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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

BY FAX

27 November 2012

Dr. Raymond LIANG
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LIANG,

WHO: Important information about out of specification results related to potency for Tuberculin 2TU

The World Health Organization (WHO) informed the Department of Health (DH) that Danish Health and Medicines Authority (DHMA) announced a regulatory notification about an out of specification (OOS) situation on potency for Tuberculin PPD RT23 SSI 2 TU (Tuberculin 2TU), which is manufactured by Statens Serum Institut (SSI), Denmark. According to DHMA, potentially all batches of Tuberculin 2TU on the Danish market were affected and so far, there is no information about the other strength.

The incident came to light when several batches of Tuberculin 2TU were found to be OOS after 18 months of storage with product's approved shelf life being 36 months. According to DHMA, SSI is going to apply for variation of shelf life and the lower potency is believed to have only minor impact on the clinical efficacy of the product, no recall was initiated in Denmark. And to avoid an out of stock situation, DHMA allowed the release of batches of Tuberculin 2TU on the basis of potency/stability data provided, combined with an evaluation of the clinical impact of the possible lower potency.

In Hong Kong, Tuberculin PPD RT 23 SSI injection 2TU/0.1ml (HK-44951), containing tuberculin, is registered by Mekim Ltd. (Mekim). It is indicated for skin testing for diagnostic use in patients infected with tuberculous mycobacteria and its approved shelf life is 36 months. Healthcare professionals should take note of the lower potency of the product and balance the risk and benefit of using the product. Mekim has set up a hotline 2774 8385 for public enquiries between 9:00am to 6:00pm.

Please encourage your members to report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 3904 1225 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html.

Yours sincerely,

(Ms. Pamela LI)
for Assistant Director (Drug)