Deregistration of pharmaceutical products containing pholcodine effective from January 1 next year

The Department of Health (DH) today (July 7) said that owing to their benefits no longer outweigh the risks, pharmaceutical products containing pholcodine would be deregistered and should not be available in the market with effect from January 1, 2024.

Pholcodine is a centrally acting cough suppressant, which is used in adults and children to treat a non-productive cough. The Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) of the Pharmacy and Poisons Board of Hong Kong, at its meeting yesterday (July 6), decided to, in the public interest as stipulated by the Pharmacy and Poisons Regulations (Cap. 138A), deregister pharmaceutical products containing pholcodine with effect from January 1, 2024, after taking into consideration various factors including the latest recommendations on pholcodine by overseas regulatory authorities, and advice given by local experts.

The Committee has consolidated information from other countries and the advice of local experts that the use of pholcodine in the 12 months before general anaesthesia with neuromuscular blocking agents (NMBAs) is a risk for developing NMBA anaphylaxis.

In Hong Kong, there are currently 27 registered pharmaceutical products containing pholcodine. These products are listed in the Attachment. They are all Part 1 poisons controlled under the Pharmacy and Poisons Ordinance (Cap. 138) and can only be sold at pharmacies under the supervision of a registered pharmacist.

The DH will issue letters to healthcare professionals and pharmaceutical traders to inform them of the Committee's decision to deregister pharmaceutical products containing pholcodine, and to advise healthcare professionals to arrange suitable alternative treatments for their patients.

"When the Committee's decision takes effect on January 1, 2024, all drug manufacturers, wholesalers, retailers and healthcare professionals must stop selling or supplying pharmaceutical products containing pholcodine. Drug manufacturers and wholesalers are also required to recall all products concerned from the market by December 31, 2023. The DH will take enforcement action against any illegal possession or sale of such products afterwards," a spokesman for the DH said.

Under the Ordinance, illegal sale or possession of unregistered pharmaceutical products and Part 1 poisons are criminal offences. The maximum penalty for each offence is a fine of $100,000 and two years' imprisonment.

The DH advised that doctors and pharmacies should stop prescribing or dispensing pharmaceutical products containing pholcodine. There are other medicines for cough treatment available in local market. Patients taking pharmaceutical products containing pholcodine should consult their healthcare professionals to review their treatment plans as soon as possible.