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This is a monthly digest of local and overseas drug safety news and information released in the previous month. For the latest news and information, please refer to public announcements or the website of the Pharmaceutical Service of the Department of Health (<http://www.psdh.gov.hk>).

Safety Update

Possible fracture risk with high dose long-term use of proton pump inhibitors issued by FDA

25 May 2010 - The U.S. Food and Drug Administration (FDA) warned consumers and healthcare professionals about a possible increased risk of fractures of the hip, wrist, and spine with high doses or long-term use of a class of medications called proton pump inhibitors. Prescription proton pump inhibitors include esomeprazole, dexlansoprazole, omeprazole, lansoprazole, pantoprazole and rabeprazole. The new safety information was based on FDA's review of several epidemiological studies that reported an increased risk of fractures of the hip, wrist, and spine with proton pump inhibitor use. Some studies found that those at greatest risk for these fractures received high doses of proton pump inhibitors or used them for one year or more. The majority of the studies evaluated individuals 50 years of age or older and the increased risk of fracture primarily was observed in this age group. At the present time, there is uncertainty about the magnitude of this risk. In light of this uncertainty, when prescribing proton pump inhibitors, healthcare professionals should consider whether a lower dose or shorter duration of therapy would adequately treat the patient's condition.

In Hong Kong, products containing a proton pump inhibitor including omeprazole, lansoprazole, pantoprazole, rabeprazole and esomeprazole are available. Department of Health has issued a press release and a "Dear Healthcare Professionals" letter to doctors and pharmacist associations reminding them to be vigilant about possible fracture risk when prescribing and dispensing proton pump inhibitors. The Registration Committee of the Pharmacy and Poisons Board has considered the issue and decided that the warning requirement on possible risk of bone fractures for patients taking

proton pump inhibitors should not be required considering that the cause of the increase risk of fractures was not proven. The Department of Health remains vigilant to the local situation and new development in the other countries.

FDA reported the association of tramadol hydrochloride with the risk of overdose or suicide for patients who are addiction-prone, taking tranquilizers or antidepressant drugs

25 May 2010 - Ortho-McNeil-Janssen and U.S. Food and Drug Administration (FDA) notified healthcare professionals of changes to the prescribing information for tramadol, a centrally acting synthetic opioid analgesic indicated for the management of moderate to moderately severe chronic pain. The strengthened information emphasized the risk of suicide for patients who are addiction-prone, taking tranquilizers or antidepressant drugs and also warned of the risk of overdose. Tramadol-related deaths had occurred in patients with previous histories of emotional disturbances or suicidal ideation or attempts, as well as histories of misuse of tranquilizers, alcohol, and other CNS-active drugs. Tramadol may be expected to have additive effects when used in conjunction with alcohol, other opioids or illicit drugs that cause central nervous system depression. Serious potential consequences of overdose with tramadol are central nervous system depression, respiratory depression and death.

In Hong Kong: Ultracet (registered by Johnson & Johnson (Hong Kong) Ltd) and other tramadol-containing products are available. Department of Health has issued a press release and a "Dear Healthcare Professional" letter to doctors reminding them not to prescribe tramadol for patients who are suicidal or addiction-prone. Extra caution should also be taken when prescribing

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tramadol for patients who are taking tranquilizers or antidepressant drugs and patients who use alcohol in excess and who suffer from emotional disturbance or depression. The Registration Committee of the Pharmacy and Poisons Board has considered the issue and decided that the warning requirement on risk of overdose or suicide for patients taking tramadol was not required. The Department of Health remains vigilant to the local situation and new development in the other countries.

Rare cases of liver injury reported with use of Xenical and Alli (orlistat) reported by FDA

26 May 2010 - The U.S. Food and Drug Administration (FDA) advised consumers and healthcare professionals about potential rare occurrences of severe liver injury in patients taking the weight-loss medication orlistat, marketed as Xenical and Alli. The agency had identified 13 cases of severe liver injury, 12 of which were reports from outside of the United States. The only U.S. report of severe liver injury involved Alli. At this time, a cause-and-effect relationship of severe liver injury with orlistat use had not been established.

In Hong Kong, Xenical and Alli are registered by Roche Hong Kong Ltd and GlaxoSmithKline Ltd respectively. Department of Health has issued a press release and a "Dear Healthcare Professionals" letter to doctors and pharmacist associations reminding them to be vigilant to this safety information.

Healthcare professionals warned not to use certain intravenous metronidazole, ondansetron, and ciprofloxacin due to contamination in U.S.

29 May 2010 - The U.S. Food and Drug Administration (FDA) alerted healthcare professionals not to use certain intravenous bags of metronidazole, ondansetron, and ciprofloxacin because of potential contamination. FDA had received reports of floating matter in IV bags manufactured by Claris Lifesciences Limited, in Ahmedabad, India. Foreign matter should not be present in a sterile injectable product. Potentially affected products were sold under the Claris, Sagent Pharmaceuticals, Pfizer, and West-Ward

Pharmaceuticals labels. A Claris customer received a complaint of white matter in a bag of metronidazole, and subsequent microbiological analysis identified the matter as a *Cladosporium* mold. Molds of this type can cause infections in susceptible patients, such as immunocompromised individuals. Another customer complained of white matter in a bag of ondansetron was received, and that bag was under analysis. At this time, FDA was not aware of any reports of injuries due to administration of these products. Claris was initiating a recall of all lots of these two products, as well as all lots of ciprofloxacin. These products were all manufactured on the same manufacturing line. FDA was investigating the situation and would notify the public when new information became available.

In Hong Kong, there are 19 products manufactured by Claris Lifesciences registered by the same company, Unico & Co. These products include metronidazole (as Metris Inj), ondansetron (as Emistop Inj), and ciprofloxacin (as Ciprocina Inj and Ciprox IV Infusion). Only one product, Ciprocina Inj, has been imported into Hong Kong and has only been supplied to Hospital Authority. The company has been instructed to recall this product in Hong Kong. There are no Claris Lifesciences products that are registered by Sagent Pharmaceuticals, Pfizer, and West-Ward Pharmaceuticals in Hong Kong.

Hospira in U.S. announced an expansion of a nationwide voluntary recall of certain lots of Liposyn and Propofol that might contain particulate matter

10 June 2010 - During the surveillance exercise of Department of Health, it was revealed from the website of U.S. Food and Drug Administration that Hospira, Inc. voluntarily recalled Propofol Injectable Emulsion 1% and Liposyn (Intravenous Fat Emulsion) products which included Liposyn II 10%, Liposyn II 20%, Liposyn III 10%, Liposyn III 20%, and Liposyn III 30% to the consumer or user level. Hospira conducted the recall because some of the containers might contain particulate matter. The particulate was primarily made up of sub-visible inert stainless steel particles. Since these particulate contaminants did not dissolve in blood they could potentially act as emboli and impede blood flow. Particulates might also cause mechanical damage to the body and might escalate

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damage through the Systemic Inflammatory Response Syndrome (SIRS). The affected lots of Liposyn were distributed between December 2008 and April 2010. The affected lots of propofol were distributed between March 2008 and April 2010. These products were distributed in the United States, Barbados, Canada, Chile, South Korea,

Australia, Dominican Republic, Japan, Philippines, Puerto Rico, Uruguay, and the U.S. Virgin Islands.

In Hong Kong, only Liposyn II 10% and Liposyn II 20% are registered by Hospira Ltd. Hospira confirms that these products have not been marketed in Hong Kong since 2006.

Drug Incident

Public urged not to consume slimming product “1 Body Beautiful” with undeclared drug ingredients

On 19 May 2010, the Department of Health (DH) urged the public not to buy or use a slimming product as they were found to have contained undeclared western drug ingredients, sibutramine and phenolphthalein, which may cause serious side effects. The product concerned was “1 Body Beautiful 1 纖瘦”, which was available for sale on a Mainland website.

The appeal was made following the investigation into a case of a 29-year-old woman who visited the Accidental and Emergency Department at Queen Elizabeth Hospital complaining about vomiting and dizziness. The patient had already been discharged. It was found that the woman had a history of taking the aforementioned slimming product which she purchased from a Mainland website and couriered to Hong Kong. Laboratory tests on the product showed the presence of sibutramine and phenolphthalein.

Public urged not to consume slimming products “苦瓜清脂減肥膠囊”, “Miyura Fit’x Capsules” and two unknown capsules with undeclared drug ingredients

On 27 May 2010 the Department of Health (DH) urged the public not to buy or use four slimming products as they were found to have contained undeclared western drug ingredients, sibutramine and phenolphthalein, which may cause serious side effects. The products concerned were 苦瓜清脂減肥膠囊, Miyura Fit’x Capsules, and two unknown capsules – an orange and white capsule, and a pearl -white capsule.

Investigations revealed that the products were

found to be offered for sale on an internet website during an investigation into a public enquiry. Laboratory results on samples of the products showed that all of them contained phenolphthalein and sibutramine.

Woman arrested for selling and possession of slimming products “USA Yaku Cell Slimming Capsules (美國雅酷細胞減肥素)”, “青瓜の排油素”, “木瓜の排油素” and “冬瓜の排油素” with undeclared drug ingredients

On 1 June 2010, a 43-year-old woman was arrested in a joint operation by the Police and the Department of Health (DH) as part of their follow-up investigation into the sale of four slimming products which were earlier found to have contained undeclared western drug ingredients that may cause serious side effects. The four products were “USA Yaku Cell Slimming Capsules (美國雅酷細胞減肥素)”, “青瓜の排油素”, “木瓜の排油素” and “冬瓜の排油素”.

The woman was suspected of selling USA Yaku Cell Slimming Capsules (美國雅酷細胞減肥素). She was also in possession of two boxes of 冬瓜の排油素 at the time of arrest. A home search subsequently resulted in the seizure of more stock of the four products.

The DH previously obtained the products concerned from an internet auction website during DH's surveillance operation. It subsequently issued a press statement on 13 May 2010 warning members of the public not to take the products after the detection of undeclared western drug ingredients, sibutramine and its analogue, as well as phenolphthalein, in the product samples by laboratory tests. The investigation revealed that

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these products were obtained from a Mainland website and offered for sale on a local auction website.

Public urged not to consume slimming products “纖婷 II (櫻花精油減肥膠囊)”, “纖婷 III (櫻花精油減肥膠囊)”, “瘦身の語 III” and “Fatloss Jimpness Beauty” with undeclared drug ingredients

On 7 June 2010 the Department of Health (DH) urged the public not to buy or use four slimming products, “纖婷 II (櫻花精油減肥膠囊)”, “纖婷 III (櫻花精油減肥膠囊)”, “瘦身の語 III” and “Fatloss Jimpness Beauty 婷美麗人”, as they were found to have contained undeclared western drug ingredients that may cause serious side effects. The first three products were purchased by DH from the internet and the fourth seized from a shop in Luen Wo Hui Market in Fanling, all acting on information from DH's surveillance programme.

Laboratory tests confirmed that “纖婷 II (櫻花精油減肥膠囊)” and “纖婷 III (櫻花精油減肥膠囊)” contained sibutramine, sibutramine-analogue and phenolphthalein; “瘦身の語 III” contained sibutramine and “Fatloss Jimpness Beauty 婷美麗人” contained both sibutramine and phenolphthalein.

Woman arrested for allegedly selling slimming product “S&S Super Slender” with undeclared drug ingredients

On 8 June 2010, a 26-year-old woman was arrested in a joint operation by the Police and the Department of Health (DH) as part of their follow-up investigation into the sale of a slimming product, “S&S Super Slender 燃脂膠囊”, which was earlier found to have contained undeclared western drug ingredients that may cause serious side effects.

In February 2010, DH obtained the product from an internet auction website, acting on information from DH's surveillance programme. The DH subsequently issued a press statement on 25 February 2010 warning members of the public not to take the product as laboratory tests detected undeclared western drug ingredients, sibutramine

and its analogue, as well as phenolphthalein, in product samples.

Sibutramine is a western medicine used as an appetite suppressant. Its side effects include increased blood pressure and heart rate, psychosis and possibly convulsion. People with heart problems, should not take it. Products containing sibutramine can be sold only on a doctor's prescription and dispensed under the supervision of a pharmacist. Sibutramine analogues, being chemically similar to sibutramine, are expected to have the same side effect as sibutramine. Phenolphthalein was once used for treating constipation but had been banned in 2001 for its cancer causing effect.

All of the aforementioned products were not registered pharmaceutical products under the Pharmacy and Poisons Ordinance in Hong Kong. A product containing any western drug ingredient must be registered before it can be sold in Hong Kong. Under the Pharmacy and Poisons Ordinance, possession or sale of unregistered pharmaceutical product is an offence liable to the maximum penalties of a \$100,000 fine and two year's imprisonment.

Members of the public should stop using the aforementioned products that contained undeclared western drug ingredients and they should see doctors if they feel unwell after taking the products. They should destroy, dispose or submit them to the Department's Pharmaceutical Service during office hours.

Useful Contact

Drug Complaint:

Tel: 2572 2068

Fax: 2147 0457 & 2123 1996

E-mail: pharmgeneral@dh.gov.hk

Adverse Drug Reaction (ADR) Reporting:

You are encouraged to report any suspected or confirmed ADR cases to our office by:

Fax: 2572 4570 E-mail: adr@dh.gov.hk

Post:

**ADR Monitoring Unit,
Pharmaceutical Service, Department of Health,
3/F, Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon**