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



28 Mar 2025

Dear Healthcare Professionals,

### **Isotretinoin: Assessing the potential risk of sacroiliitis**

Your attention is drawn to the Health Canada's announcement that it reviewed the potential risk of sacroiliitis associated with the use of isotretinoin. The safety review was triggered by a labelling update by the European Medicines Agency.

Isotretinoin is a prescription drug authorized for sale in Canada for the treatment of severe forms of acne in patients 12 years of age and older that should be used when the acne fails to respond to other treatments.

Health Canada reviewed the available information provided by manufacturers, as well as from searches of the Canada Vigilance database, international databases and the scientific literature. Health Canada reviewed 24 international cases of sacroiliitis in patients taking isotretinoin. Of those 24 cases, 23 were found to be possibly linked to the use of isotretinoin and 1 was unlikely to be linked. The average age was 20 years in cases where the age was provided. No deaths were reported among the 24 cases reviewed.

Health Canada also reviewed 18 articles published in the scientific literature. While the studies supported a link between the risk of sacroiliitis and the use of isotretinoin, they did not identify a clear biological mechanism to explain how isotretinoin use could lead to sacroiliitis. In both the cases reviewed and the scientific literature, sacroiliitis improved after discontinuation of isotretinoin and appropriate treatment.

Health Canada's review of the available information found a possible link between isotretinoin and the risk of sacroiliitis. Health Canada is working with the manufacturers to update the Canadian product

monograph for isotretinoin-containing products to include the risk of sacroiliitis. Health Canada will also inform healthcare professionals about this update through a Health Product InfoWatch communication.

Please refer to the following website in Health Canada for details:

<https://dhpp.hpfb-dgpsa.ca/review-documents/resource/SSR1739474283557>

In Hong Kong, there are 13 registered pharmaceutical products containing isotretinoin. All products are prescription-only medicines. So far, with regard to isotretinoin, the Department of Health (DH) has received 2 cases of adverse drug reaction, but these cases were not related to sacroiliitis. 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](mailto: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. (Vincent CHIANG)  
for Assistant Director (Drug)