taking metformin to keep their diabetes under control. It could be dangerous for patients with this serious condition to stop taking their metformin without first talking to their healthcare professional. The FDA recommends prescribers continue to use metformin when clinically appropriate, as the FDA investigation is still ongoing, and there are no alternative medications that treat this condition in the same way.

NDMA is a common contaminant found in water and foods including cured and grilled meats, dairy products and vegetables. Everyone is exposed to some level of NDMA. The FDA and the international scientific community do not expect it to cause harm when ingested at low levels. The acceptable daily intake limit for NDMA in the US is 96 nanograms. Genotoxic substances such as NDMA may increase the risk of cancer if people are exposed to them above acceptable levels and over long periods of time, but a person taking a drug that contains NDMA at-or-below the acceptable daily intake limit every day for 70 years is not expected to have an increased risk of cancer.

The FDA will continue to investigate the source of these impurities, but it is important to note that there are multiple reasons why NDMA can be present in drugs. Previously, the FDA found the source of NDMA can be related to the drug's manufacturing process or its chemical structure or even the conditions in which they are stored or packaged. As food and drugs are processed in the body, nitrosamines, including NDMA, can be formed. The FDA continues to test and research possible sources for the several drugs found to contain NDMA.

As on 6 January 2020 in Hong Kong, there are 124 registered pharmaceutical products containing metformin. All products are prescription-only medicines. As on 6 January 2020, the DH has received 17 cases of ADR related to metformin. None of them is concluded to be related to the presence of NDMA.

Related news on the detection of NDMA in metformin products was previously issued by the Singapore HSA and other overseas drug regulatory authorities. The DH issued a letter to inform local healthcare professionals to draw their attention on 6 December 2019. The DH has contacted the HSA for further information regarding the detection of NDMA in metformin products and reply is pending. The DH has contacted the certificate holders of all registered metformin products for follow up on the local impact of the issue. The DH has collected samples of metformin-containing products in the local market for analysis. When any health risks are posed to the public, a press statement will be issued as soon as possible. Please find update information at Drug Office's website (www.drugoffice.gov.hk). The DH will remain vigilant on the development of the issue and any safety update of the drug issued by overseas drug regulatory authorities for consideration of any action deemed necessary.

Patients who are taking metformin-containing products should not stop taking the medicines, but should seek advice from their healthcare

professionals for proper arrangement.

Australia: Update: Tocilizumab and hepatotoxicity

On 10 December 2019, the Therapeutic Goods Administration of Australia announced that, following the July 2019 Medicines Safety Update article regarding tocilizumab and hepatotoxicity, the Product Information for tocilizumab has been updated to include more information about this potential safety issue. Tocilizumab is marketed in Australia under the brand name Actemra.

A comprehensive assessment of reports of serious hepatic injury associated with tocilizumab use has been performed across all available clinical and post-marketing data sources. The sponsor of Actemra, Roche, has identified eight cases of tocilizumab-related moderate to severe drug-induced liver injury, including acute liver failure, hepatitis and jaundice. These events occurred between two weeks to more than five years after initiation of tocilizumab, with median latency of 98 days. In these eight cases, two cases of acute liver failure required liver transplantation.

These events are considered rare and the benefit-risk profile of tocilizumab in the approved indications remains favourable.

Health professionals are reminded that tocilizumab is known to cause transient mild to moderate elevation of hepatic transaminases, with increased frequency when used in combination with other potentially hepatotoxic drugs (such as methotrexate).

Patients treated with tocilizumab should be closely monitored for liver adverse events and advised to seek immediate medical advice if they have signs or symptoms of hepatotoxicity such as jaundice, dark urine, itch, loss of appetite, nausea or vomiting. Patients presenting with signs or symptoms of hepatotoxicity should be promptly investigated.

It is not recommended to initiate tocilizumab treatment in patients with elevated alanine aminotransferase (ALT) or aspartate aminotransferase (AST) greater than 1.5 times the upper limit of normal (ULN), except in cases of cytokine release syndrome. In patients who develop elevated ALT or AST greater than five times ULN, discontinue tocilizumab.

Health professionals are advised to follow all guidance relating to liver enzyme abnormalities, including dose modification and tocilizumab discontinuation, contained in the updated Product Information.

In Hong Kong, there are 4 registered pharmaceutical products containing tocilizumab, namely Actemra Conc for Soln for Infusion 400mg/20ml (HK-59200), Actemra Conc for Solution for Inf 200mg/10ml (HK-59201), Actemra Conc for Soln for Infusion 80mg/4ml (HK-59202) and Actemra Solution for Injection in Pre-filled Syringe 162mg/0.9ml (HK-63771). All products are registered by Roche Hong Kong Limited (Roche), and are prescription-only medicines. As on 6 January 2020, the DH has received 8 cases of ADR related to tocilizumab, but these cases are not related to hepatotoxicity.

Related news was previously issued by various overseas drug regulatory authorities, and was reported in the Drug News Issue No. 114 and 115. The DH issued a letter to inform local healthcare professionals to draw their attention on 12 April 2019. In December 2019, the Registration Committee of the Pharmacy and Poisons Board (Registration Committee) discussed the matter and noted that Roche had submitted application to update the package inserts with information relevant to hepatotoxicity. The DH is working with the company to update the safety information of the local products, and will remain vigilant on safety update of the drug issued by other overseas drug regulatory authorities.

UK: Domperidone for nausea and vomiting: lack of efficacy in children; reminder of contraindications in adults and adolescents

On 16 December 2019, the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom (UK) announced that domperidone is no longer licensed for use in children younger than 12 years or those weighing less than 35 kg. Results from a placebo-controlled study in children younger than 12 years with acute gastroenteritis did not show any difference in efficacy at relieving nausea and vomiting compared with placebo.

A European review of the safety of domperidone in 2014 introduced new restrictions following continued reports of cardiac side effects. At the time, there were limited data to support paediatric

use in the relief of the symptoms of nausea and vomiting, and studies were requested to provide further data to support efficacy.

A multicentre, double-blind, randomised, placebo-controlled, parallel-group, prospective study evaluated the safety and efficacy of domperidone in 292 children with acute gastroenteritis aged between 6 months and 12 years (median age 7 years). In addition to oral rehydration treatment (ORT), patients were randomised to receive domperidone oral suspension at 0.25 mg/kg (up to a maximum of 30 mg domperidone per day), or placebo, 3 times a day, for up to 7 days. This study did not show domperidone suspension plus ORT to be significantly more effective than placebo plus ORT at reducing vomiting episodes during the first 48 hours after the first treatment administration. The study did not reveal any new safety concern.

A European review assessed this new evidence that domperidone is not as effective in this population as previously considered. Consequently, the product information for the UK domperidone medicines has been updated to remove the indication in children younger than 12 years of age.

Domperidone is also used outside of its authorised indications in children in the UK for gastrokinetic effects in conditions other than nausea and vomiting. If a specialist physician considers, based on their professional judgement and available evidence of the medical condition, that domperidone use in any condition is justified in a child younger than 12 years, the patient or parent/ caregiver should be fully informed of the potential benefits and risks of the different options.

The European safety review in 2014 confirmed risk of serious cardiac ADRs related to domperidone, including QTc prolongation, torsade de pointes, serious ventricular arrhythmia, and sudden cardiac death. The review concluded that additional risk minimising measures were necessary to improve the balance between benefits and risks and to reduce the risk of serious cardiac adverse events. Recent regulatory studies in several European countries, including the UK, show a proportion of physicians are not aware of the changes in indication and the contraindications introduced in 2014. All healthcare professionals are thus reminded to follow the precautions for safe use of domperidone-containing products.

Healthcare professionals are advised:

- Domperidone is now authorised in the UK for the relief of symptoms of nausea and vomiting only in adults and adolescents 12 years of age or older and weighing 35 kg or more.
- Consider alternative treatments to domperidone in children younger than 12 years of age who need relief of symptoms of nausea and vomiting.
- European regulatory studies show that some physicians, including in the UK, are not aware of the important precautions for use of domperidone introduced in 2014.
- Domperidone is contraindicated:
  - in patients with moderate to severe hepatic impairment,
  - in patients with known existing prolongation of cardiac conduction intervals (particularly QTc),
  - in patients with underlying cardiac diseases such as congestive heart failure,
  - in patients with significant electrolyte disturbances,
  - during co-administration with QT-prolonging drugs,
  - during co-administration with potent cytochrome P450 3A4 (CYP3A4) inhibitors (regardless of their QT-prolonging effects),
  - in patients with hypersensitivity to domperidone,
  - in patients with a prolactin-releasing pituitary tumour,
  - in patients in which stimulation of the gastric motility could be harmful (for example, in patients with gastro-intestinal haemorrhage, mechanical obstruction, or perforation).
- For adults and adolescents 12 years of age or older and weighing 35 kg or more, the recommended maximum dose in 24 hours is 30 mg (dose interval: 10 mg up to 3 times a day).
- Domperidone should be used at the lowest effective dose for the shortest possible duration and maximum treatment duration should not usually exceed 1 week.

In Hong Kong, there are 42 registered pharmaceutical products containing domperidone, and all products are prescription-only medicines. As on 6 January 2020, the DH has not received any case of ADR related to domperidone.

News related to risk of serious cardiac ADRs

related to domperidone was previously issued by various overseas drug regulatory authorities, and was reported in the Drug News Issue No. 29, 53, 59, 63 and 91. The DH issued letters to inform local healthcare professionals to draw their attention on 8 March 2012 and 10 March 2014. In February 2012 and May 2014, the Registration Committee discussed the matter and decided to update the sales pack or package insert of domperidone-containing products to include the appropriate safety information related to cardiovascular risk and to tighten the control over the sale of oral domperidone products.

In light of the above MHRA's announcement regarding removal of the indication in children younger than 12 years of age, the DH issued a letter to inform local healthcare professionals to draw their attention on 17 December 2019, and the matter will be discussed by the Registration Committee.

US: FDA warns about serious breathing problems with seizure and nerve pain medicines gabapentin (Neurontin, Gralise, Horizant) and pregabalin (Lyrica, Lyrica CR)

On 19 December 2019, the US FDA announced that it is warning that serious breathing difficulties may occur in patients using gabapentin (Neurontin, Gralise, Horizant) or pregabalin (Lyrica, Lyrica CR) who have respiratory risk factors. These include the use of opioid pain medicines and other drugs that depress the central nervous system (CNS), and conditions such as chronic obstructive pulmonary disease that reduce lung function. The elderly are also at higher risk.

The FDA evaluation shows that the use of these medicines, often referred to as gabapentinoids, has been growing for prescribed medical use, as well as misuse and abuse. Gabapentinoids are often being combined with CNS depressants, which increases the risk of respiratory depression. CNS depressants include opioids, anti-anxiety medicines, antidepressants, and antihistamines. There is less evidence supporting the risk of serious breathing difficulties in healthy individuals taking gabapentinoids alone.

The FDA is requiring new warnings about the risk of respiratory depression to be added to the prescribing information of the gabapentinoids. The FDA has also required the drug manufacturers to conduct clinical trials to further evaluate their abuse potential, particularly in combination with opioids, because misuse and abuse of these products together is increasing, and co-use may increase the risk of respiratory depression. Special attention will be paid to the respiratory depressant effects during this abuse potential evaluation.

Patients and caregivers should seek medical attention immediately if they or someone they are caring for experience symptoms of respiratory problems, because these can be life-threatening. Symptoms to watch for include: confusion or disorientation, unusual dizziness or lightheadedness, extreme sleepiness or lethargy, slowed, shallow, or difficult breathing, unresponsiveness, bluish-colored or tinted skin, especially on the lips, fingers, and toes. Always inform their healthcare professional about all the drugs they are taking, including prescription and over-the-counter medicines and other substances such as alcohol.

Healthcare professionals should start gabapentinoids at the lowest dose and monitor patients for symptoms of respiratory depression and sedation when co-prescribing gabapentinoids with an opioid or other CNS depressant such as a benzodiazepine. Patients with underlying respiratory disease and elderly patients are also at increased risk and should be managed similarly.

The FDA recognizes that incorporating one or more medications with non-drug therapies is the prevailing approach for optimizing analgesia. However, pairing an opioid with any CNS depressant will increase the risk of respiratory depression. Shifting treatment from one CNS depressant to another may pose similar risks. Be aware of the potential additive effects of all these CNS depressants and plan accordingly, by starting with low doses, titrating carefully, and informing patients of the potential for CNS and respiratory depression and their symptoms. The gabapentinoid prescribing information already includes guidance for healthcare professionals to caution patients about dizziness, somnolence, and the potential for impaired ability to operate a car or complex machinery.

The FDA reviewed several sources of data, including case reports submitted to the FDA or published in the medical literature, observational studies, clinical trials, and animal studies. Reports submitted to the FDA and data from the medical literature show that serious breathing difficulties

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can occur when gabapentinoids are taken by patients with pre-existing respiratory risk factors. Among 49 case reports submitted to the FDA over the 5-year period from 2012 to 2017, 12 people died from respiratory depression with gabapentinoids, all of whom had at least one risk factor. This number includes only reports submitted to the FDA, so there may be additional cases about which the FDA is unaware. The FDA also reviewed the results of two randomized, double-blind, placebo-controlled clinical trials in healthy people, three observational studies, and several studies in animals. One trial showed that using pregabalin alone and using it with an opioid pain reliever can depress breathing function. The other trial showed gabapentin alone increased pauses in breathing during sleep. The three observational studies at one academic medical center showed a relationship between gabapentinoids given before surgery and respiratory depression occurring after different kinds of surgeries. The FDA also reviewed several animal studies that showed pregabalin alone and pregabalin plus opioids can depress respiratory function.

In Hong Kong, there are 25 registered pharmaceutical products containing gabapentin, and 49 products containing pregabalin. All products are prescription-only medicines. As on 6 January 2020, the DH has received ADR related to gabapentin (3 cases) and pregabalin (10 cases), but these cases are not related to respiratory depression.

Related news on risk of severe respiratory depression of gabapentin and concomitant use of gabapentin and opioids was previously issued by the MHRA, and was reported in the Drug News Issue No.96. The DH issued a letter to inform local healthcare professionals to draw their attention on 27 October 2017. In December 2017, the Registration Committee discussed the matter, and decided that relevant safety information should be included in gabapentin-containing products.

Also, related news on increased risk of opioid overdose and serious side effects (including respiratory depression) when taking gabapentin or pregabalin with an opioid was previously issued by Health Canada, and was reported in the Drug News Issue No.119. The DH issued a letter to inform local healthcare professionals to draw their attention on 18 September 2019.

In light of the above FDA's announcement on the addition of relevant warnings of respiratory depression to the prescribing information of pregabalin and gabapentin, the matter will be discussed by the Registration Committee.

Drug Recall

DH endorsed batch recall of Cyramza Concentrate for Solution for Infusion 100mg ／ 10ml (HK-64421)

On 10 December 2019, the DH endorsed a licensed medicine wholesaler, Eli Lilly Asia, Inc. (Eli Lilly), to recall one batch (Batch No.: D086749A) of Cyramza Concentrate for Solution for Infusion 100mg/10ml (HK-64421) (Cyramza) from wholesale level due to a potential quality issue.

The DH received notification from Eli Lilly that the vial containing broth medium was found being mixed up in a batch of the above product. This batch was repackaged and supplied to Hong Kong under the batch No. D086749A. Preliminary investigation by the manufacturer found that the vial of broth medium was probably introduced to the batch of Cyramza from previous processing steps. The vial of broth medium does not contain active ingredient and its content differs from Cyramza in both color and volume; therefore, vials of broth medium should be readily identified by visual inspection. As a precautionary measure, Eli Lilly is initiating a wholesale-level recall of the affected batch.

The above product, containing ramucirumab, is a prescription medicine used to treat advanced gastric cancer, metastatic colorectal cancer and non-small cell lung cancer. According to Eli Lilly, the affected batch have been supplied to the Hospital Authority, private hospitals and private doctors.

Healthcare professionals should carefully inspect the vials for any discoloration before using the product. The volume of the broth vial is smaller than that of Cyramza vial and the broth content is yellow to light brown colour. Eli Lilly will also provide advice to affected healthcare professionals and hospitals and will replace the batch of product when unaffected batches are available.

Patients who have used the above product should seek advice from their healthcare professionals if in doubt.

Drug Recall

As on 6 January 2020, the DH has not received any case of ADR in connection with the concerned batch of product. A notice was posted on the Drug Office website on 10 December 2019 to alert the public of the product recall.

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.

Under the Import and Export Ordinance (Cap. 60), pharmaceutical products must be imported or exported under and in accordance with an import or export licence issued under the Import and Export Ordinance. Illegal import or export of pharmaceutical products are offences under the Import and Export Ordinance (Cap. 60) and the maximum penalty is a fine of $500,000 and 2 years' imprisonment.

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

Drug Complaint:

Tel: 2572 2068

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E-mail: pharmgeneral@dh.gov.hk

Adverse Drug Reaction (ADR) Reporting:

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E-mail: adr@dh.gov.hk

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

Post: ***Undesirable Medical Advertisements and Adverse Drug Reaction Unit,***
Drug Office, Department of Health,
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon

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.