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

United Kingdom:Incorrect labelling of GONAL-f 450IU/0.75ml solution for injection in a pre-filled pen

16 November 2010 - Merck Serono UK informed the Medicines and Healthcare products Regulatory Agency (MHRA) that there was an error on the label of the pen injection device for six batches of GONAL-f 450IU/0.75ml solution for injection in pre-filled pens. The concentration of the product was stated correctly in the heading (line1) on the pen label against the product name. The delivery dose was repeated on line 4 of the label, but read as 450IU/0.5ml instead of 450IU/0.75ml. The concentration was stated correctly on the label of the external packaging and in the package leaflet.

In Hong Kong, Gonal-f Pre-filled Pen for Inj. 450IU/0.75ml is registered by Merck Pharmaceutical (HK) Limited. It is a prescription medicine indicated for anovulation in women unresponsive to treatment with clomiphene citrate and for stimulation of multifollicular development in patients undergoing superovulation for assisted reproductive techniques. The company confirmed that the affected batches in the United Kingdom (UK) had not been imported into Hong Kong.

Worldwide recall of certain batches of Methotrexate & Fluorouracil manufactured by Ebewe Pharma

November 2010 – EBEWE Pharma Ges.m.b.H.Nfg.KG initiated a worldwide recall of certain batches of Fluorouracil Solution for Injection and Methotrexate Solution for Injection because glass particles were identified in a small number of vials during routine testing. According to the company, the root cause had been identified and corrective measures were commenced. The affected countries and the products concerned were listed as follows:

Country	Product affected
UK	• Fluorouracil 50mg/ml Solution for Injection 10ml • Methotrexate 100mg/ml Solution for Injection 10ml
Hong Kong, Macau & China	• Methtrexate –Ebewe 50mg/50ml for Injection • Methtrexate –Ebewe 500mg/50ml for Injection • Methtrexate –Ebewe 1000mg/10ml for Injection

In Hong Kong, the concerned products are registered by a local company, Novartis Pharmaceuticals (HK) Ltd. Methotrexate and Fluorouracil are prescription medicines and are mainly used for treatment of malignant tumours. The company initiated a recall of Methotrexat-Ebewe in clear tubing glass vials on 15 November, 2010. The Department of Health (DH) had issued press statements and letters to healthcare professionals about the recall. For 5-Fluorouracil Inj 50mg/ml (Ebewe), the company confirmed that the concerned batches had not been imported into Hong Kong and the one registered in Hong Kong is in amber glass vials and thus was not affected by this recall.

Canada: Important new restrictions on the use of rosiglitazone products (Avandia®, Avandamet® and Avandaryl®) in Canada due to the information on cardiovascular related events

19 November 2010 – Further to the assessment of data collected from a meta-analysis of clinical trials

and some observational studies, suggesting an elevated risk of cardiovascular events in patients treated with rosiglitazone, GlaxoSmithKline Inc., in consultation with Health Canada, decided to impose new usage restrictions on relevant products, namely Avandia® (rosiglitazone), Avandamet® (rosiglitazone and metformin), and Avandaryl® (rosiglitazone and glimepiride). These medications are now indicated only in patients with type II diabetes for conditions where other antidiabetic agents cannot adequately control the blood sugar level, or are contraindicated, or cause intolerance. Furthermore, physicians are advised to counsel each patient on the risk and benefits of the medications and obtain patient's written consent on using the drugs.

The details of the safety information concerning the rosiglitazone products and the situation in Hong Kong were reported previously in Issue No. 12 of Drug News. The package inserts of rosiglitazone products available in Hong Kong have been revised to include the safety information indicating that the drug should only be used in patients with Type II diabetes who cannot control their diabetes on other medications and should not be used in patients with heart failure, or history of heart failure.

European Union: European Medicines Agency confirmed that the unexpected viral DNA as detected in some live attenuated vaccines did not pose a public health risk

19 November 2010 - The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) had finalised a review on the impact of unexpected viral DNA fragments detected in some live attenuated vaccines, including rotavirus vaccines, by a new testing method known as metagenomics. It was concluded that the unexpected viral DNA as detected did not pose a risk to public health, because the type of virus found does not cause disease in humans.

In Hong Kong, there are two rotavirus vaccines registered, namely Rotarix Vaccine Oral Suspension (by GlaxoSmithKline Ltd) and Rotateq Vaccine Oral Suspension (by Merck Sharp & Dohme (Asia) Ltd). These two products were once recalled from the market in March and May 2010 respectively as a precautionary measure and finally resumed for use later in May 2010 after review and examination by the DH. More details regarding the rotavirus vaccines were reported in Issue No. 10 of Drug News.

United Kingdom: Recall of Janssen-Cilag Ltd - Velcade 3.5mg powder for solution for injection

19 November 2010 - Janssen-Cilag Limited recalled all remaining stock of various batches (8EZSQ00, 8EZSP00, 9FZSK00, 9FZSK01, 9GZSK00, 9JZSV00) of Velcade 3.5mg powder for solution for injection as a precaution. This was because the company had received five reports of visual particulates after product reconstitution in samples from two batches. Batches of Velcade other than those listed were not affected.

In Hong Kong, Velcade for Inj 3.5mg is registered by Johnson & Johnson (Hong Kong) Ltd. and is a prescription medicine. It is indicated for the treatment of multiple myeloma in patients who have received at least 1 prior therapy. The company confirmed that the above batches had not been imported into Hong Kong.

Withdrawal of propoxyphene-containing products

20 November 2010 - The European Medicines Agency (EMA) recommended to withdraw propoxyphene across the European Union (EU) in phases in 2009. The assessment by the U.S. FDA at that time concluded that the benefits of propoxyphene for pain relief at recommended dose outweighed the safety risk. In November, 2010, the FDA requested all manufacturers to voluntarily withdraw their propoxyphene-containing products from the U.S. market as the new clinical data received showed that propoxyphene put patients at risk of potentially serious or even fatal heart rhythm abnormalities. In view of these data and other information including new epidemiological data, FDA concluded that the risks of taking the medication outweigh the benefits. Following the above decision, Paladin Labs Inc.had also decided to voluntarily recall and withdraw all lots of Darvon-N (dextropropoxyphene, also known as propoxyphene) from the Canadian market and discontinue the sale of the product concerned.

After considering all the available information,

including the effects of propoxyphene on human cardiac electrophysiology at therapeutic dose range, the availability of alternative analgesic drugs in Hong Kong and regulatory actions taken by other lead regulatory agencies, at the meeting held on 29 December 2010, the Registration Committee of the Pharmacy and Poisons Board decided to deregister products containing propoxyphene in Hong Kong for public health protection, starting from 10 January 2011.

The DH issued letters to healthcare professionals on 22 November 2010 and 29 December 2010; and press statements on 20 & 25 November 2010 and 2 & 29 December 2010 about the updated safety information and deregistration of the drug. Members of the public are advised to stop using these products and consult healthcare providers if they are in doubt or unwell. Wholesalers concerned were requested to stop trading or distributing propoxyphene-containing products and recall them from shelves before or by January 10, 2011. Doctors and pharmacists were requested to stop prescribing or dispensing propoxyphene-containing products and return their stocks to the respective wholesalers.

Propoxyphene is an opioid analgesic for alleviating mild to moderate pain. Before the deregistration, propoxyphene was available as dextropropoxyphene and there were 21 registered products containing dextropropoxyphene in the local market. All dextropropoxyphene-containing products were only allowed to be sold at pharmacy under the supervision of pharmacist.

United Kingdom: Recall of ViraferonPeg 50 micrograms powder and solvent for solution for injection in pre-filled pen

30 November 2010 - Following the company–led recall of certain batches of 80, 100, 120 and 150 microgram presentations of ViraferonPeg on 29 October 2010 which was previously reported in Issue No. 12 of Drug News, Merck Sharp and Dohme Limited also recalled certain batches of ViraferonPeg 50 micrograms powder as a precaution. This was because a defect in glass stopper of the cartridge has been identified in a very small number of prefilled pens and sterility assurance could not be guaranteed in them. ViraferonPeg is indicated for treatment of patients with chronic hepatitis C.

In Hong Kong, the above product is registered as Peg-Intron by Schering-Plough Div. of SOL Limited. The concerned product had been supplied to public and private hospitals and private practitioners and stock replacement had already been completed.

The United States: Voluntary recall of certain over-the-counter children's and infants' liquid product

9 December 2010 - McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., in consultation with the U.S. FDA, had initiated a voluntary recall of certain over-the-counter (OTC) children's and infants' liquid products manufactured nationwide and internationally.

Item No.	Recalling Firm	Product Description	Public Reason for Recall
1.	Johnson & Johnson-Merck Consumer Pharmaceuti-cals, Co.	Mylanta and Alternagel Liquid Products	mislabeled - alcohol content not listed on front panel
2.	McNeil Consumer Healthcare, Div of McNeil-PPC, Inc.	Tylenol Cold Multi Symptom Daytime Liquid 8 oz Citrus Burst	mislabeled - alcohol content not listed on front panel
3.	McNeil Con-sumer Healthcare, Div of McNeil-PPC, Inc.	Rolaids Extra Strength Softchews, Cherry Flavor, 36 count container	uncharacteristic consistency - crystallized sugar
4.	McNeil Con-sumer Healthcare, Div of McNeil-PPC, Inc.	Jr Strength Motrin Caplets in 24 count packages	insufficient development during manufacturing

Item No.	Recalling Firm	Product Description	Public Reason for Recall
5.	McNeil Consumer Healthcare, Div of McNeil-PPC, Inc.	Children's Benadryl Allergy FastMelt Tablets Cherry Flavor in 18 count containers	insufficient development of manufacturing process
6.	McNeil Consumer Healthcare, Div of McNeil-PPC, Inc.	Tylenol 8 hour Caplets in 50 count bottles	off odor - musty/moldy
7.	Johnson & Johnson Merck, Ft Washington, PA	1) PEPCID Complete Tablet, 10 mg, 800 mg, 165 mg; 50 count bottles. 2) PEPCID AC Tablets, 10 mg, 90 Count Bottle.	defective Container: small number of bottles have been punctured at the bottom edge during the packaging process.
8.	Blacksmith Brands, Inc., Tarrytown, NY. Manufacturer: McNeil Consumer Healthcare, Div of McNeil-PPC, Inc., Fort Washington, PA.	1) PediaCare Children's Multi-Symptom Cold, Grape Flavor Liquid, 4 fl oz (118 mL) 2) PediaCare Children's Long-Acting Cough, Grape Flavor Liquid, 4 fl oz (118 mL) 3) PediaCare Children's Decongestant, Raspberry Flavor Liquid, 4 fl oz (118 mL) 4) PediaCare Children's Allergy & Cold, Grape Flavor Liquid, 4 fl oz (118 mL)	GMP deficiencies at manufacturing site.
9.	Johnson & Johnson Consumer Group of Companies, Inc., Skillman, NJ	Sterile Visine All Day Eye Itch Relief Opthalmic Solution Antihistamine Eye Drops ; 0.17oz (5 ml) bottle	failed pH specifications

Items 1 to 8 are not registered in Hong Kong. As for item 9, there are currently 3 Visine products registered in Hong Kong. They are Visine AC Eye Drops (HK-31030), Visine Eye Drops 0.05% (HK-30105) and Advanced Relief Visine Eye Drops (HK-43555). The sale of the former 2 products had already been discontinued for a few years while the sale of the latter one had never been launched in Hong Kong.

European Union: EMA initiated a review of the safety of somatropin-containing medicines

13 December 2010 - The EMA initiated a review of the safety of somatropin-containing medicines authorised centrally or by national procedures in the EU to reassess their benefit-risk balance. This review was initiated further to the information received from the French medicines agency on a long-term epidemiological study in patients treated with somatropin-containing medicines during childhood for growth hormone deficiency or short stature of unknown cause. The results suggested an increased risk of mortality with somatropin therapy compared to the general population. The risk appeared to be particularly increased when high doses were used (beyond doses as recommended in the Summary of Product Characteristics). However, it was found that the association could not be certain based on this observational study alone and further analyses would be needed to confirm the results.

In Hong Kong, there are 13 pharmaceutical products registered to contain somatropin and all of them are prescription medicines. Somatropin is a synthetic human growth hormone indicated for long-term treatment of children with pituitary growth failure due to inadequate production and secretion of growth hormone, and growth failure due to Turner's syndrome confirmed by chromosome analysis. The DH remains vigilant to any updates on EMA progress and actions from other health authorities.

Drug Recall

Recall of Elisone Cream 0.1% (HK-57340)

On 19 November 2010, Zenfields (H.K.) Limited (Zenfields), a licensed drug wholesaler, initiated a recall of all batches of Elisone Cream 0.1% (HK-57340) from the market because the product label on the aluminium tube showed an incorrect strength.

The recall was initiated after Zenfields found that the product label on the aluminium tube was incorrectly printed as "Each gm contains: Mometasone furoate 10mg" while the correct label should be "Each gm contains: Mometasone furoate 1mg". The external packing and package insert of the product were correctly labelled. Although the issue would not cause immediate safety, quality and efficacy concern, Zenfields opted for voluntary recall as a precautionary measure. After assessment, the DH endorsed Zenfields' decision and closely monitored the recall. Zenfields had set up a hotline for public enquiries.

Elisone Cream is a prescription medicine. It contains mometasone furoate which is a steroid indicated for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

Recall of Anlina Viginal Tablet (HK-43469)

On 10 December 2010, the DH instructed a licenced drug wholesaler, Deltapharm Limited, to recall its product Anlina Vaginal Tablet (HK-43469) from clients because the product was found to disintegrate slower than the acceptable level.

Investigation revealed that the drug wholesaler had imported a total of 1,056 boxes (100 tablets each) of the product (batch no. 0T59001) in July and August 2009 from Thailand. Through Suntol Medical Limited, another licensed drug wholesaler, the product was distributed to pharmacies and registered medical practitioners. DH had not received any reports of discomfort in patients using the medicine. Press statement was issued on 10 December 2010.

Anlina Vigina Tablet, a prescription medicine containing nystatin, chloramphenicol and diiodohydroxyquinoline, is used for the treatment of vaginal infection. The tablet can only be sold in pharmacies on doctor's prescription and under the supervision of pharmacist.

Deltapharm Limited had set up a hotline for public enquiries. DH closely monitored the recall. Healthcare professionals are urged to stop supplying the product to clients. Members of the public who have the product are advised to stop using it and seek advice from healthcare professionals if in doubt.

Drug Incidents

Two persons arrested for allegedly selling slimming products with undeclared and banned western drug ingredients

On 8 December 2010, the DH appealed to members of the public not to buy or consume unknown or doubtful slimming prdoucts from the internet as they might contain undeclared drug ingredients that are dangerous to health.

The appeal followed the arrest of two men aged 26 and 38 respectively in two separate joint operations by the Police and the DH for suspected sale of six slimming products which were found to contain undeclared and banned western drug ingredients. The six products were "Miaozi Qiantijiaonang 百邦妙姿纖體膠囊", "Leptin Slimup Fuel Coffee 美國美國立普婷・瘦の素三合一美體咖啡", "Leptin Coffee Weight Loss 美國立普婷 ·曲而美靈芝減肥咖啡", "Relacore South African Hoodia Capsule 美國立普婷・瘦の素天然花草塑身膠囊", "Rehuoshoushen II Xinzixilie Pilipeifang 惹火瘦身 II 新姿系列啤朵配方" and "Rehuoshoushen III Xinzixile Boluopeifang 惹火瘦身 III 新姿系列菠蘿配方". A number of suspected unregistered pharmaceutical products were also seized from the 38-year-old man at the time of the arrest.

The department previously obtained the six concerned products from internet auction websites during the department's surveillance operation. Laboratory tests confirmed that all six products contained sibutramine, and three of them also contained phenolphthalein.

Drug Incidents

Sibutramine was once a western medicine used as appetite suppressant. Since November 2010, sibutramine containing products have been banned because of the increased cardiovascular risk. Phenolphthalein was once used for treating constipation but has been banned since 2001 for its cancer-causing effect.

Weight control should be achieved through healthy diet and appropriate exercise. People should consult healthcare professionals before using any medication for weight control.

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 under the Ordinance before it can be sold in Hong Kong. Under the Pharmacy and Poisosn 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 are exhorted not to sell products of unknown or doubtful composition. 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 using 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: 2147 0457

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