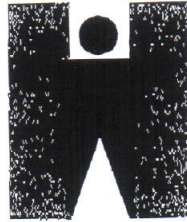


衛生署藥物辦公室
藥物註冊及進出口管制部

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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND
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(來函請註明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

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

Dear Dr. LIANG,

HSA - Reports of lymphadenitis following administration of BCG Vaccine SSI®

Singapore Health Sciences Authority (HAS) would like to update healthcare professionals on the suspected reports of lymphadenitis following the administration of the Bacillus Calmette-Guérin (BCG) Vaccine Staten Serum Institute (SSI)®, the sole BCG vaccine registered in Singapore since June 2003. BCG vaccine is used for the immunisation against tuberculosis.

In Singapore, BCG vaccine is routinely given to newborns as part of the National Childhood Immunisation Schedule. From January to October this year, HSA received a total of 53 reports of lymphadenitis, out of which 27 cases presented as suppurative lymphadenitis. The cases of suppurative lymphadenitis appeared to have doubled compared to 2010. Studies have revealed that the incidence of suppurative lymphadenitis is dependent on a number of factors including the strain of BCG vaccine and its constituents, host-related factors as well as administration techniques.

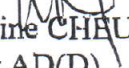
Healthcare professionals are reminded that intradermal administrative technique plays an important role in minimising BCG-associated complications such as suppurative lymphadenitis. This consideration is important when administering reactogenic vaccines such as the BCG Vaccine SSI®. It is also advisable for healthcare professionals to inform parents of possible suppurative lymphadenitis following vaccination so that early treatment can be sought. The median duration of symptoms prior to patient's presentation at the clinic is two months. For details, please refer to HSA's website:

http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/safety_information/product_safety_alerts/safety_alerts_2011/reports_of_lymphadenitis.html

In Hong Kong, BCG Vaccine SSI Powder for Inj 0.75mg/ml (HK-44952) is registered by Mekim Ltd. and manufactured by Staten Serum Institute. It is a prescription-only medicine. BCG vaccine is part of the Hong Kong Childhood Immunisation Programme. Drug Office has received one adverse drug reactions report on a 4-month old boy who developed lymphadenitis and the patient had recovered after aspiration. Department of Health will keep vigilant against any updated safety news of the drug.

Please remind your members to report any adverse events caused by the drugs to the Adverse Drug Reaction Monitoring Unit of Department of Health (tel. no.: 2319 2920, fax: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website: <http://www.drugoffice.gov.hk> at Drug Office under "Reporting an Adverse Drug Reaction".

Yours sincerely,


(Ms Christine CHEUNG)
for AD(D)