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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

8 October 2015

Dear Healthcare Professionals,

Azithromycin: Risk of drug reaction with eosinophilia and systemic symptoms (DRESS)

Your attention is drawn to Singapore Health Sciences Authority's (HSA) announcement regarding the risk of drug reaction with eosinophilia and systemic symptoms (DRESS) associated with the use of azithromycin.

Azithromycin is an azalide, a subclass of macrolide antibiotics. DRESS is a severe drug reaction characterised by rash, fever, lymphadenopathy, and single or multiple organ involvement (e.g., liver, kidney) that typically occurs within eight weeks of drug initiation. Haematologic abnormalities, including eosinophilia and atypical lymphocytosis, are also key characteristics of this syndrome.

In April 2014, Health Canada highlighted in its Canadian Adverse Reaction Newsletter that the package inserts (PI) for azithromycin-containing products have been updated with information on DRESS following the receipt of a domestic report of DRESS, as well as review of published literature on DRESS in patients treated with azithromycin. Further information on the cases can be found in the HSA's website.

To date, HSA has not received any reports of DRESS associated with the use of azithromycin. The company has initiated a labelling update for the Zithromax® (Pfizer Pte Ltd) range of products in Singapore to warn of reports of DRESS.

Healthcare professionals are encouraged to be vigilant to the signs and symptoms of DRESS as described above in patients who are prescribed azithromycin. Early and prompt discontinuation of the offending drug is important to achieve the best outcome in patients with DRESS.

Please refer to the HSA's website for details:

http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Safety_Information_and_Product_Recalls/Product_Safety_Alerts/2015/azithromycin-anddrugreactionwitheosinophiliaandsystemicsymptomsd.html

In Hong Kong, there are 70 registered pharmaceutical products containing azithromycin, and are prescription-only medicines. So far, the Department of Health (DH) has received one case of adverse drug reaction on azithromycin, and it was not related to DRESS. In view of the Singapore HSA's announcement, the matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board. 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,

A handwritten signature in black ink, appearing to read 'Grant NG', with a large, stylized flourish extending from the bottom.

(Grant NG)
for Assistant Director (Drug)