PHARMACY BULLETIN

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Updates on Product Recall : Atorvastatin & Methylprednisolone Acetate

On 9th November 2012, Ranbaxy Pharmaceuticals Inc., a major maker of generic Lipitor has voluntarily issued a massive recall of 41 lots of Atorvastatin, a cholesterol lowering drug from the US market. The recall is in relation to its 10mg, 20mg and 40mg dosage strengths, pack in 90's and 500's bottles, and only with respect to certain selected lot numbers. The recall does not affect or relate to the 80mg strength or any other Ranbaxy Product in the market.

The recall is being conducted in the U.S. at the retail level for selected batches that may contain a foreign substance (small glass particles approximately less than 1mm in size). Ranbaxy is proactively recalling the drug product lots out of cautionary actions. No injuries so far have been reported from the impurities found in the drug. This recall is being conducted with the full knowledge of the U.S. FDA.

Ranbaxy, an Indian firm, is owned by Japan's Daiichi Sankyo Co. According to *The Wall Street Journal*, Ranbaxy's generic Lipitor makes up 44% of the U.S. market for atorvastatin, including generic and name-brand products. FDA spokeswoman Sarah Clark-Lynn stated in her email that the FDA is working with other atorvastatin makers to address any potential shortage as a result of the ongoing recall. A list of the recalled products, including lot and NDC numbers, is posted on the Ranbaxy web site.

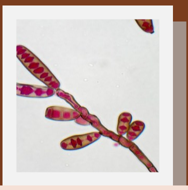
In another shocking news outbreak, on 4th October 2012, the Massachusetts Department of Public Health issued a recall of all NECC medications, advising hospitals and clinics to remove and segregate all lots from their stock inventory. NECC also announced on that day they were suspending all of their operations and voluntarily surrendered their licenses to the Massachusetts Department of Health and Human Services. This is due to the fungal meningitis outbreak in 19 states of USA, with state of Tennenessee had the highest cases reported. This is due to tainted batches of contaminated preservative-free methylprednisolone acetate (MPA) used in spinal injections.

Further investigations by the Center for Disease Control and Prevention (CDC), state and local health departments, as well as FDA traced and linked the outbreak to fungal contamination in 3 lots of medication used for epidural steroid injection produced by NECC. The investigation also include other infections from injections in a peripheral joint, such as a knee, shoulder, or ankle. Patients who received injections in peripheral joints only are not believed to be at risk for meningitis, but they could be at risk for joint and other infections.

Initially, the main suspect was the fungus Aspergillus, however CDC and FDA have confirmed the presence of a fungus known as *Exserohilum rostratum* in unopened medication vials of preservative-free MPA from 2 of 3 implicated lots. Similar fungus was found in the cerebrospinal fluid of several patients, which confirmed that the fungus caused the meningitis. The laboratory confirmation further links steroid injections from these lots from NECC to the outbreak. One patient, the index case, had a laboratory-confirmed *Aspergillus fumigatus* infection. These fungi are common in the environment; and fungal infections are not transmitted from person to person. CDC and state health departments estimated that approximately 14,000 patients may have received injections with medication from the 3 implicated lots of methylprednisolone, and nearly 97% have now been contacted for further follow-up. Patients and clinicians need to remain vigilant for onset of symptoms because fungal infections can be slow to develop. In this outbreak, symptoms typically have appeared 1-4 weeks following injection, but longer and shorter periods between injections and onset of symptoms have been reported.

UPDATED FIGURES ON MENINGITIS OUTBREAK (AS OF 30/11/2012)

Total Case Counts	Meningitis (with or without other infection)*	Stroke without Lumbar Puncture only	Paraspinal/ Spinal Infection only	Peripheral Joint Infection only	Deaths
510*	360	8	128	14	36



Exserohilum rostratum; the structure of the fungus found in the unopened vial of MPA.

References :

1. http://www.cdc.gov/hai/outbreaks/currentsituation/

BANNED TRADITIONAL MEDICINE — AN UPDATE

Drug Control Authority (DCA) at its 236th meeting on 27th September 2012 has cancelled the registration of two traditional medicines following the detection of scheduled poisoned inside both products. The affected products are **MY-MEN PLUS** and **JIN FEI CAO SAN EXTRACT POWDER SHENG CHANG.** Director General of Health Malaysia, Dato' Sri Dr. Hasan bin Abdul Rahman advised the public to stop using both products and seek further advice from healthcare professionals if experiencing any unpleasant effects or adverse events. Anyone who is in possession of this product is advised to immediately cease selling, distributing or using it.

MYMEN PLUS CAPSULE 400mg

Reg. No : MAL09082840TC

Manufacturer : Sabit Banani Industries Sdn Bhd, Kota Bharu, Kelantan

Registration holder: ZA Natural Herbs Marketing, Terengganu **Indication on label**: For traditional use to promote blood circulation, reduce fatigue and tiredness, relief muscle and joints pain, relief waist-ache and backache, and improve digestive and wind.

This product contains **TADALAFIL** which is indicated for the treatment of erectile dysfunction. Usage of tadalafil without proper diagnosis and monitoring by doctor can cause serious side effects such as reduced or loss of vision and hearing, lower blood pressure to dangerous levels and may result in cardiovascular events such as stroke and myocardial infarction. This product may cause detrimental effects to consumers, particularly angina patients receiving nitrates.

JIN FEI CAO SAN EXTRACT POWDER SHENG CHANG

Reg. No : MAL09111756T

Manufacturer : Sheng Chang Pharm Co Ltd., Taipei, Hsien, Taiwan.

Registration holder: Lifecare Essential Sdn. Bhd., Kuala Lumpur

Indication on label: For traditional use to relief common cold, cough, phlegm and headache.

This product contains **PSEUDOEPHEDRINE/EPHEDRINE** often found as decongestants in cold medications. Their usage at therapeutic doses prescribed by healthcare professionals provide benefit to patients, but if used indiscriminately without proper diagnosis and supervision can cause adverse events such as hypertension, anxiety, dizziness, tachycardia, drowsiness, and restlessness. Hence, it can be harmful to consumers especially those with underlying heart diseases, hypertension & hyperthyroidism.

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