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**HEALTH SCIENCES AUTHORITY
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HSA ALLOWS CHINESE PROPRIETARY MEDICINES CONTAINING BERBERINE FOR SALE IN SINGAPORE FROM 1 JANUARY 2013

The Health Sciences Authority (HSA) will allow the sale of Chinese Proprietary Medicines (CPM)¹ containing berberine (小檗碱) in Singapore from 1 January 2013. This was announced today by the Minister for Health, Mr. Gan Kim Yong, at the Forum on TCM by Overseas Experts.

Background

2 Berberine is an alkaloid present naturally in some herbs such as *Rhizoma coptidis* (黄连) and *Cortex phellodendri* (黄柏) and used in Traditional Chinese Medicine (TCM) for its 'heat-clearing' and 'dampness-drying' (清热燥湿) properties. The prohibition of the use of berberine, as controlled under the Poisons Act, was implemented by the Ministry of Health in 1978, arising from local safety concerns that berberine could cause severe jaundice and brain damage in glucose-6-phosphate dehydrogenase (G6PD) deficient² babies.

Review of Prohibition on Berberine

3 The Health Sciences Authority, together with its expert committees, has been monitoring the situation and conducting ongoing scientific reviews on the safety profile of berberine. This includes literature review of scientific publications on the safety of berberine, and surveillance of adverse reactions reported in other places which practise TCM such as China, Taiwan and Hong Kong. The feedback from the local TCM community and developments in the local regulatory landscape were also factors considered in the review of berberine.

4 The latest review conducted by the Berberine Expert Panel (see [Annex](#) for panel members) indicates that there are no major safety concerns when berberine is

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

² G6PD deficiency is a genetic disorder that results in the breakdown of red blood cells, 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.

used appropriately, but it should still be avoided in infants, G6PD deficient individuals of all ages, pregnant and breastfeeding women.

5 Based on the recommendations of the Berberine Expert Panel and taking into consideration that there are sufficient safeguards in-place (which include the pre-market approval of CPM products and the compulsory registration of TCM practitioners), HSA, in consultation with MOH, will adopt a phased approach in the lifting of the prohibition on berberine in Singapore. For a start, the use of CPM containing berberine, (e.g. capsules, oral liquid preparations, powders and granules used by TCM practitioners in their dispensing) would be allowed with effect from 1 January 2013. In the absence of major safety issues, the HSA will review the possible further lifting of prohibition on Chinese herbs containing berberine by 2015.

6 To safeguard public health, CPM containing berberine will be subjected to the current regulatory regime whereby HSA will review the safety and quality of these preparations before they are placed in the local market. Additional labelling requirements, in the form of appropriate cautionary statements to warn against use in infants, G6PD deficient individuals of all ages, pregnant and breastfeeding women, will be imposed on these products.

7 With the lifting of the ban, HSA will continue to monitor the situation closely for any occurrence of adverse reactions. In addition, educational programmes to TCM practitioners to share on adverse reactions reporting and the precautions that should be taken when using CPM containing berberine will be conducted. HSA will also engage the TCM industry to provide them with the relevant safety information, so as to reach out to Chinese medical halls and retailers, as well as conduct dialogue sessions with the industry on the relevant technical requirements for these CPM.

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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, 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.

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