

衛生署藥物辦公室
藥物註冊及進出口管制部

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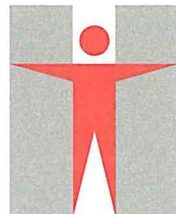
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DEPARTMENT OF HEALTH
DRUG OFFICE

DRUG REGISTRATION AND
IMPORT/EXPORT CONTROL DIVISION

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382 Nam Cheong Street, Kowloon, Hong Kong

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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Beta-lactam antibiotics - Assessing the potential risk of severe skin side effects

Your attention is drawn to the Health Canada's announcement that it reviewed the risk of Severe Cutaneous Adverse Reactions (SCAR) with beta-lactam antibiotics because of information submitted by a manufacturer that suggested a potential risk of SCAR with amoxicillin-clavulanic acid. Since the risk of SCAR is included in the product information for some beta-lactam antibiotics, Health Canada decided to review all beta-lactam antibiotics, focusing on products that do not already include SCAR in their product information. These reactions include Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), acute generalized exanthematous pustulosis (AGEP) and drug reaction with eosinophilia and systemic symptoms complex (DRESS).

At the time of the review, Health Canada had received 45 Canadian reports of SCAR related to beta-lactam antibiotics use. Of these reports, 26 were further assessed as they met the criteria set for this review. Of these 26 reports, 19 were found to have a possible link between the use of beta-lactam antibiotics and SCAR, 4 unlikely to have a link and 3 could not be assessed due to lack of information. A search in the World Health Organization's Adverse Drug Reaction Database found 8855 reports of SCAR in patients treated with beta-lactam antibiotics. Health Canada's review found that there was more frequent reporting of SCAR for the majority of beta-lactam antibiotics than expected in the general population. This safety review also examined the medical and scientific literature. There were 9 published studies and 79 reported cases of SCAR for beta-lactam antibiotics. Health Canada's review of the published studies and cases supported a possible link between SCAR and beta-lactam antibiotics use.

Health Canada's review found a possible link between the use of beta-lactam antibiotics and the risk of SCAR. Health Canada will be working with manufacturers to update the product safety information of beta-lactam antibiotics (that do not already include SCAR) to inform healthcare professionals and patients about this potential risk.

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

<https://hpr-rps.hres.ca/reg-content/summary-safety-review-detail.php?lang=en&linkID=SSR002>

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In Hong Kong, there are 668 registered pharmaceutical products which are beta-lactam antibiotics, including penicillins, cephalosporins and related drugs. All products are prescription-only medicines. So far, the Department of Health (DH) has received 31 cases of adverse drug reaction related to beta-lactam antibiotics, of which one case is related to Stevens-Johnson syndrome. In light of the above Health Canada's 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)