

Regulatory control of skin antiseptic products containing chlorhexidine to be enhanced

The Department of Health (DH) today (October 8) said that following the decision of the Pharmacy and Poisons Board of Hong Kong to enhance the control of skin antiseptic products containing chlorhexidine, the relevant guidance notes have been revised and will take effect on July 8, 2020.

In response to some chlorhexidine-containing skin antiseptics found to have been contaminated with bacteria recently, the Board has decided that the sales control of such antiseptic products should be tightened after reviewing the existing definition of pharmaceutical products and taking reference of overseas regulatory practices for antiseptic products.

The "Guidance Notes on Classification of Products as Pharmaceutical Product under the Pharmacy and Poisons Ordinance (Cap 138)" related to chlorhexidine have been revised as follows:

Skin antiseptic products containing chlorhexidine for human or animal use are classified as pharmaceutical products unless otherwise stated, or except when:

- (i) they are clearly labelled in English and Chinese for washing hands only (or equivalent); or
- (ii) chlorhexidine is used as a preservative or antimicrobials in cosmetic products.

When the new regulatory control takes effect, antiseptic products containing chlorhexidine that fulfil the definition of a pharmaceutical product must be registered with the Board before they can be legally sold in Hong Kong. Possession and sale of an unregistered pharmaceutical product are criminal offences under the Ordinance. The maximum penalty for each offence is a fine of \$100,000 and two years' imprisonment.

The DH is issuing letters to inform traders and stakeholders about the new regulatory control decided by the Board. To allow traders sufficient time to make preparations to meet the new requirement, the Board decided that the revision will take effect in nine months' time on July 8, 2020.

For more information on the new regulatory control and antiseptic products, please visit the website of the DH's Drug Office at www.drugoffice.gov.hk.