Drug News
藥 物 情 報

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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

The association of bevacizumab (Avastin) with hypersensitivity reactions and infusion reactions announced by Health Sciences Authority in Singapore

18 March 2010 - Roche updated healthcare professionals on the risk of patients experiencing hypersensitivity reactions or infusion reactions after receiving Avastin (bevacizumab). Roche noted imbalances in hypersensitivity and infusion reactions among patients treated with Avastin and chemotherapy in some clinical studies. A cumulative search of Roche's safety database also identified reports of hypersensitivity, though it noted that majority of the cases were confounded by concomitant chemotherapy. Physicians were advised to closely monitor patients during and after Avastin infusion and to stop the infusion and administer appropriate therapies if a reaction occurs.

Avastin is registered by Roche Hong Kong Limited in Hong Kong, and its package insert has been updated regarding this safety issue. In addition, Department of Health has issued a "Dear Healthcare Professionals" letter to inform healthcare professionals about this safety information.

Ongoing safety review of high-dose Zocor (simvastatin) and increased risk of muscle injury by US Food and Drug Administration

19 March 2010 - Based on review of data from a large clinical trial and other sources, there was an increased risk of muscle injury in patients taking the highest approved dose of the cholesterol-lowering medication, Zocor (simvastatin) 80mg, compared to patients taking lower doses of simvastatin and possibly other drugs in the "statin" class. The US Food and Drug Administration (FDA) was also reviewing other data to better understand the relationship between high-dose simvastatin use and muscle injury.

FDA warned patients and healthcare providers about the potential for increased risk of muscle injury from the Zocor 80mg. Although muscle injury (called myopathy) is a known side effect with all statins, the warning highlighted the greater risk of developing muscle injury, including rhabdomyolysis, for patients when they are prescribed and use higher doses of this drug. Rhabdomyolysis is the most serious form of myopathy and can lead to severe kidney damage, kidney failure, and sometimes death.

Zocor and other products containing simvastatin are available in Hong Kong. Zocor is registered by Merck Sharp & Dohme (Asia) Ltd. At present, there is a warning in the package insert of Zocor that all patients starting therapy with simvastatin, or whose dose of simvastatin is being increased, should be advised of the risk of myopathy and told to report promptly any unexplained muscle pain, tenderness or weakness; and simvastatin therapy should be discontinued immediately if myopathy is diagnosed or suspected. Healthcare professionals are reminded to exercise extra

caution when prescribing and supplying simvastatin 80mg to patients, due to the potential for increased risk of myopathy, including rhabdomyolysis. The Department of Health remains vigilant to any new findings regarding simvastatin.

Updated labelling for antibiotic Avelox (moxifloxacin) regarding rare risk of severe liver injury

22 March 2010 - Health Canada informed healthcare professionals and Canadians of changes to the labelling information for the prescription antibiotic Avelox (moxifloxacin). The updated labelling incorporated important safety information related to the rare risk of severe liver injury. Avelox belongs to a family of antibiotic drugs known as quinolones and is used to treat a broad range of bacterial infections, including respiratory infections. It can be taken by mouth in a tablet format, or administered by injection. Health Canada had conducted a safety review and concluded that Avelox may be associated with the rare but potentially life threatening risk of liver injury, including liver failure.

In Hong Kong, Avelox is registered by Bayer Healthcare Ltd. Department of Health has issued a press release and notified health professionals regarding this safety information. The Registration Committee of the Pharmacy and Poisons Board has reviewed the issue and decided that products containing moxifloxacin are required to include the warning on its rare risk of severe liver injury.

Recall of Prevnar Pneumococcal 7-valent Conjugate Vaccine, 0.5 mL single dose pre-filled syringe (10 per package), Wyeth in United States

22 March 2010 - Wyeth, a part of Pfizer Inc., voluntarily recalled four lots (E25197, OE28211, E37556 and E38749) of Prevnar Vaccine, single dose pre-filled syringes. During a routine physical inspection of Prevnar pre-filled syringes, Wyeth determined that a potential existed for syringes to have been distributed with a rubber formulation in the syringe tip caps that was not approved for use with Prevnar. Wyeth performed a medical assessment and had concluded that the affected syringes present no health or safety risk to patients. Further, there would be no expected loss of potency and there is no need to revaccinate children who may have received a dose of Prevnar from an affected syringe.

In Hong Kong, Prevnar is registered as "Prevenar" by Wyeth (HK) Ltd. The company has confirmed that the affected batches have not been imported into Hong Kong.

European Medicines Agency recommended precautionary recall of batches of clopidogrel-containing medicines by GloChem Industries Ltd in India

25 March 2010 - The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommended the recall of all batches of centrally-authorised generic clopidogrel-containing medicines, for which the active substance was manufactured by Glochem Industries Ltd in its factory in Visakhapatnam (India). The Committee's recommendation followed an inspection of the Glochem Visakhapatnam manufacturing site, which identified failings in Good Manufacturing Practices (GMP). The GMP failings raised concerns about the processes used to manufacture the active substance and the Committee was not reassured about the quality of medicines made with clopidogrel from this manufacturing site. The Marketing Authorisation Holder of all these medicines was Acino Pharma GmbH. The Committee also recommended that the Glochem Visakhapatnam manufacturing site be removed from the list of sites allowed to supply clopidogrel to Acino Pharma GmbH for their generic medicines.

In Hong Kong, clopidogrel in all registered clopidogrel-containing products is not supplied by GloChem Industries Ltd in India.

US Food and Drug Administration communicated ongoing safety review of Stalevo (entacapone/carbidopa/ levodopa) and possible development of Prostate Cancer

31 March 2010 - The US Food and Drug Administration (FDA) was evaluating a clinical trial data that might suggest that patients taking Stalevo, a Parkinson's disease medication, may be at an increased risk for developing prostate cancer. In this trial, patients taking Stalevo were compared to those taking carbidopa and levodopa (sold as Sinemet), a combination medication also used to treat Parkinson's disease. An unexpected finding in the trial was that a greater number of patients taking Stalevo were observed to have prostate cancer compared to those taking carbidopa/levodopa.

FDA's review of Stalevo is ongoing and no new conclusions or recommendations about the use of this drug have been made. The agency will update the public as soon as this review is completed.

In Hong Kong, Stalevo is registered by Novartis Pharmaceuticals (HK) Ltd. The Department of Health remains vigilant to any new findings about Stalveo.

Post-marketing reports of renal impairment associated with zoledronic acid 5mg solution for infusion (Aclasta) reported by Health Sciences Authority in Singapore

1 April 2010 - Novartis updated healthcare professionals on post-marketing reports of renal impairment following administration of Aclasta. Majority of the cases were reported in patients with pre-existing medical conditions, risk factors (advanced age, renal impairment, concurrent or preceding dehydration), or with concurrent exposure to nephrotoxic agents. Rare cases of renal failure requiring dialysis or with fatal outcomes had also been reported. Physicians were advised to consider thoroughly their patient's renal function before initiating Aclasta and not to use it in patients with severe renal impairment (CrCl < 35ml/min).

In Hong Kong, Aclasta is registered by Novartis Pharmaceuticals (HK) Ltd. The current package insert has been updated to include this safety information. In addition, a "Dear Healthcare Professionals" letter regarding this safety information has been issued in March 2010 by Novartis to alert healthcare professionals who are using Aclasta.

Discontinuation of sale of Zeftera (ceftobiprole medocaril) for Injection in Canada

8 April 2010 - Janssen-Ortho decided to discontinue sale of Zeftera (ceftobiprole medocaril) for Injection in Canada effective on 16 April 2010. This action was taken by Janssen -Ortho following discussions with Health Canada in response to recent regulatory recommendations in the United States and European Union to not approve Zeftera due to concerns regarding the studies had not been conducted in compliance with good clinical practice.

In Hong Kong, Zeftera is registered by Johnson & Johnson (Hong Kong) Ltd. The company has confirmed that Zeftera has not been imported into Hong Kong, and has also voluntarily cancelled the product's registration in Hong Kong.

Drug Recall

Recall of pharmaceutical products – U-Caine Lozenges (HK-27990) and U-Multivit Tab (HK-28668)

On 29 March 2010, Neochem Pharmaceutical Laboratories Limited (Neochem), a licensed drug manufacturer, initiated recall of the product U-Caine Lozenges (batch number 081228), which was found to have contained lower than registered content in one of the active ingredients, benzocaine. The Department of Health conducted investigation immediately.

On 14 April 2010, two products namely U-Multivit Tab (batch number 070756) and another batch of U-Caine Lozenges (batch number 071382) were found to have contained lower than registered content of their active ingredients. Neochem initiated recall of the two products accordingly.

According to the label of U-Caine Lozenges, one piece of lozenge should contain 1mg benzocaine. Analysis result showed that the concerned product only contained 0.5mg and 0.36mg per lozenge for batch number 081228 and 071382 respectively.

According to the label of U-Multivit Tab, each tablet should contain Vitamin A at 200 International Units (I.U.) and Vitamin D at 100 I.U.. Tests made no detection of Vitamin A or Vitamin D in the concerned batch of the product.

Deviations from the registered content of active ingredients of a pharmaceutical product would affect treatment effectiveness. U-Caine Lozenges is used for the relief of sore throat and should be sold in pharmacy under the supervision of pharmacists. U-Multivit Tab is a vitamin supplement which could be sold over the counter.

The above products were supplied to private doctors and pharmacies. The manufacturer initiated a recall at retail level and had set up a hotline to answer clients' enquiries. Members of the public should stop using the aforementioned products. People who have sore throat not relieved or aggravated after taking U-Caine Lozenges were advised to consult their healthcare providers. The licence for manufacturer of Neochem was temporarily suspended until it has instituted adequate remedial measures to ensure total compliance with Good Manufacturing Practices.

Drug Incident

Public urged not to consume slimming product "Kartien Easy to Slim" with undeclared drug ingredients

On 19 March 2010, the public was urged not to buy or use a slimming product named "Kartien Easy to Slim 康婷醫之纖" as it was found to have contained undeclared western drug ingredient sibutramine that may cause serious side effects.

The Department of Health (DH) received a report by the Hospital Authority concerning a 35-year-old woman, who presented symptoms of psychosis, had history of taking the product for weight reduction. Laboratory results showed that samples collected from the patient contained sibutramine.

The woman alleged that she bought the concerned slimming product from a Chinese Medical Centre in Tsim Sha Tsui last year and took it from July to December 2009. The Chinese Medical Centre in Tsim Sha Tsui had a related wholesaling company "Harmonic Health Pharmaceutical Company Limited" in Wan Chai.

Investigation revealed that the company had records of selling the unregistered product in July 2009 despite an earlier instruction to recall the product from the market in May 2008.

Public urged not to consume Po Chai Pills with undeclared drug ingredients

On 24 March 2010, the Department of Health (DH) directed licensed manufacturer in

proprietary Chinese medicines Li Chung Shing Tong (Holdings) Ltd. HK to recall Po Chai Pills Capsule Form and Po Chai Pills Bottle Form from local retail outlets and consumers as its capsule form was found in Singapore to have contained undeclared western drug ingredients phenolphthalein and sibutramine, which may cause very serious side effects.

In Hong Kong, Po Chai Pills Bottle Form is registered as proprietary Chinese medicine and sold locally while Po Chai Pills Capsule Form was applying for registration as a proprietary Chinese medicine.

The recall of Po Chai Pills Capsule Form and Po Chai Pills Bottle Form was a precautionary measure because of the serious potential side effects of phenolphthalein and sibutramine, and that the products were commonly used by a whole spectrum of the population in Hong Kong, including vulnerable groups like children and the elderly.

Samples of Po Chai Pills Capsule Form and Po Chai Pills Bottle Form and their raw materials had been tested by the Government Laboratory. Investigation findings suggested the source of contamination likely to be in powder form raw materials used to fill capsules and 11 samples from Po Chai Pills Capsule Form and its raw materials confirmed the detection of phenolphthalein and sibutramine.

The manufacturer had been barred from supplying further stocks of any of its products to the market since 24 March 2010. After a number of remedies were put in place and trial production of the product launched since end of April 2010, production of Po Chai Pills Bottle Form resumed on 11 May 2010. The Capsule Form had been ceased to be produced.

Public urged not to consume slimming products "LiPO-4 Cap, LiPO-8 and Glucomi 600 Cap" with undeclared drug ingredient

On 1 April 2010, members of the public were urged not to buy or consume three slimming products called "LiPO-4 Cap", "LiPO-8 Cap" and "Glucomi 600 Cap" as they were found to have contained an undeclared western drug ingredient sibutramine that may cause serious side effects.

The products were found to be offered for sale on an Internet website during an investigation into a public enquiry. Laboratory results of the samples showed the presence of sibutramine in the products.

Phenolphthalein was once used for treating constipation but had been banned in 2001 for its cancer causing effect. 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.

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.

Drug wholesaler "Julius Chen & Co (HK)" instructed to recall illegally packaged products

On 12 April 2010, the Department of Health (DH) instructed a licensed drug wholesaler Julius Chen & Co (HK) Ltd to recall a product

called Puricos 300mg Tablet (HK-31027) from consumer level because the company was found to have packaged the product without manufacturing licence.

The product is used for treatment of gout and hyperuricaemia. It can be sold in pharmacies under the supervision of a pharmacist. The product in question had been sold to private doctors and pharmacies.

It was found that the company illegally stored medicines in unapproved premises and was involved in illegal packaging of pharmaceutical products without manufacturing licence.

There was an incidental finding of another illegally packaged product, namely Nutribes Folic Acid Tablet, in which the company imported for re-export to Macao. DH informed the Macao authorities about the finding.

Wholesale activities of Julius Chen & Co (HK) Ltd were suspended to facilitate investigation.

Further, on 14 April 2010, the Department of Health revealed more illegally packaged products and therefore instructed Julius Chen & Co (HK) Ltd to recall seven more pharmaceutical products from consumer level.

The products were Nutribes Vitamin E Capsules 400IU (HK-35319), Vita Prima B1 + B6 + B12 Tablets (HK-53232), Nutribes Beta Carotene Capsules 25000IU (HK-40740), Archon Glucosamine Tablets 750mg (HK-51162), Nutribes Century Tablets (HK-51738), Arnet Oyster Shell Calcium Tablets (HK-48618), Doctor's Elect Calcium Carbonate-1500 Tablets (HK-56860).

These products are all non-prescription products including vitamins and minerals.

The company had set up a hotline to answer public enquiries. The wholesale poisons licence of the company was temporarily suspended. The company subsequently implemented a number of remedial measures in relation to the proper handling of drugs, and the licence of the wholesaler was restored on 21 June 2010.

No person shall manufacture any pharmaceutical product (including packaging) on any premises unless he is the holder of a licence to manufacture pharmaceutical products on those premises. Under Pharmacy and Poisons Ordinance, illegal manufacturing of pharmaceutical products is an offence liable to the maximum penalties of a $100,000 fine and two year's imprisonment.

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