衞生署藥物辦公室
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(來函請敍明此檔案號碼)
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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

26 October 2016

Dear Healthcare Professionals,

Testosterone and other anabolic androgenic steroids (AAS): Risks associated with abuse and dependence

Your attention is drawn to the U.S. Food and Drug Administration's (FDA) announcement regarding the risk of abuse and dependence associated with the use of testosterone and other anabolic androgenic steroids (AAS). FDA approved class-wide labeling changes for all prescription testosterone products, adding a new Warning and updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other AAS.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. Examples of these conditions include failure of the testicles to produce testosterone because of genetic problems, or damage to the testicles from chemotherapy or infection.

The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act. Testosterone and other AAS are abused by adults and adolescents, including athletes and body builders. Abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia.

The FDA alerts prescribers to the following labelling changes:

- New Warning on the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse.
- Revised labeling of all testosterone products to include information in the Abuse and Dependence section about adverse outcomes reported in association with abuse and dependence of testosterone/AAS.
- Warning and Precautions section advising prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

Please refer to the FDA's website for details:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm526151.htm

In Hong Kong, there are six registered pharmaceutical products containing testosterone, and one registered pharmaceutical product containing methyltestosterone, which are all prescription only medicines. News on the cardiovascular risk of testosterone was previously issued by the EMA, US FDA, Health Canada and Singapore HSA, and was posted on the Drug Office website since February 2014, with the last update posted on October 2015. Letters to inform local healthcare professionals were issued on 16 July 2014 and 13 October 2014. The matter was discussed by the Registration Committee of the Pharmacy and Poisons Board (the Registration Committee) on 17 February 2015. The Registration Committee noted that the Department of Health (DH) had informed the relevant registration certificate holders to include the warnings on cardiovascular risk on their testosterone products. So far, DH has received one case of adverse drug reaction related to testosterone and associated with non-specific lips swelling. In view of the above US FDA announcement on the risk of abuse and dependence with anabolic androgenic steroids including testosterone, the matter will be discussed by the Registration Committee. 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 the DH (tel. no.: 2319 2920, fax: 2319 6319 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,

(Joseph LEE)

for Assistant Director (Drug)