Dear Dr. LI,

De-registration of Rectal Suppository Containing Domperidone 10mg

Your attention is drawn to the deregistration of rectal suppository containing domperidone 10mg. On 7 July 2014, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Registration Committee) decided to deregister a pharmaceutical product of rectal suppository containing domperidone 10mg under regulation 36(8) of the Pharmacy and Poisons Regulations with effect from 1 October 2014 because the benefits of the product no longer outweigh its risks.

The Registration Committee’s decision was made after taking into consideration the findings from the review conducted by the European Medicines Agency’s Committee on Medicinal Products for Human Use and the usage information of the product in Hong Kong. The Registration Committee noted that domperidone in certain dose is clearly associated with a small increased risk of QT prolongation, arrhythmia and sudden cardiac death while data supporting the effectiveness of suppositories 10mg are limited, it was decided to de-register rectal suppository containing domperidone 10mg with effect from 1 October 2014.

In Hong Kong, there are currently one registered rectal suppository containing domperidone 10mg, namely Domper Suppository HK-42477 and is a non-prescription medicine.

For oral products containing domperidone, the Registration Committee has recommended the manufacturers and wholesalers to strengthen the product’s information on dosage and indication to be in-line with the recommendations of the European Medicines Agency.

Healthcare professionals should stop prescribing or dispensing rectal suppository containing domperidone 10mg and review the treatment plans of their patients as soon as possible. Please report any adverse events caused by oral domperidone products to the Department of Health (DH’s Pharmacovigilance Unit (tel. no.: 2319 2920, fax no.: 2186 9845 or email: adr@dh.gov.hk). For details, please refer to the DH Drug Office website under "ADR Reporting": http://www.drugoffice.gov.hk/adr/html. You may also wish to visit the website for subscription and browsing the "Drug News", which is a monthly digest of drug safety news and information issued by the DH Drug Office.

Yours sincerely,

(T K YIM)
for Assistant Director (Drug)