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

DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG INFORMATION AND
IMPORT/EXPORT CONTROL DIVISION
Suites 2002-05, 20/F, AIA Kowloon Tower
Landmark East, 100 How Ming Street
Kwun Tong, Kowloon, Hong Kong

2 August 2024

Dear Healthcare Professionals,

Azithromycin and rare risk of cardiovascular death

Your attention is drawn to the Australia Therapeutic Goods Administration (TGA)'s announcement that an updated warning about the risk of sudden cardiovascular death has been added to the Product Information (PI) and Consumer Medicine Information (CMI) documents for azithromycin.

Azithromycin already carried a warning of ventricular arrhythmias associated with prolonged QT interval. The update describes an increased short-term risk of cardiovascular death with azithromycin compared to other antibacterial drugs, including amoxicillin. This risk is rare but appears to be greater during the first 5 days of azithromycin use.

The new warning also advises that healthcare professionals should consider a screening electrocardiogram (ECG) in patients at high risk of a prolonged QT, based on their medical history or ongoing medical treatments.

The update was made following a recommendation from the Advisory Committee on Medicines. This was based on the Committee's review of published literature including observational studies, the seriousness of the adverse event and updated warnings by the Food and Drug Administration in the United States.

The Committee noted that the information in the observational studies was insufficient to establish or exclude a causal relationship between acute cardiovascular death and azithromycin use due to inconsistent results between studies.

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Health professionals should be aware of this potential adverse event so they can balance the benefits of azithromycin with the rare but serious risk of sudden cardiac death. Consider precautionary ECG screening for patients with a high risk of a prolonged QT.

Please refer to the following website in TGA for details:
https://www.tga.gov.au/news/safety-updates/azithromycin-and-rare-risk-cardiovascular-death

In Hong Kong, there are 46 registered pharmaceutical products containing azithromycin, and all products are prescription-only medicines. So far, the Department of Health (DH) has received 8 cases of adverse drug reaction related to azithromycin, but these cases are not related to sudden cardiovascular death. Related news about risks of cardiac death was previously issued by various overseas drug regulatory authorities, and was posted on the Drug Office website since 18 May 2012, with the latest update posted on 18 May 2013. Letters to inform local healthcare professionals were issued by the DH on 18 May 2012 and 20 May 2013. In Feb 2015, the Registration Committee of the Pharmacy and Poisons Board decided that the sales pack label and/or package insert of azithromycin products should include the relevant safety information. In light of the above TGA's announcement, with updated warning about the risk of the sudden cardiovascular death, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. 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 Clinical Trials and 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,

pp (Terence MAN)
for Assistant Director (Drug)