衞生署藥物辦公室
藥物註冊及進出口管制部

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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

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(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

MHRA: Advice on prescribing and dispensing oral tacrolimus products

Your attention is drawn to that the Medicines and Healthcare products Regulatory Agency (MHRA) advised healthcare professionals should prescribe and dispense oral tacrolimus products by brand name only, as a precautionary measure, to minimize the risk of inadvertent switching between products which has been associated with previous reports of toxicity and graft rejection.

This advice followed the review conducted by the Commission on Human Medicines (CHM), which considered that in light of the growing numbers of tacrolimus products, the risk of medication errors between the different oral pharmaceutical forms of tacrolimus may increase. The CHM concluded that to ensure maintenance of therapeutic response when a patient is stabilised on a particular brand, oral tacrolimus products should be prescribed and dispensed by brand name only.

This recommendation made by the MHRA does not imply that a patient's treatment cannot be changed to a different tacrolimus pharmaceutical form or brand if the prescriber considers this appropriate. However, any changes between brands (which may or may not involve changes in dosing regimen) should be accompanied by careful therapeutic monitoring under the supervision of an appropriate specialist.

Tacrolimus is a drug with a narrow therapeutic index, and even minor differences in blood levels have the potential to cause transplant rejection or adverse reactions.

Please refer to MHRA's website for details:

http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con152759.pdf

In Hong Kong, tacrolimus in oral dosage form is registered under three brand names, namely Prograf Cap, Advagraf Prolonged-release Hard Cap and Tacrolimus Sandoz Cap, and all with strength 0.5mg, 1mg and 5mg. All the products are prescription-only medicines and are indicated for the prophylaxis of transplant rejection.

Please report any adverse events caused by the drugs to the Pharmacovigilance 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 at Drug Office under "Reporting an Adverse Drug Reaction": http://www.drugoffice.gov.hk/eps/root/en/healthcare_providers/adr_reporting/index.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly drug safety digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Ms. Lilly HO)
for AD(D)