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

8 May 2017

Dear Healthcare Professionals,

ARANESP (darbepoetin alfa) - Risk of severe skin reactions: Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis

Your attention is drawn to the Health Canada's announcement regarding the risk of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) associated with ARANESP (darbepoetin alfa). Health Canada is currently working with the manufacturer to include this safety information in the Canadian Product Monograph.

ARANESP (product for subcutaneous and intravenous use) is an erythropoiesis-stimulating agent. In Canada, it is indicated for the treatment of anemia associated with chronic kidney disease (CKD) or anemia in cancer patients receiving chemotherapy. As of October 31, 2016, cumulative exposure to ARANESP was estimated to be over 6 million patient-years in the post-marketing setting. The potential risk of SJS/TEN with ARANESP use was evaluated using the global safety databases. As of April 5, 2017, 11 cases of SJS and 4 cases of TEN have been reported internationally in patients treated with ARANESP. To date no Canadian cases of SJS/TEN related to ARANESP treatment have been identified.

Health Canada reminds healthcare professionals to:

- discontinue ARANESP therapy immediately if a severe skin reaction occurs or SJS/TEN is suspected.
- permanently discontinue ARANESP if SJS/TEN is confirmed.

Please refer to the following website in Health Canada for details:
http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2017/63198a-eng.php

In Hong Kong, there are 12 registered pharmaceutical products containing darbepoetin alfa, and all are prescription only medicines registered by Kyowa Hakko Kirin (Hong Kong) Co., Limited. So far, the Department of Health (DH) has not received any adverse drug reaction report on darbepoetin alfa. In view of the above Health Canada announcement, the matter will be discussed by 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,

(Joseph LEE)
for Assistant Director (Drug)