PHARMACY AND POISONS BOARD
HONG KONG
香港藥劑業及毒藥管理局

Your Ref. **:**
貴處檔號

Our Ref. **:** DH DO PRIE/1-55/1
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20樓2002-05室
衞生署藥物辦公室

6th November 2024

To: Certificate holders of registered pharmaceutical products

Dear Sir/Madam,

New Warnings for Pseudoephedrine

The Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) under the Pharmacy and Poisons Board has considered, in its meeting on 31st October 2024, the latest warnings related to the risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) associated with the use of pseudoephedrine by the drug regulatory authorities of the European Union and the United Kingdom, and decided that the sales pack labels and/or package inserts of all registered products containing pseudoephedrine shall include the following new safety information (or equivalent [Note 1]) as appropriate:

"Contraindications

- *Severe hypertension or uncontrolled hypertension*
- *Severe acute or chronic kidney disease/renal failure*

[Note 1] Related safety information with other wording in accordance with reputable references and/or approved package inserts from drug regulatory authorities of reference countries may also be accepted on a case-by-case basis.

Special warnings and precautions for use

Posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)

Cases of PRES and RCVS have been reported with the use of pseudoephedrine containing products. The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure.

Pseudoephedrine should be discontinued and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances. Most reported cases of PRES and RCVS resolved following discontinuation and appropriate treatment.

Undesirable effects

'Posterior reversible encephalopathy syndrome (PRES)' and 'Reversible cerebral vasoconstriction syndrome (RCVS)' are listed as adverse reactions under 'Nervous system disorders' with frequency 'Not known'."

You are therefore required to ensure the sales pack labels and/or package inserts of the concerned products registered by your company contain the above safety information to comply with the new requirements.

In addition, you are reminded that as previously endorsed by the Committee, pharmaceutical products for cold and cough, including those containing pseudoephedrine, shall not have dosage instructions on the sales pack label and/or the package insert for children under 6 years of age.

Please submit application for the change of the registered particular(s) to the Drug Office via the online Pharmaceutical Registration System 2.0 (PRS 2.0) at www.drugoffice.gov.hk/prs2-ext/client_authentication.jsp for approval within 2 months from the date of this letter. Failing to comply with the above requirements may result in de-registration of the products or registration not being renewed by the Committee upon certificate expiry.

For further enquiries on the registration matters of pharmaceutical products, please contact the Drug Office at 3974 4175.

Yours faithfully,

(Y. F. YEUNG)
Secretary,
Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee

c.c. 7-15/3, Product Files