European Union: EMA confirms measures to minimise the risk of serious side effects with medicines containing pseudoephedrine

European Medicines Agency (EMA) announces that its human medicines committee (CHMP) endorsed the measures recommended by the Pharmacovigilance Risk Assessment Committee (PRAC) to minimise the risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) for medicines containing pseudoephedrine.

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. CHMP confirmed that 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 in patients with severe acute (sudden) or chronic (long-term) kidney disease or failure.

In addition, 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 recommendations follow a review of all available evidence, including post-marketing safety data, which concluded that pseudoephedrine is associated with risks of PRES and RCVS. During the review, PRAC sought advice from an expert group of general practitioners, otorhinolaryngologists (specialists in diseases of the ear, nose, throat, head and neck), allergologists (specialists in the treatment of allergies) and a patient representative. PRAC also considered information submitted by a third party representing healthcare professionals.

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. Restrictions and warnings are already included in the product information of these medicines to reduce cardiovascular and cerebrovascular ischaemic (involving reduced blood supply to the heart and brain) risks.

The CHMP opinion will now be sent to the European Commission, which will issue a legally binding decision across the EU.

Information for healthcare professionals:

- An EMA review has found that pseudoephedrine-containing medicines are associated with risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS), serious conditions affecting the cerebral

blood vessels. This follows an evaluation of all available data including few reported cases of these conditions.

- There were no fatal cases of PRES or RCVS reported, and most of the cases resolved following discontinuation of the medicine and appropriate treatment.
- Pseudoephedrine-containing medicines must not be used in patients with severe or uncontrolled hypertension or severe acute or chronic kidney disease or renal failure, as these are risk factors for developing PRES or RCVS.
- Patients should be advised to discontinue treatment and seek immediate medical assistance if they develop symptoms of PRES or RCVS such as sudden, severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances.
- The risks of PRES and RCVS should be considered alongside other risks associated with pseudoephedrine-containing medicines, including cardiovascular or ischaemic events.

A direct healthcare professional communication (DHPC) will be sent in due course to relevant healthcare professionals. The DHPC will also be published on a dedicated page on the EMA website.

Please refer to the following website in EMA for details:
http://www.ema.europa.eu/en/news/ema-confirms-measures-minimise-risk-serious-side-effects-medicines-containing-pseudoephedrine

In Hong Kong, there are 100 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, 27 Feb 2023 and 2 Dec 2023. Letters to inform local healthcare professionals were issued by the DH on 4 Dec 2023.

In light of the above EMA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

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