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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Testosterone Products – Potential for Venous Thromboembolism (VTE)

Your attention is drawn to the US Food and Drug Administration's (FDA) announcement regarding the potential for venous thromboembolism (VTE) associated with the use of testosterone.

The FDA announced that it is requiring manufacturers to include a general warning in the drug labeling of all approved testosterone products about the risk of venous thromboembolism (VTE), include deep vein thrombosis (DVT) and pulmonary embolism (PE). The risk of VTE is already included in the labeling of testosterone products as a possible consequence of polycythemia, an abnormal increase in the number of red blood cells that sometimes occurs with testosterone treatment. As there have been postmarket reports of VTE unrelated to polycythemia, FDA is requiring a change to drug labeling of all testosterone products to provide a more general warning regarding venous blood clots and to ensure this risk is described consistently in the labeling of all approved testosterone products.

Please refer to the FDA's website for details:

http://www.fda.gov/Drugs/DrugSafety/ucm401746.htm

In Hong Kong, there are eight registered pharmaceutical products containing testosterone indicated for hypogonadism, and all the products are prescription-only medicines. The FDA and European Medicines Agency (EMA) have started investigating the risk of cardiovascular events of testosterone products and related news was posted on the Drug Office website on 4 February 2014 and 12 April 2014 respectively. So far, the Department of Health has not received any adverse drug reaction report on VTE associated with the use of the drug. In view of the announcement by the FDA, the matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board for consideration of updating the warning on the product label and/or package insert of the products containing testosterone. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 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. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Grant NG)
for Assistant Director (Drug)