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

US Food and Drug Administration reported chondrolysis in continuously infused local anesthetics

13 November 2009 - US Food and Drug Administration (FDA) notified healthcare professionals of 35 reports of chondrolysis (necrosis and destruction of cartilage) in patients given continuous intra-articular infusions of local anesthetics (marketed as bupivacaine, chlorprocaine, lidocaine, mepivacaine, procaine and ropivacaine) with elastomeric infusion devices to control post-surgical pain. The local anesthetics (with and without epinephrine) were infused for extended periods of time (48 to 72 hours) directly into the intra-articular space using an elastomeric pump. Joint pain, stiffness, and loss of motion were reported as early as the second month after receiving the infusion. In more than half of these reports, the patients required additional surgery, including arthroscopy or arthroplasty (joint replacement).

Local anesthetics are approved as injections for the production of local or regional anesthesia or analgesia. The approved drug labels for local anesthetics do not include an indication for continuous intra-articular postoperative infusions or use of infusion devices, such as elastomeric pumps.

Likewise, in Hong Kong, local anesthetics are approved as injections for local or regional anesthesia or analgesia and they are not approved as intra-articular infusions.

Foreign particle contamination of several Genzyme products which may lead to serious adverse events announced by the US Food and Drug Administration

13 November 2009 - US FDA warned healthcare professionals about the potential for foreign particle contamination of several products manufactured by Genzyme Corporation that are used to treat rare, serious, and life-threatening diseases. The foreign particles, believed to be found in less than 1% of products, included stainless steel fragments, non-latex rubber from the vial stopper, and fiber-like material from the manufacturing process. This problem affected Cerezyme, Fabrazyme, Myozyme, Thyrogen and Aldurazyme products with all lots which have the prefix "A" (e.g., Lot A12345).

Considered that the potential for serious adverse events, the likelihood that the recommendations would significantly reduce the risk of administration of contaminated products, and the lack of FDA-approved therapeutic alternatives for these products, the FDA allowed these products to continue to be marketed. The FDA is still investigating the nature of the contamination and seeking immediate implementation of corrective actions to mitigate the situation.

In Hong Kong, the lots of Cerezyme and Thyrogen which have the prefix "A" are available in HK. Department of Health has issued press release and informed healthcare professionals about the safety alert and the importer, Genzyme Asia Limited, has issued a “Dear Healthcare Professional” letter informing healthcare professionals how to reduce the risk of administering a contaminated product.

European Medicines Agency made recommendations to minimise risk of nephrogenic systemic fibrosis with gadolinium-containing contrast agents

20 November 2009 - The European Medicines Agency (EMEA) had adopted a set of recommendations aimed at minimising the risk of nephrogenic systemic fibrosis (NSF) with gadolinium-containing contrast agents in patients at

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risk of developing the condition. Gadolinium-containing contrast agents are used in patients undergoing magnetic resonance imaging or magnetic resonance angiograph scans. NSF is a rare, serious and sometimes life-threatening condition that is characterized by formation of connective tissues in the skin, joints, muscles and internal organs, in patients with severe kidney problems.

EMEA classified gadolinium-containing contrast agent into three categories of risk (high-, medium-, and low-risk groups) depending on the risk of developing NSF. For high-risk agents (gadoversetamide, gadodiamide and gadopentetic acid), the products are contraindicated in patients with severe kidney problems, liver transplant and in newborn babies up to four weeks of age. For medium-risk agents (gadofosveset, gadoxetic acid and gadobenic acid) and low-risk agents (gadoteric acid, gadoteridol and gadobutrol), new warnings concerning their use in patients with severe kidney problems and liver transplant should be added in the prescribing information.

In Hong Kong, the current package inserts of the available gadolinium-containing contrast agents have included precautions in patients with severe kidney problems in response to similar news reported worldwide in 2007. The registration holders will further update the package inserts once EMEA has finalized its version.

US Food and Drug Administration made a reminder about increased risk of neural tube defects and other major birth defects in babies exposed to valproate sodium and related products during pregnancy

3 December 2009 - US FDA reminded healthcare professionals about the increased risk of neural tube defects and other major birth defects, such as craniofacial defects and cardiovascular malformations, in babies exposed to valproate sodium and related products (valproic acid and divalproex sodium) during pregnancy. Women of childbearing potential should only use valproate if it is essential to manage their medical condition. The FDA is still working with the manufacturers of these products to address labeling changes.

In Hong Kong, the Registration Committee had decided during its meeting in early December 2009 that the registration holders of valproate sodium and related products should revise the product inserts or labels to include the above warnings.

Drug Incident

Warning about Slimming Products

Warning about slimming product "Xi Zhi Su" with undeclared drug ingredients

On 12 November 2009, the Department of Health called on people not to buy or use a slimming product labelled as "Xi Zhi Su 吸脂素", which was found to have contained undeclared western drug ingredients which may cause serious side effects.

The appeal was made after the investigation into an incidental finding of phenolphthalein and sibutramine in the product. Laboratory tests on the product sample showed the presence of the above two undeclared western drug ingredients.

Warning about slimming product "Show Shen Jiao Guan – Ti Nei Yun Dong Wan " with undeclared drug ingredients

On 13 November 2009, the Department of Health urged members of the public not to buy or consume a slimming product labelled "Shou Shen Jiao Guan – Ti Nei Yun Dong Wan 瘦身教館 – 體內運動丸", which was found to have contained undeclared western medicine that may cause serious side effects.

A sample of the product was obtained from an internet auction website during a recent surveillance operation. Laboratory tests on the product showed the presence of undeclared western drugs, sibutramine and phenolphthalein.

On 19 November 2009, the Department of Health conducted a follow-up joint operation with the police and resulted in the arrest of a 27-year-old female internet seller for selling the above slimming product "Shou Shen Jiao Guan – Ti Nei Yun Dong Wan ". Six other slimming products, which were suspected to contain unknown western medicines,

were also seized during the operation.

On 23 November 2009, the Department of Health urged members of the public not to buy or consume the above six slimming products as they were also found to have contained undeclared western medicines, sibutramine and phenolphthalein, which may cause serious side effects. The products were named "瘦身教館 – 體內運動丸(減全身肥胖)", "瘦身教館 – 體內運動丸 (減下半身)", "Seven Slim 7 色瘦(青春少女型), "Seven Slim 7 色瘦(結實型)", "Seven Slim 7 色瘦(鬆弛型)" and "Seven Slim 7 色瘦(貴夫人型)". The investigation revealed that the products were obtained from a Mainland website and sent to Hong Kong by post.

Public urged not to take slimming product "Pai You Guo" with undeclared drug ingredients

On 16 November 2009, the Department of Health urged the public not to buy or consume the slimming product called "Pai You Guo" which was found sold via internet either in a box of 30 capsules or a bag of 10g powder as it was found to have contained undeclared western drug ingredients which may cause serious side effects.

The US Food and Drug Administration (FDA) informed GMP Herbal Products, Inc. in USA that Pai You Guo, a weight control dietary supplement sold and marketed by the firm was found to have contained undeclared drug ingredients. FDA laboratory tests on the product samples showed the presence of undeclared western drugs, sibutramine and phenolphthalein.

Warning about slimming product "Sliming Beauty" with undeclared drug ingredients

On 24 November 2009, the Department of Health urged members of the public not to buy or consume a slimming product labelled as "Sliming Beauty" as it was found to have contained undeclared western medicines which may cause serious side effects.

A sample of product was obtained from an internet auction website during a recent surveillance operation. Laboratory tests on the product showed the presence of sibutramine and phenolphthalein.

On 16 December 2009, the Department of Health conducted a follow-up joint operation with the police and resulted in the arrest of a 27-year-old male internet seller for selling the above slimming product. The investigation revealed that the product was obtained from a Mainland website and sent to Hong Kong by post.

Public urged not to consume slimming product "Ten Day Slim" with undeclared drug ingredients

On 25 November 2009, the Department of Health urged members of the public not to buy or consume a slimming product labelled as "Ten Day Slim 十日瘦" as it was found to have contained undeclared western medicines which may cause serious side effects.

The appeal was made following the arrest of a man and a woman for selling a slimming product with undeclared western drug ingredients during a joint operation with the police. Laboratory tests on the product showed the presence of sibutramine and two analogues of sibutramine.

The investigation revealed that the product concerned was bought from the Mainaln d and sent to Hong Kong by post. It was then put up on a local internet auction site for sale.

Public urged not to consume slimming product "Qingzhi Santian Shou" with undeclared drug ingredients

On 10 December 2009, the Department of Health urged members of the public not to buy or consume a slimming product called "Qingzhi Santian Shou 清脂三天瘦" in capsules as it was found to have contained undeclared western medicines which may cause serious side effects.

A sample of the product was obtained from an internet auction website during a recent surveillance operation. The appeal was made after laboratory tests on the product showed the presence of sibutramine and its analogue.

Drug Incident

Public urged not to consume slimming products "Comecoo" and "Zhongcaoyao – Jiankangjianfei" with undeclared drug ingredients

On 11 December 2009, the Department of Health urged people not to buy or consume two slimming products called "Comecoo 康柯美 – 完美自我" and "Zhongcaoyao – Jiankangjianfei 中草藥 – 健康減肥軟胶囊" as they were found to have contained undeclared western medicines which may cause serious side effects.

Samples of the product were obtained from an internet auction website during a recent surveillance operation. The appeal was made after laboratory tests on the products showed the presence of sibutramine, phenolphthalein and two analogues of sibutramine.

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 has been banned for its cancer-causing effect.

The Department of Health exhorted members of the public not to sell or resell products of unknown or doubtful composition. Public should also not buy products with unknown ingredients as their safety and quality are doubtful.

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

Warning about Other Products

Public urged not to take Neovidan with undeclared western drug ingredients

On 12 November 2009, the Department of Health reminded members of the public not to buy or consume a product called "Neovidan 德國漢堡療濕痛膠囊" which was found to have contained undeclared western drug ingredients which may cause serious side effects.

The appeal was made following an investigation into a case involving a 79-year-old woman who had taken Neovidan, allegedly manufactured by K ENNEN A.G. in Hamburg, W. Germany. The woman showed symptoms of facial puffiness, proximal muscle weakness, lower limb swelling and thin skin after consuming the drug.

Neovidan was earlier found to have contained western drug ingredients including prednisolone and mefenamic acid. Prednisolone is a steroid. Taking prednisolone for a long time can cause side effects such as moon face (round face), high blood pressure, high blood sugar and peptic ulcer. Mefenamic acid is a non-steroidal anti-inflammatory drug. The known side effects include gastro-intestinal discomfort, nausea, stomach pain and bleeding. Products containing prednisolone and/or mefenamic acid can be sold only on a doctor's prescription and dispensed under the supervision of a pharmacist.

People who had taken Neovidan are advised to seek medical advice before stopping the medication to avoid the adverse effects of sudden withdrawal of medication.

Public urged not to consume product "特效風濕骨痛靈" adulterated with undeclared western medicine

On 20 November 2009, the Department of Health called on members of the public not to buy or use a product for joint pain called "特效風濕骨痛靈", which was found to have been adulterated with an undeclared western medicine, dexamethasone, that may cause serious side effects.

The appeal was made after the investigation into an incidental finding of dexamethasone in the product. Laboratory tests on the product showed the presence

of dexamethasone, a steroidal anti-inflammatory drug used for suppression of inflammation, allergic disorders, and treatment of joint pain. Taking dexamethasone for a long time can cause side effects including moon face, central obesity, hypertension, high blood sugar and peptic ulcer. In July 2009, the Department had cautioned against a product with the same name "特效風濕骨痛靈" as it was found to have contained undeclared western medicine ingredient, indomethacin. Products containing dexamethasone and/or indomethacin can be sold only on a doctor's prescription and dispensed under the supervision of a pharmacist.

Public urged not to consume virility product "2H&2D" with undeclared drug ingredients

On 9 December 2009, the Department of Health appealed to people not to buy or use a product named "2H&2D" for managing sexual dysfunction as it was found to have contained undeclared western drug ingredients which may cause serious side effects.

A sample of the product was obtained from a retailer during a recent surveillance operation. Laboratory tests on the product showed the presence of undeclared western drug ingredient, tadalafil, which is usually used for treating male sexual dysfunction. Its side effects include low blood pressure, headache, vomiting, dizziness, and transient visual disturbances. It may also interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure of patients to dangerous levels. Products containing tadalafil can be sold only on a doctor's prescription and dispensed under the supervision of a pharmacist. The distributor, Man Shing International (HK) Ltd., was instructed to immediately recall the product from the market.

Recall of "Ditang Element" with western drug ingredient

On 15 December 2009, HK SZYY Pharmaceutical Holding Ltd. was instructed to recall a product, "Ditang Element 敵糖素". The product was a herbal product labeled and found containing a western drug ingredient, Vitamin C. The company has set up a hotline (Tel.: 2244 6109) to answer enquiries.

Based on the available information, there was no immediate safety concern with the use of the product.

All of the aforementioned products were not registered pharmaceutical products 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 and they should see doctors if they feel unwell after taking the products. They should destroy and dispose of the aforementioned products 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.

Drug Recall

The following recalls have been initiated:

Product name(s) (HK registration no.):	**1. Ca-C 1000 Sandoz Effervescent Tablets (Lemon) 30's (HK-06449)** **2. Ca-C 1000 Sandoz Effervescent Tablets (Orange) 30's (HK-01600)**	**Seven Seas Joint Care Extra High Strength capsule 60's (HK-56458)**	**Arthrostrong sachet 28's (HK-58089)**
Batch number:	R9002, R9003 and R9005 (Lemon) R9003, R9004 and R9005 (Orange)	381265, 381894, 382234, 382365 and 390138	5847
Recall initiate on:	17.11.2009	14.12.2009	14.12.2009
Reason(s) for recall:	Use of unapproved additional label on the package of the product	Use of unapproved sales package	Use of unapproved additional label on the package of the product.
Remarks:	Based on the available information, there is no immediate safety, quality and efficacy concern with the use of the products.	Based on the available information, there is no immediate safety, quality and efficacy concern with the use of the product.	Based on the available information, there is no immediate safety, quality and efficacy concern with the use of the products.
Importer:	Novartis Pharmaceuticals (H. K.) Limited	Merck Pharmaceutical (H. K.) Limited	Lakon International Limited
Hotline of importer:	2839 4320	2170 7732	2148 1662

For more information about the recalls,
please visit the website of Pharmaceutical Service, Department of Health
http://www.psdh.gov.hk