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

Statement on rosiglitazone (Avandia and Avandamet) by the Medicines and Healthcare products Regulatory Agency in United Kingdom

15 April 2010 - The Medicines and Healthcare products Regulatory Agency in United Kingdom issued an announcement following enquiries regarding completion of a two-year inquiry by a United States Senate committee, which had questioned the cardiovascular safety of the anti-diabetes medicine, Avandia (rosiglitazone). The available data considered during this US inquiry had previously been considered as part of Europe-wide reviews, which concluded that the balance of risks and benefits remains favourable. The prescribing information had been updated to include warnings about the risk of myocradial infarction and also to advise that, in patients with ischaemic heart disease, rosiglitazone should be used only after careful evaluation of every patient's individual risk.

In Hong Kong, there are two registered pharmaceutical products, Avandia and Avandamet, contain rosiglitazone. Warnings about the risk of myocradial infarction have been included in the package inserts of Avandia and Avandamet. The Department of Health remains vigilant to any new findings about rosiglitazone.

New boxed warning on severe liver injury with propylthiouracil issued by US Food and Drug Administration

21 April 2010 - The US Food and Drug Administration (FDA) had added a boxed warning to the label for propylthiouracil, a drug used to treat hyperthyroidism (overactive thyroid), to include information about reports of severe liver injury and acute liver failure, some of which had been fatal, in adult and pediatric patients using this medication. The agency identified 34 cases of severe liver injury associated with propylthiouracil used between 1969 and 2009. Twenty-three cases were in adult patients and 11 were in pediatric patients. Of the 23 adult cases, 13 deaths and five liver transplants were reported. Among the 11 pediatric cases, two cases resulted in death and seven patients required a liver transplant; one patient died while on the transplant list.

Propylthiouracil containing products are available in Hong Kong. The Registration Committee of the Pharmacy and Poisons Board has reviewed the issue, and decided that package inserts or labels of products containing propylthiouracil should include the warning on severe liver injury. In addition, Department of Health has issued a press statement and a "Dear Healthcare Professionals" letter to inform healthcare professionals about this safety information.

Reports of adverse reactions to 2010 seasonal flu vaccine in children in Western Australia

23 April 2010 - The Therapeutic Goods Administration (TGA) investigated reports of an increase in adverse events to the seasonal flu vaccine in Western Australia (WA), where all children 6 months to 5 years had been offered a

free seasonal flu vaccination. The TGA investigated the WA data to determine whether the adverse reactions reported in WA relate to the vaccine, or the WA program delivery. However, until it could be established what was causing the rise in adverse events in some children in WA, all immunisation providers were advised not to administer seasonal flu vaccinations to all children 5 years of age and under until further notice. The TGA contacted the manufacturer, CSL Ltd, to confirm which batches of vaccine were used in WA and obtained samples of the vaccine to test in its laboratories to determine if there were any abnormalities in the batches of vaccine used in WA.

In Hong Kong, the influenza vaccine concerned, which is registered by Luen Cheong Hong Ltd., is solely for the southern hemisphere. The company has confirmed that the affected vaccine has not been imported into Hong Kong.

Ongoing safety review of Gonadotrophin-releasing Hormone (GnRH) agonists used to treat prostate cancer by US Food and Drug Administration

3 May 2010 - The US Food and Drug Administration (FDA) notified healthcare professionals and patients of FDA's preliminary and ongoing review which suggested an increase in the risk of diabetes and certain cardiovascular diseases in men treated with GnRH agonists. GnRH agonists (sold under the brand names Lupron (leuprolide acetate), Zoladex (goserelin acetate), Trelstar (triptorelin pamoate), Viadur (leuprolide acetate), Vantas (histrelin acetate), Eligard (leuprolide acetate) and Synarel (nafarelin acetate)) are drugs that lower male hormones, which has the effect of shrinking prostate tumors or slowing the growth of prostate cancer. This therapy is known as Androgen Deprivation Therapy or ADT.

In Hong Kong, the products containing GnRH agonist are Zoladex (goserelin), Decapeptyl (triptorelin) and Diphereline (triptorelin) which are registered by AstraZeneca Hong Kong Ltd, Ferring Pharmaceuticals Ltd and Beaufour Ipsen International (HK) Ltd respectively. The Department of Health remains vigilant to any new findings about these drugs.

Serious adverse events related to medication errors/misuse of Exelon Patch (rivastigmine transdermal patch) announced by Health Canada

5 May 2010 - Novartis Pharmaceuticals Canada Inc. ("Novartis"), in consultation with Health Canada, informed that serious adverse events including death, had occurred following rivastigmine overdose due to medication errors/ misuse of Exelon Patch. Therefore, Novartis would like to remind the importance of the proper use and application of Exelon Patch (rivastigmine transdermal patch) and the need to instruct patients and caregivers on correct application techniques for the use of Exelon Patch. Healthcare providers should inform patients and caregivers on the proper use of rivastigmine patch prior to initiating therapy, and advise them to strictly follow instructions on patch usage. Only one transdermal patch should be applied per day. The previous day's patch must be removed before applying a new patch to a different skin location after 24 hours of use.

In Hong Kong, Exelon Patch is registered by Novartis Pharmaceuticals (HK) Ltd and its package insert has been updated to emphasize the proper use of Exelon Patch. In addition, Department of Health has issued a “Dear Healthcare Professionals” letter to inform healthcare professionals about this safety information.

Blanket recall of Quality Pharmaceutical Lab products

On 7 May 2010, the Department of Health (DH) conducted investigation against a licensed drug manufacturer Quality Pharmaceutical Laboratory Ltd. (Quality) following an incident of recall of its products (2 types of Mefenamic acid tablets) which were found to have failed the disintegration time test on 20 April 2010). DH conducted immediate investigation and sampled some 90 products for laboratory analysis. Out of which, a total of 13 products with defects had been found. 9 products were found to have failed the disintegration time test and four were found to contain lower than registered content of active ingredients.

The quality defects reflected that there were likely to be deficiencies during the manufacturing processes and the DH directed the manufacturer to recall all of its products.

Quality had set upa hotline for public enquiries. The DH would closely monitor the recall. The DH had issued a press statement to alert healthcare professionals and retailers to stop supplying the products manufactured by Quality to their clients. People who have used the product should consult healthcare professionals if in doubt. The licence of manufacturer of Quality was temporarily suspended until it has instituted adequate remedial measures to ensure full compliance with Good Manufacturing Practices.

Voluntary recall of Zithromax Powder for Oral Suspension 200mg/5ml (HK-36432) because of suspected quality defect

On 12 May 2010, Pfizer Corporate Hong Kong Ltd (Pfizer), a licensed drug wholesaler, initiated a recall of one batch of Zithromax Powder for Oral Suspension 200 mg/5ml (Batch no: 96415502) from the market in view of its possible quality defect.

The product is manufactured in Italy. It is an antibiotic used for various infectious diseases. It can only be sold in pharmacies on a doctor's prescription and under the supervision of a pharmacist. Around 39,000 boxes of the affected product were imported into Hong Kong. Among them, 33,000 boxes were supplied to public and private hospitals, private doctors and pharmacies. Some were exported to Macao.

The recall was made after Pfizer had received two complaints in Hong Kong concerning black particles were found in the affected batch of Zithromax Powder. Preliminary investigations by Pfizer suggested that the product was likely to be contaminated with rubber particles, with an average size of 0.27mm.

Although the recall was related to quality defects, Pfizer opted to initiate a voluntary recall as a precautionary measure as the product is commonly used in children - a vulnerable group. On assessment, the Department of Health (DH) endorsed Pfizer's decision and would closely monitor the exercise and the development. Pfizer has set up a hotline for public enquiries.

DH has issued a press statement to alert healthcare professionals and retailers to stop supplying the product to their clients. People who have used the product should consult healthcare professionals if in doubt.

Drug Incident

Public urged not to consume slimming products "USA Yaku Cell Slimming Capsules ("美國雅酷細胞減肥素)", 青瓜D排油素", "木瓜D排油素" and "冬瓜D排油素" with undeclared drug ingredients

On 13 May 2010, members of the public were urged not to buy or use four slimming products named "USA Yaku Cell Slimming Capsules (美國雅酷細胞減肥素)", "青瓜排油素", "木瓜D排油素" and "冬瓜D排油素" as they were found to have contained undeclared western drug ingredients that may cause serious side effects.

The products were purchased from the internet during the Department of Health's market surveillance exercise. Laboratory results of the samples showed the presence of sibutramine and its analogue, as well as phenolphthalein, in the products.

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 effects as sibutramine. Phenolphthalein was once used for treating constipation but had been banned 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***