



FOR IMMEDIATE RELEASE

**HEALTH SCIENCES AUTHORITY
PRESS RELEASE
21 MARCH 2016**

HSA ALLOWS SALE AND IMPORT OF CHINESE HERBS CONTAINING BERBERINE FROM 1 APRIL 2016

The Health Sciences Authority (HSA) will allow the sale and import of Chinese herbs containing berberine (小檗碱) in Singapore from 1 April 2016. This is part of a phased approach by HSA to lift the restrictions on the sale and use of berberine. Since January 2013, HSA had allowed the local sale and use of Chinese Proprietary Medicines containing berberine (e.g. capsules, oral liquid preparations, powders and granules), while maintaining the prohibition on Chinese herbs containing berberine.

2 Berberine is an alkaloid present naturally in some herbs such as Rhizoma Coptidis (黄连) and Cortex Phellodendri (黄柏), used in Traditional Chinese Medicine (TCM) for their “heat-clearing” and “dampness-drying” (清热燥湿) properties. The prohibition on the use of berberine, as controlled under the Poisons Act, was implemented in 1978 arising from local safety concerns that berberine could cause severe jaundice and brain damage in glucose-6-phosphate dehydrogenase (G6PD) deficient¹ babies.

3 Since allowing Chinese Proprietary Medicines (CPM) containing berberine from 1 January 2013, more than 140 of such CPM have been listed with HSA. To date, HSA has not received any adverse reports directly resulting from the consumption of these products containing berberine. There have also not been any new safety concerns reported in scientific publications on the use of berberine in CPM. Based on these findings and in consultation with advisory committees as well as the Ministry of Health, it was assessed that there were no major safety concerns with Chinese herbs containing berberine when used appropriately.

4 As lifting the prohibition on Chinese herbs containing berberine will allow TCM practitioners more options in the use of such herbs in their practice, HSA will be sending advisories to remind TCM practitioners and the TCM industry on the relevant safety information and to warn against the use of berberine in infants, G6PD deficient individuals of all ages, pregnant and breastfeeding women.

5 Currently, Chinese herbs for traditional medicinal uses are not subject to pre-market approval and licensing for their import and sale. Dealers (including importers,

¹ G6PD deficiency is a genetic disorder with a risk of red blood cells breaking down, leading to anaemia, when the person is exposed to external factors such as infection, as well as certain medicines (e.g. anti-malarials, aspirin) and chemicals (e.g. naphthalene in mothballs). Individuals with the condition are not normally anaemic and display no symptoms.

wholesalers, distributors, re-packers and retailers) are responsible for the safety and quality of the herbs with which they are dealing. They are to ensure that those herbs comply with the relevant regulatory requirements, e.g. do not contain any prohibited substances or toxic heavy metals above permissible limits.

6 As these herbs containing berberine can be freely sold, consumers should be aware that as with other health products, the effects of Chinese herbs may vary from one individual to another. Please consult a medical doctor or TCM practitioner if you are unsure whether Chinese herbs containing berberine are suitable for you. Such herbs should also be avoided in infants, G6PD deficient individuals, pregnant and breastfeeding women.

7 HSA will continue to monitor the situation on Chinese herbs containing berberine closely and will update the public on any developments where necessary.

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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.