



FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE

HSA ALLOWS IMPORT AND SALE OF *CORYDALIS YANHUSUO* HERB IN SINGAPORE FROM 1 JUNE 2018

The Health Sciences Authority (HSA) will allow the import and sale of *Corydalis yanhusuo* (延胡索) herb and Chinese Proprietary Medicines (CPM)¹ containing the naturally occurring substance tetrahydropalmatine (THP)² in Singapore from 1 June 2018. Traditional Chinese Medicine (TCM) practitioners would now be able to use such products in their practice.

Background

2 THP is a substance present naturally in some herbs, of which *Corydalis yanhusuo* is the most commonly used one in TCM practice. *Corydalis yanhusuo* is a Chinese medicinal herb with documented uses in TCM references for *activating blood and moving qi* (活血行气). It is generally used to relieve pain (e.g. menstrual cramps and headaches). The Ministry of Health (MOH) had disallowed the use of THP-containing herbs and their use in herbal medicines since 1995. The ban was implemented after THP was controlled under the Poisons Act, following overseas reports that THP could cause liver toxicity when consumed.

Review of Prohibition on *Corydalis yanhusuo*

3 Following feedback from the Singapore Chinese Medicines and Health Products Merchant Association³ (SCMHPMA) to lift the ban on the THP-containing herb, *Corydalis yanhusuo*, HSA, together with its Expert Panel (refer to [Annex](#) for members), conducted an extensive review of the safety of THP-containing herbs. This is part of HSA's ongoing efforts to keep the regulations for health products relevant to industry while ensuring public health and safety. The review involved studying adverse reactions reported overseas and obtaining feedback from the local TCM community.

4 While HSA's review indicated that there are no major safety concerns when THP-containing herbs are used appropriately, there is some evidence of an association between high levels of THP and liver toxicity in the scientific literature. After conducting

¹ Chinese Proprietary Medicines refer to finished products containing Chinese medicinal materials used according to the TCM system of therapeutics.

² Tetrahydropalmatine (THP) – 延胡索乙素, also known as 四氢巴马汀

³ An industry association which consists mainly of importers dealing with local TCM products.

a study, HSA has determined that an acceptable daily intake for THP is 19 mg. HSA has also assessed that the amount of THP in *Corydalis yanhusuo* raw herb remains well below this limit when used according to the recommendations of the Chinese Pharmacopoeia (a standard reference used for TCM).

5 Given that there are sufficient safeguards in place, including a regulatory framework requiring the pre-market approval of CPM products, HSA, in consultation with MOH, will implement the following changes from 1 June 2018:

- a) Allow the import and supply of the *Corydalis yanhusuo* raw herb;
- b) Allow the import and supply of *Corydalis yanhusuo* and other THP-containing herbs in Chinese Proprietary Medicines; and
- c) Allow the import and supply of other THP-containing herbs for the local manufacturing of Chinese Proprietary Medicines.

6 To ensure the safe use of *Corydalis yanhusuo* and other THP-containing herbs, HSA will review the safety and quality of CPM containing these herbs before they are placed in the local market. HSA will impose additional labelling requirements, in the form of appropriate cautionary statements to ensure the safe use of these products, as well as require compliance with a THP dose limit of 19 mg per day.

7 HSA will continue to monitor the situation closely for any occurrence of adverse reactions and update the public on any developments where necessary. Consumers should be aware that as with any other health product, the effects of CPM and herbs may vary from one individual to another. Individuals with liver disease should avoid using CPM or herbs containing THP. All consumers are advised to consult a medical professional or TCM practitioner if they are unsure whether CPM or herbs containing THP are suitable for their use.

**HEALTH SCIENCES AUTHORITY
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About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.

**EXPERT PANEL FOR THE REVIEW OF HERBS CONTAINING
NATURALLY OCCURRING POISONS**

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