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(IN REPLY PLEASE QUOTE THIS FILE REF.)

4 December 2023

Dear Healthcare Professionals

PRAC recommends measures to minimise the risk of serious side effects with medicines containing pseudoephedrine

Your attention is drawn to the European Medicines Agency's (EMA) announcement that its safety committee, Pharmacovigilance Risk Assessment Committee (PRAC), has recommended new measures for medicines containing pseudoephedrine to minimise the risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). Pseudoephedrine is a stimulant that is often used as a decongestant in people who have a cold or allergies. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain, potentially causing serious, life-threatening complications. With prompt diagnosis and treatment, symptoms of PRES and RCVS usually resolve.

Medicines containing pseudoephedrine are not to be used in patients with high blood pressure that is severe or uncontrolled (not being treated or resistant to treatment), or with severe acute (sudden) or chronic (long-term) kidney disease or failure.

Healthcare professionals should advise patients to stop using these medicines immediately and seek treatment if they develop symptoms of PRES or RCVS, such as severe headache with a sudden onset, feeling sick, vomiting, confusion, seizures and visual disturbances.

The PRAC's recommendations follow a review of all available evidence, including post-marketing safety data, which showed that pseudoephedrine is associated with risks of PRES and RCVS.

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The product information for all pseudoephedrine-containing medicines will be updated to include the risks concerning PRES and RCVS and the new measures to be taken.

Please refer to the following website in EMA for details:
https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-27-30-november-2023

In Hong Kong, there are 102 registered pharmaceutical products containing pseudoephedrine. All products are pharmacy only medicines. So far, the Department of Health (DH) has received 2 cases of adverse drug reaction with pseudoephedrine, but these cases were not related to PRES or RCVS. Related news was previously issued by EMA and MHRA, and was posted on the Drug Office website on 11 Feb 2023 and 27 Feb 2023. In light of the above EMA'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 Adverse Drug Reaction 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,

(Terence MAN)
for Assistant Director (Drug)