

衛生署藥物辦公室  
藥物註冊及進出口管制部

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28 December 2011

Dear Healthcare Professionals,

**TGA's review of Pneumovax 23 and revaccination recommendation**

Your attention is drawn to the news released by the Australian Therapeutic Goods Administration (TGA) regarding the outcome of a review of Pneumovax 23 adverse events and advice about revaccination.

In March 2011, TGA recalled a batch of Pneumovax 23 due to a cluster of seven severe local injection site reactions was reported. In April 2011, as a result of a continued increase in severe injection site reaction reports, the TGA issued advice to health professionals not to administer a second or subsequent dose of Pneumovax 23 pending the outcome of a review

The review has now been completed. The TGA has determined that the adverse events were not a batch-related problem. The TGA considers that the increased numbers of reports of severe reactions were a result of the known high rates of local reactions; the increased number of people having a repeat dose following the inclusion of Pneumovax 23 in the National Immunisation Program in 2005 with revaccination after five years; and the increased reporting that followed the publicity of the batch recall.

The TGA is advising that revaccination with Pneumovax 23 can be undertaken in accordance with the approved product information. For details, please refer to the following TGA website: <http://www.tga.gov.au/safety/alerts-medicine-pneumovax-111223.htm>

In Hong Kong, Pneumovax 23 is registered by Merck Sharp & Dohme (Asia) Ltd. and is a prescription drug. The local approved product recommendation for revaccination is in-line with the TGA's current recommendation. According to product information, revaccination of immunocompetent persons previously vaccinated with 23-valent polysaccharide vaccine is not routinely recommended. However, revaccination once is recommended for persons  $\geq 2$  years of age who are at highest risk of serious pneumococcal infection and those likely to have a rapid decline in pneumococcal antibody levels, provided that at least five years have passed since receipt of a first dose of pneumococcal vaccine.

Please 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](mailto: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)