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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dr. Donald LI  
President  
Hong Kong Academy of Medicine  
(Fax Number: 2505 5577)

Dear Dr. LI,

**Proton pump inhibitors: very low risk of subacute cutaneous lupus erythematosus**

Your attention is drawn to the Medicines and Healthcare products Regulatory Agency's (MHRA) announcement regarding very low risk of subacute cutaneous lupus erythematosus (SCLE) in patients taking proton pump inhibitors (PPIs).

According to the announcement, PPIs are associated with very infrequent cases of SCLE, a non-scarring dermatosis that can develop in sun-exposed areas. PPIs reduce the secretion of stomach acid and are widely used medicines for management of acid-related conditions, including: reflux oesophagitis; gastric and duodenal ulcers; and Zollinger-Ellison syndrome. The PPIs available in the UK include esomeprazole, lansoprazole, omeprazole, pantoprazole and rabeprazole.

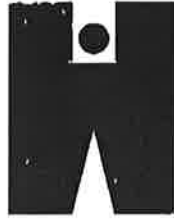
SCLE is characterised by polycyclic erythematous scaly plaques or confluent psoriasiform papulosquamous lesions, which may be accompanied by arthralgia. Skin tests (such as direct immunofluorescence) and serological tests (including presence of antibodies against Ro or Sjögren's-syndrome-related antigen A [SSA]) can be used to diagnose SCLE. Drug-induced SCLE can occur weeks, months or even years after exposure to the drug.

Considering the extensive use of PPIs, very few cases of SCLE have been reported. Nevertheless, evidence from clinical literature and from cases reported to medicines regulators including via the Yellow Card Scheme in the UK supports a causal association between PPIs and SCLE. Details of the case reports can be found in the MHRA's website. Product information in the UK is being updated to include this advice for healthcare professionals and patients or carers.

Healthcare professionals are reminded of the following if a patient treated with a proton pump inhibitor (PPI) develops lesions—especially in sun-exposed areas of the skin—and it is accompanied by arthralgia:

- advise them to avoid exposing the skin to sunlight
- consider subacute cutaneous lupus erythematosus (SCLE) as a possible diagnosis
- consider stopping use of the PPI unless it is imperative for a serious acid-related condition; a patient who develops SCLE with a particular PPI may be at risk of the same reaction with another
- in most cases, symptoms resolve on PPI withdrawal; topical or systemic steroids might be necessary for treatment of SCLE only if there are no signs of remission after a few weeks or months

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aspire to be an internationally renowned public health authority*



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BY FAX

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Please refer to the MHRA's website for details:

<https://www.gov.uk/drug-safety-update/proton-pump-inhibitors-very-low-risk-of-subacute-cutaneous-lupus-erythematosus>

In Hong Kong, there are 177 registered pharmaceutical products belonging to the class of PPIs, including 20 products containing esomeprazole, 68 products containing omeprazole, 18 products containing lansoprazole, 2 products containing dexlansoprazole, 43 products containing pantoprazole and 26 products containing rabeprazole. All products are prescription-only medicines except omeprazole-containing products which are pharmacy-only medicines. So far, the Department of Health (DH) has received one case of adverse drug reaction (ADR) on pantoprazole, and it is not related to SCLE. No ADR case has been received on the other PPIs. In view of the MHRA'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](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 sincerely,



(Grant NG)

for Assistant Director (Drug)