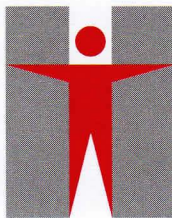


衛生署藥物辦公室
藥物註冊及進出口管制部

香港九龍南昌街 382 號公共衛生檢測中心三樓



DEPARTMENT OF HEALTH
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本署檔號 OUR REF.: DH DO PRIE/7-30/15

16 July 2014

(來函請註明此檔案號碼)

(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Testosterone products – Risk of possible cardiovascular problems

Your attention is drawn to Health Canada's announcement regarding testosterone hormone replacement products and a risk of serious and possibly life-threatening cardiovascular problems.

Testosterone hormone replacement products are used in men who are experiencing medical conditions arising from insufficient level of testosterone in the body. Health Canada has recently completed a safety review on testosterone replacement products. This review found a growing body of evidence for serious and possible life-threatening cardiovascular problems such as heart attack, stroke, blood clot in the lungs or legs; and increased or irregular heart rate with the use of testosterone replacement products. Health Canada is working with manufacturers to update the Canadian product labels regarding this risk.

Health Canada reminded the public of the following important information from the Canadian Product Monographs regarding the use of testosterone products:

- they should not be used in men for non-specific symptoms if laboratory tests have not been done to confirm a low testosterone level and other possible causes for the symptoms have not been excluded;
- they should not be used in children under the age of 18 as the safety and effectiveness has not been established in these patients; and
- they should not be used by women.

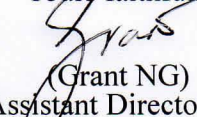
Please refer to the Health Canada's website for details:

<http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/40587a-eng.php>

In Hong Kong, there are eight registered pharmaceutical products containing testosterone which are prescription-only medicines. The Department of Health (DH) noted that the United States Food and Drug Administration (US FDA) and European Medicines Agency (EMA) started reviewing the risk of cardiovascular events of testosterone products and conclusion has not yet been drawn, and related news was posted on the Drug Office website on 4 February 2014 and 12 April 2014 respectively. News on risk of venous thromboembolism has been released by the US FDA, and was posted on the Drug Office website on 20 June 2014. Letter to healthcare professionals was issued on the same day to draw their attention to the matter. So far, the DH has not received any adverse drug reaction report on heart failure or cardiovascular complications related to the drug. In view of the above Health Canada's announcement, the matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board. The DH will remain vigilant on any safety updates on the drug by other overseas regulatory authorities. 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)

*We build a healthy Hong Kong and
aspire to be an internationally renowned public health authority*