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

Overseas - Recall of Invega Sustenna Injection

16 February 2011 - Drug manufacturer Johnson & Johnson Company recalled certain batches of Invega Sustenna Injection 234mg (or 150mg calculated as base of the active ingredient paliperidone) because cracks were found in some of the syringes pre-filled with Invega Sustenna Injection of the 234mg strength. The cracks might not be detectable by the user but could, theoretically, compromise the sterility of the syringe contents.

In Hong Kong, Invega Sustenna Injection 234mg (paliperidone) is a prescription medicine registered by Johnson & Johnson (Hong Kong) Ltd. It is an antipsychotic agent indicated for the treatment of schizophrenia in adults. The company has confirmed that the current recall does not affect Hong Kong because the product has never been marketed in Hong Kong.

China - Nimesulide might be associated with dealth in children

16 February 2011 – Recently, there are media reports in China and Hong Kong about the hazard related to the use of a non-steroidal anti-inflammatory drug, nimesulide, among children. It was reported that nimesulide might cause damage to central nervous system and liver, and even be associated with dealth cases. Currently, the product could be bought in retail shops in China without an authorized prescription.

In Hong Kong, there are 18 registered pharmaceutical products containing nimesulide. All are prescription medicines. Nimesulide is used to treat acute pain, osteoarthritis, and dysmenorrhoea. In 2007, the Registration Committee of the Pharmacy and Poisons Board adopted the recommendation of the European Medicines Agency (EMA) that the package insert of nimesulide should include the possible risk of liver damage and its use should be limited to a maximum of 15 days. Recently, at its meeting held on 11 May 2011, the Registration Committee of the Pharmacy and Poisons Board decided that the sales pack label and/or package insert of products containing nimesulide should include information that the product is contraindicated in children under 12 years of age.

Canada - Serotonin toxicity associated with the concomitant use of Methylene Blue Injectable and serotonin reuptake inhibitors

18 February 2011 - Health Canada informed the medical staff working in the hospital that cases of serotonin toxicity had been reported in patients with concomittant use of methylene blue injectable and drugs with serotonin reuptake inhibition properties e.g. selective serotonin reuptake inhibitors (SSRIs). SSRIs are prescription medicines used for the treatment of depression. The cases of serotonin toxicity (also known as serotonin syndrome) presented with agitation or diaphoresis or hypertonia accompanied with pyrexia (> 38° C), and tremor, hyperreflexia or clonus (spontaneous, inducible or ocular). Health Canada would be working with the market authorization holders of methylene blue injectable products to include the following points in the Canadian prescribing information for this agent:

1. Serotonin toxicity/serotonin syndrome has been reported when methylene blue was administered intravenously in patients also receiving other drugs with serotonin reuptake

inhibition properties. Several of these cases required admission to intensive care unit.

2. If drugs with serotonin reuptake inhibition properties are being taken, careful consideration needs to be given to stop them before administrating methylene blue injectable to allow a washout period equivalent to at least 4-5 half-lives.

In Hong Kong, Methylene Blue Injection is registered by Sino-Asia Pharmaceutical Supplies Ltd and used in the treatment of methemoglobinemia. Upon instruction of the Department of Health (DH), the company has updated the package insert in accordance with Canadian requirement. The DH issued letters and press statement to remind healthcare professionals and general public about this issue respectively on 18 February 2011.

US – Cautious uses of an asthma drug Terbutaline for preterm labour

18 February 2011 - The US Food and Drug Administration (FDA) warned against the use of terbutaline, by injection, infusion, or by mouth, for the prevention or prolonged (beyond 48-72 hours) treatment of preterm labour in pregnant women because of potential serious maternal heart problems and even death. In addition, the FDA required to include this warning on the drug labeling.

The decision was made based on the FDA's review of post-market safety reports and medical literature. In view of the reports of heart problems and even death associated with terbutaline use for obstetric indications and lack of evidence to support its safety and effectiveness in preventing preterm labour and improving infant outcomes, the FDA concluded that the risk of serious adverse events outweighed any potential benefit to pregnant patients for either prolonged use of terbutaline injection beyond 48-72 hours or use of oral terbutaline for prevention or treatment of preterm labour.

Terbutaline has smooth muscle relaxation action. Uses in preventing and treating narrowing of the airways (bronchospasm) associated with asthma, bronchitis, and emphysema are approved by the FDA. Its off-label obstetric indications include the treatment of preterm labour and uterine hyperstimulation as well as the prevention of recurrent preterm labour.

In Hong Kong, there are 38 registered pharmaceutical products containing terbutaline. Oral terbutaline is pharmacy only medicine and parenteral terbutaline is prescription medicine. The DH has not received any adverse event reports concerning the use of this drug in pregnant mothers. The DH issued letters and press statement to inform healthcare professionals and general public about this issue respectively on 18 February 2011. In view of the FDA's action, the issue was discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board held on 11 May 2011 and it was decided that the sales pack label and/or package insert of products containing terbutaline should include information about the contraindication and warnings against the use of terbutaline for preterm labour treatment.

US - Recall of Jantoven Warfarin Sodium Tablets 3mg due to mislabeled bottles containing higher dosage

18 February 2011 – The US FDA announced that Upsher-Smith Laboratories recalled one lot of Jantoven Warfarin Sodium Tablets 3 mg (Lot no.: #284081 with expiration date in September 2012) because bottles in this lot were found to contain tablets at a higher strength of 10mg. Warfarin Sodium is an anticoagulant used in the treatment and prophylaxis of thromboembolic disorders.

The two Jantoven tablets can be readily identified by colour - the 3mg tablet is tan and the 10mg tablet is white. In addition, the 3mg tablet is imprinted with the letters WRF, a line, and the number 3 below the line. The reverse side of the 3mg tablet carries the number 832. The 10mg tablet is imprinted with the letters WRF, a line, and the number 10 below the line. The reverse side of the 10mg tablet also carries the number 832.

In Hong Kong, there is no record of registration of Jantoven Warfarin Sodium USP Tablets, whether 3mg or 10mg. In view of the serious consequence of life threatening haemorrhage by substituting 10mg warfarin for 3mg, the DH issued press statement on 18 February 2011 and advised patients to seek advice from healthcare providers if in doubt.

EU - Restriction on the use of Zerit

19 February 2011 – The Committee for Medicinal Products for Human Use (CHMP) of the EMA completed a review of Zerit (stavudine), marketed by the Bristol-Myers Squibb Pharma EEIG in EU, and recommended to restrict its therapeutic indications in view of its side effects. The Committee recommended that, for both adults and children, the medicine should be used for as short a time as possible and only when there are no appropriate alternatives. Zerit is used in combination with other antiviral medicines to treat adults and children who are infected with human immunodeficiency virus.

In Hong Kong, there are 7 registered pharmaceutical products containing stavudine and all of them are prescription medicines. The DH issued letters to inform healthcare professionals about this recommendation of the CHMP on 21 February 2011. After consideration, the Registration Committee of the Pharmacy and Poisons Board decided, at its meeting held on 11 May 2011, to adopt CHMP's recommendation for the pharmaceutical products containing stavudine registered in Hong Kong and decided that the registration holders should revise the sales pack label and/or package insert accordingly.

EU - Restriction on the use of Tygacil

19 Feb 2011 – The CHMP recommended that the product information for Tygacil (tigecycline), marketed by the Wyeth Europa Ltd in EU, should be amended to ensure that the medicine is used appropriately, by making prescribers aware that the medicine had been associated with an increased mortality in clinical studies. The Committee recommended that the medicine should only be used in its approved therapeutic indications, namely in the treatment of complicated skin and soft tissue infections and complicated intra-abdominal infections, and only when other antibiotics are not suitable.

In Hong Kong, Tygacil (tigecycline) is a registered prescription medicine. The DH issued letters to inform healthcare professionals about this recommendation by the CHMP on 21 February 2011. After consideration, the Registration Committee of the Pharmacy and Poisons Board decided, at its meeting held on 11 May 2011, to adopt CHMP's recommendation for Tygacil registered in Hong Kong and that decided the registration holder should revise the sales pack label and/or package insert accordingly.

EU - Review of Buflomedil-containing medicines

19 February 2011 – The CHMP began looking at the high risk of cardiac and nervous toxicity, especially following accidental or voluntary overdose, in patients taking buflomedil-containing medicines for the treatment of symptoms of peripheral arterial occlusive disease. The review was initiated following the suspension of the marketing authorization of these medicines in France, based on the review of all available safety information. The CHMP would review all available data thoroughly, including published data, non-clinical and clinical data, post-marketing reports and pharmacoepidemiological studies, and would assess their impact on the balance of the risks and benefits of these medicines.

In Hong Kong, there is 1 registered pharmaceutical product containing buflomedil. Buflomedil is a vasodilator used in the treatment of cerebrovascular and peripheral vascular disorders. The DH remains vigilant to any new findings about buflomedil.

EU - Review of Pholcodine-containing medicines

19 February 2011 – The CHMP began looking at the potential link between the use of pholcodine-containing medicines and anaphylactic reactions in patients subsequently exposed to neuromuscular blocking agents (NMBA) used in anaesthesia. The review was initiated following the publication of studies suggesting that pholcodine induced immunologic stimulation in exposed individuals, and that in some Member States where pholcodine was no longer marketed, a decrease in reports of NMBA-related anaphylaxis had been observed. Pholcodine-containing medicines are used to treat cough in children and adults. The CHMP would review all available data thoroughly, including published data, non-clinical and clinical data, post-marketing reports and pharmacoepidemiological studies, and would assess their impact on the balance of risks and benefits of these medicines.

In Hong Kong, there are 39 registered

pharmaceutical products containing pholcodine and all must be sold under the supervision of pharmacist. The DH remains vigilant to any new findings about pholcodine.

US – Updates on the antipsychotic drug labels regarding their uses during pregnancy and risks of abnormal muscle movements and withdrawal symptoms in newborns

23 February 2011 – The US FDA informed healthcare professionals that the Pregnancy section of drug labels for the entire class of antipsychotic drugs had been updated to include consistent information about the potential risk for abnormal muscle movements (extrapyramidal signs) and withdrawal symptoms in newborns whose mothers were treated with these drugs during the third trimester of pregnancy. Healthcare professionals were advised to be aware of the effects of antipsychotic drugs on newborns when they were used during pregnancy. Patients were advised not to stop taking these drugs if they became pregnant without consulting their healthcare professional, as abruptly stopping antipsychotic drugs could cause significant complications for treatment.

In Hong Kong, there are 229 registered pharmaceutical products containing the active ingredients as listed on the website of the FDA. All of them are prescription medicines. In view of the FDA's action, the issue was discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board held on 11 May 2011. It was decided that the sales packs or package insert of these products should include information about the potential risk of abnormal muscle movements (extrapyramidal signs) and withdrawal symptoms in newborns whose mothers were treated with these drugs during the third trimester of pregnancy.

Australia - Rotavirus vaccination and risk of intussusception

28 February 2011 - The Therapeutic Goods Administration (TGA), Australia, had undertaken an investigation of a possible association between the use of the rotavirus vaccines, namely Rotarix (GSK) and RotaTeq (Merck/CSL), and the occurrence of a rare form of bowel obstruction known as intussusception (IS). Intussusception is a condition caused by the telescoping of one segment of the bowel into another. This interim analysis provided evidence that both vaccines were likely to be associated with an increase in risk of IS in the 7 days following the first dose of both Rotarix and RotaTeq. Despite the identification of a small increase in risk of IS following the first dose of rotavirus vaccination, the TGA considered that their overall risk benefit balance remains positive. Both the World Health Organization and the Australian Technical Advisory Group on Immunisation had recommended the continued use of rotavirus vaccine for infants. The Product Information documents for both vaccines would be amended to reflect these findings.

4 March 2011 –The US FDA issued approval for Rotarix to update the package insert and patient package insert to include "history of intussusception" as a contraindication to vaccination.

In Hong Kong, Rotarix Vaccine Oral Suspension is registered by Glaxosmithkline Limited, and RotaTeq Oral Vaccine is registered by Merck Sharp & Dohme (Asia) Limited. Both Rotarix and RotaTeq are prescription pharmaceutical products. The DH sent letters to inform healthcare professionals about the updated safety information on 28 February 2011. The issue was discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board held on 11 May 2011. It was decided that the package inserts of both products should be amended according to the Australian package inserts to include information relating to intussusception.

US – Updates on the safety review on the possible increased risk of heart attack associated with Abacavir

2 March 2011 – The US FDA updated the public about an ongoing safety review of abacavir and a possible increased risk of heart attack. There had been conflicting information on the potential increased risk of heart attack with abacavir treatment. An increased risk of heart attack (myocardial infarction or MI) with the use of abacavir had been seen in several observational studies and one randomized controlled trial but was not observed in other randomized controlled trials and the safety database maintained by the drug manufacturer.

The FDA conducted a meta-analysis of 26 randomized clinical trials to evaluate abacavir. This meta-analysis did not show an increased risk of MI associated with the use of abacavir. The FDA would continue to inform the public when any new safety information became available.

In Hong Kong, 4 registered pharmaceutical products, namely Ziagen Tab, Ziagen oral Solution, Trizivir Tab and Kivexa Tab, contain abacavir. All these products are registered by GlaxoSmithKline Ltd and are prescription medicines. Abacavir is used in the treatment of human immunodeficiency virus infection and acquired immunodeficiency syndrome. The DH remains vigilant to any new safety information of abacavir.

US - Removal of unapproved drugs from US market

3 March 2011 – The US FDA took action against companies that manufacture, distribute, or market certain unapproved prescription oral cough, cold, and allergy products. The affected products could not be legally marketed in the United States and their safety, effectiveness and quality had not been evaluated by the FDA. People might be at greater risk when using these products than when using FDA-approved prescription drugs or drugs that were appropriately marketed over-the-counter. Companies that had previously listed products subject to this action with FDA were expected to stop manufacturing them within 90 days and stop shipping the products within 180 days. Companies that had not previously listed products subject to this action with FDA were expected to stop manufacturing and shipping their products immediately.

In Hong Kong, one of the products as listed by the FDA, namely Deconamine SR Cap (HK-41507), is registered by a local company called the International Medical Co. Ltd. The company has confirmed that the product has been discontinued for about 2 years and it is no longer marketed in Hong Kong.

US - Low magnesium levels associated with long-term use of Proton Pump Inhibitor drugs

3 March 2011 – The US FDA informed the public that prescription proton pump inhibitor (PPI) drugs might cause low serum magnesium levels (hypomagnesemia) if taken for prolonged periods of time, in most cases longer than one year. In approximately one-quarter of the cases reviewed, magnesium supplementation alone did not improve low serum magnesium levels and required the discontinuation of the PPI drugs. Healthcare professionals were advised to check serum magnesium levels before initiating prescription PPI treatment and check the levels periodically thereafter for patients expected to be on these drugs for long periods of time, as well as patients who take PPIs with medications such as digoxin, diuretics or drugs that may cause hypomagnesemia. Information about the potential risk of hypomagnesemia with the use of PPIs would be added to the warnings and precautions sections of the labels for all prescription PPIs.

PPI drugs work by reducing the amount of acid in the stomach and are used to treat conditions such as gastroesophageal reflux, stomach and small intestine ulcers, and inflammation of the esophagus.

In Hong Kong, there are 140 proton pump inhibitor drugs registered. The ingredients include esomeprazole, lansoprazole, omeprazole, pantoprazole and rabeprazole. All these products are prescription medicines except the products containing omeprazole. In view of the FDA's action, the DH issued letters and press statement to inform healthcare professionals and general public about the new safety information respectively on 3 March 2011. The issue was discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board on 11 May 2011. It was decided that the sales pack label and/or package insert of all PPI products should include information about the potential risk of low serum magnesium levels as endorsed by the FDA.

US - Risk of oral birth defects in babies born to mothers taking topiramate

5 March 2011 – The US FDA informed the public of new human data which showed an increased risk for the development of cleft lip and/or cleft palate (oral clefts) in infants born to women treated with topiramate (Topamax and generic products) during pregnancy. Topiramate was approved to treat certain types of seizures and prevent migraine headaches. In response, the FDA would give a

stronger warning in the prescribing information (labeling) and patient medication guide of topiramate. The pregnancy category would be changed to Pregnancy Category D because there was positive evidence of human fetal risk based on human data, but the potential benefits of the drug in pregnant women might outweigh the risks in certain situations. Healthcare professionals were advised to warn patients of childbearing age about the potential hazard to the fetus when topiramate was used during pregnancy before prescribing topiramate.

In Hong Kong, there are 15 registered pharmaceutical products containing topiramate. All of them are prescription medicines. The DH issued letters to inform healthcare professionals about this issue on 7 March 2011. In light of the new information, the issue was discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board held on 11 May 2011. It was decided that the sales pack label and/or package insert of products containing topiramate should include warning relating to the potential hazard of the products to the fetus when the products are taken during pregnancy.

China - Safety concern of Orlistat

5 March 2011 – The State Food and Drug Administration (SFDA) of China advised healthcare providers, pharmaceutical manufacturers and the public to be aware of the safety of a slimming product, orlistat. The abovementioned advice was issued after taking into consideration of various factors including the warning announced by the US FDA in May 2010 related to the potential severe but rare liver injury in patients taking orlistat, and the case reports of adverse drug reaction associated with the drug from the database maintained by the National Centre for ADR Monitoring of China as at 31 December 2010. The SFDA instructed the pharmaceutical manufacturers to include the updated warning on the product package. The SFDA also reminded consumers to read and follow the product package information while consuming the drug for weight control. Healthcare providers were also reminded to educate their patients on proper use of the drug and report any adverse drug reaction associated with the drug.

In Hong Kong, there are 3 registered pharmaceutical products containing orlistat, namely Xenical, Zerocal and Alli. In response to the safety alert of orlistat issued by the US FDA in May 2010, the DH issued a press release and letters to healthcare professionals reminding them to be vigilant to this safety information on 27 and 28 May 2010 and had been reported previously in Issue No. 8 of Drug News. At the meeting held on 5 October 2010, the Registration Committee of the Pharmacy and Poisons Board decided that the package inserts of all orlistat-containing products should include the warning of the potential risk of severe liver injury.

Suspension of two paediatric vaccines in Japan

6 March 2011 – The Japan's Ministry of Health, Labour and Welfare (MHLW) decided to suspend two types of publicly subsidised childhood vaccines, Prevnar produced by Pfizer and Act-HIB produced by Sanofi-Aventis, and conduct investigation for their association with 4 Japanese children's death. Prevnar and Act-HIB are vaccines for the protection against pneumococcal disease and Haemophilus influenzae type B (Hib) meningitis respectively. An expert panel convened by Japan's MHLW on 8 March 2011 found no evidence of a causal relationship between the deaths of the two vaccines, but did call for further studies. After considering the discussion of its advisory committee, MHLW has resumed the use of the two vaccines in Japan since April 2011.

In Hong Kong, pneumococcal vaccination has been included in the childhood immunisation programme since 2009, whereas Hib vaccination has not. Pfizer Corporation Hong Kong Ltd (Pfizer) has registered two pneumococcal vaccines, respectively under the brand names of Prevenar which targets at 7 serotypes and Prevenar 13 which targets up to 13 serotypes. They are prescription pharmaceutical products.

Prevenar has been used by both local public and private healthcare providers, including the DH, since the launch of the pneumococcal vaccination programme in 2009. However, except for the one off Pneumococcal Vaccination Catch-up Programme for children above two years of age which has finished by the end of March 2011, the DH has replaced Prevenar with GlaxoSmithKline Ltd's Synflorix since October 2010 according to tender award result.

The DH has liaised with Pfizer to collect further

information on the Japanese situation and clarify the local stock situation of its two pneumococcal vaccines and their origins. Meanwhile, the DH has no record of untoward event report associated with Prevenar and Act-HIB. The DH issued letters to healthcare professionals to remind them about this issue on 7 March 2011. They were advised to report any adverse events caused by the two vaccines to the DH. The DH also issued press statements to inform the public about this matter on 6 and 9 March 2011. Patients receiving the two vaccines were advised to contact their healthcare providers if they were unsure or felt unwell. The DH remains vigilant to any updates about this matter.

US - Serious health problems seen in premature babies given Kaletra oral solution

9 March 2011 – The US FDA informed healthcare professionals of serious health problems that had been reported in premature babies receiving Kaletra (lopinavir/ritonavir) oral solution. Kaletra oral solution contains alcohol and propylene glycol. Premature babies may be at a higher health risk because their abilities to eliminate propylene glycol are lower which can lead to adverse events such as serious heart, kidney, or breathing problems.

In fact, a safe and effective dose for babies less than 14 days of age (whether born premature or full term) had not been established. In view of the potential severe or even fatal consequences of using Kaletra oral solution in babies immediately after birth, the label was being revised to include a new warning. The use of Kaletra oral solution should be avoided in premature babies until 14 days after their due date, or in full-term babies younger than 14 days of age unless a healthcare professional believed that the benefit of using Kaletra oral solution to treat human immunodeficiency virus infection immediately after birth outweighs the potential risks. In such cases, the US FDA strongly recommended monitoring for increases in serum osmolality, serum creatinine, and other signs of toxicity.

In Hong Kong, Kaletra Oral Solution is registered by Abbot Lab Ltd and it is a prescription medicine. It is indicated for patients over 6 months of age in combination with other antiretroviral agents for the treatment of human immunodeficiency virus infection. In view of the FDA's action, DH issued letters to inform healthcare professionals about the new safety information on 9 March 2011.

UK - Discontinued production of Pulmicort CFC–free Inhaler 100/200 micrograms and NebuChamber Spacer (Budesonide)

10 March 2011 - AstraZeneca UK Ltd discontinued production of the above products with immediate effect due to complex manufacturing issues. The NebuChamber spacer was only licensed for use with these two inhaler presentations. This issue did not apply to any other AstraZeneca inhalers or components which would remain in normal supply and use. Patients were advised to continue using PULMICORT CFC-free Inhaler 100 and 200 micrograms until their current supply is finished and then change to an appropriate alternative inhaled corticosteroid treatment for their specific medical condition.

In Hong Kong, Pulmicort Inhaler is registered by AstraZeneca Hong Kong Ltd. and it is a prescription medicine used for the treatment of asthma. The company had informed healthcare professionals about its decision to discontinue the production of the above products. Patients are advised to consult their doctors for alternative treatment.

Recall of Act-HIB Vaccine in Japan

11 March 2011 - Sanofi-Aventis Hong Kong Ltd. informed the DH that there was a voluntary recall of 13 lots of "ActHIB" Vaccine (Haemophilus influenza type b conjugate vaccine) in Japan. This was due to the report of a rare imperfection in two syringes. This action was not related to the recent suspension of vaccination in Japan. The affected lots were specific for Japan and not distributed in Hong Hong. In Japan, ActHIB were manufactured by Sanofi Pasteur and distributed by Daiichi Sankyo.

Sanofi Pasteur was notified by 2 Japanese health-care providers on 8 March 2011 that 2 syringes of diluent used to reconstitute its Hib vaccine were potentially faulty. These 2 doses of vaccine were not administered and were returned to Sanofi Pasteur for investigation. The preliminary investigation showed that these 2 syringes from the selected lots contained foreign matter remaining

from the syringe manufacturing process. Sterility of the diluent was not compromised and there was no reason to believe there was any safety concern.

In Hong Kong, Sanofi-Aventis' Act-HIB vaccine is a registered and prescription pharmaceutical product. It is not a component of childhood immunisation programme.

Drug Recall

Recall of Tridewel Cream (HK-47225)

On 25 February 2011, Bright Future Pharmaceuticals Factory (Bright Future), a licensed drug manufacturer, initiated a recall of Tridewel Cream (HK-47225, batch no. 1009016 and 1009017) from the market because of the improper sealing of tamper-proof lid, which might lead to slight discoloration of the cream. Although there is no immediate safety, quality and efficacy concern with the use of the product, Bright Future opted for voluntary recall as a precautionary measure. After assessment, the Department of Health (DH) endorsed Bright Future's decision and closely monitored the recall.

Tridewel Cream is a prescription medicine registered by Bright Future. It is used for the treatment of skin infection and inflammation.

Recall of Fluarix vaccine (HK-43003), Infanrix-IPV/Hib vaccine (HK-47367) and Synflorix vaccine (HK-58098)

On 4 March 2011, the DH ordered GlaxoSmithKline Ltd. (GSK), a licensed drug company, to recall 144 units of three of its vaccines from the market because of suspected quality defect.

The products recalled were 115 units of Fluarix vaccine (HK-43003, batch no. AFLUA510AB) from 8 private practitioners and 2 units from Hong Kong Baptist Hospital (HKBH); 20 units of Infanrix -IPV/Hib vaccine (HK-47367, batch no. A20CA598A) from Hong Kong Sanatorium and Hospital Ltd (HKSH); and 2 units of Synflorix vaccine (HK-58098; batch no. ASPNA023DC) from DH's Anne Black Maternal and Child Health Centre (MCHC) and 5 units from Ap Lei Chau MCHC.

GSK reported to the DH earlier this January that a total of 260 units of the above 3 products were collected from a private practitioner via its distributor, Zuellig Pharma Ltd (Zuellig), a licensed wholesaler, because of possible breakage in the cold chain while the items were in the practitioner's custody. The vaccines were being quarantined in Zuellig's store, pending assessment by GSK before disposal. However, they were mistakenly released in February because of staff oversight.

Fluarix is a vaccine for use in adults and children above 6 months for the prevention against influenza. Infanrix-IPV/Hib is for immunisation against diphtheria, tetanus, pertussis; poliomyelitis and Haemophilus influenzae type B in clients aged 2 months. Synflorix is a vaccine against pneumococcal disease. All of them are prescription pharmaceutical products. Investigation into the records of GSK and Zuellig showed that the suspicious vaccines were released by GSK and distributed by Zuellig to DH's Anne Black and Ap Lei Chau MCHCs, 8 private practitioners' clinics and 2 private hospitals, HKSH and HKBH, between February 16 and 23. Further tracing revealed that 116 units had already been administered, comprising 38 units of Synflorix to clients of Anne Black MCHC between February 23 and 24; 73 units of Fluarix to clients of the 8 private practitioners after February 16; and 5 other units of Fluarix to clients of HKBH after February 16. There was no record of Infantrix-IPV/Hib ever having been given out by HKSH, nor has DH received any report of related adverse event thus far.

Inappropriate storage temperature could reduce or even destroy the effectiveness of vaccines, resulting in inadequate or no immune response. According to most international authorities, including the World Health Organization, re-vaccination would likely be required. GSK had set up a hotline for enquiries. DH closely monitored the recall besides investigating further into the modes of product distribution in both GSK and Zuellig.

Meanwhile, DH's Anne Black MCHC called back its involved clients for assessment besides providing reassurance to those not affected. A designated telephone line had been set up by the DH

for related enquiries. The DH urged healthcare providers in reception of the affected batches to stop supplying the products further and get in touch with GSK. Patients were also advised to discuss with healthcare providers their need for re-vaccination for adequate protection, although safety is unlikely a concern in this incident.

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