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(來函請敍明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

28 Mar 2024

Dear Healthcare Professionals,

Amiodarone: Assessing the potential risk of primary graft dysfunction following heart transplantation

Your attention is drawn to the Health Canada's announcement that it reviewed the potential risk of primary graft dysfunction (PGD) following heart transplantation with the pre-transplant use of amiodarone. The safety review was triggered by a labelling update in the United Kingdom.

Health Canada reviewed information provided by the manufacturers, and from searches of the Canada Vigilance database and the scientific literature. At the time of the review, Health Canada had not received any Canadian reports of PGD related to the pre-heart transplant use of amiodarone. Health Canada reviewed 7 international cases of PGD in patients taking amiodarone before heart transplantation. In all 7 cases, the role of amiodarone could not be determined due to insufficient clinical information about factors that could have contributed to the risk of PGD, such as the use of other medications and patient medical conditions. Health Canada also reviewed 6 articles published in the scientific literature. While these studies had a number of weaknesses, including the presence of confounders (other factors that may have contributed to the occurrence of PGD) and bias (conscious or unconscious influencing of a study and its results), overall the evidence reviewed was sufficient to support an increased risk of PGD in patients taking amiodarone before heart transplantation.

Health Canada's review found a possible link between the pre-heart transplant use of amiodarone and the risk of PGD. Health Canada will work with the manufacturers to update the Canadian Product Monograph of amiodarone-containing products to include the risk of PGD following heart transplantation.

Please refer to the following website in Health Canada for details:
https://dhpp.hpfb-dgpsa.ca/review-documents/resource/SSR1706035839788

In Hong Kong, there are 8 registered pharmaceutical products containing amiodarone. All products are prescription-only medicines. So far, the Department of Health (DH) has received 2 cases of adverse drug reaction related to amiodarone, but these cases were not related to PGD. In light of the above Health Canada's announcement, 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,

p.p. (Terence MAN)
for Assistant Director (Drug)