

28 Mar 2016

To: All Registered TCM Practitioners

Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-03 Helios
Singapore 138667
Website: www.hsa.gov.sg
Fax: 6478 9069

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

The Health Sciences Authority (HSA) would like to inform all registered TCM Practitioners that the sale and import of Chinese herbs containing berberine in Singapore will be allowed from 1 April 2016. This is part of a phased approach by HSA to lift the restrictions on the sale and use of berberine, after allowing the local sale and use of Chinese Proprietary Medicines (CPM) containing berberine since January 2013.

2 Since allowing CPM containing berberine (e.g. capsules, oral liquid preparations, powders and granules) from 1 January 2013, 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.

3 However, CPM and Chinese herbs containing berberine should still **strictly be avoided** for the following patients:

- (a) infants
- (b) glucose-6-phosphate dehydrogenase (G6PD) deficient individuals of all ages
- (c) pregnant women and
- (d) breastfeeding women

Please refer to press release at Appendix A for more details.

4 TCM practitioners are strongly encouraged to report any adverse events suspected to be related to health products, including CPM and Chinese herbs containing naturally occurring berberine to the Vigilance and Compliance Branch of HSA at Tel: 6866 3538/9, Fax: 6478 9069, Email: HSA_productsafety@hsa.gov.sg or online via the weblink http://www.hsa.gov.sg/ae_online.

5 Should you have any queries on the above topic, please contact Mr Kenneth Low (tel: 6304 5476) or Ms Jessica Kuah (tel: 6304 5475), or email: HSA_CHP@hsa.gov.sg

Thank you.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Hui Foong Mei', is positioned above the printed name and title.

HUI FOONG MEI (MS)
DIRECTOR
COMPLEMENTARY HEALTH PRODUCTS BRANCH
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY

cc Chairman, Traditional Chinese Medicine Practitioners Board



**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, 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.

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.

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.

**HEALTH SCIENCES AUTHORITY
SINGAPORE
21 MARCH 2016**

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.

药物安全讯息 编号 6



2016年3月24日

致全体注册中医师:

Health Products Regulation Group
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11 Biopolis Way #11-03 Helios
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Fax: 6478 9069

自2016年4月1日起，卫生科学局将允许进口及销售含有小檗碱的中药材

卫生科学局现将最新情况通报给所有注册中医师。自2016年4月1日起，卫生科学局将允许含有小檗碱的中药材进口并在新加坡销售。这将是自2013年1月起允许含有小檗碱的中成药在本地销售及使用以来，分阶段解逐步解除对小檗碱销售和使用限制的又一举措。

2 自2013年1月1日开始解禁含小檗碱成分的中成药（如胶囊、水剂、由中医师配方使用的粉剂、颗粒剂等）以来，卫生科学局未接获因服食含有小檗碱成分的中成药而直接导致的不良反应报告，医学文献也没有报道新的有关使用小檗碱的安全问题。鉴于上述考量，以及咨询了卫生部和专家委员会的意见后，经评估认为，适当地使用含小檗碱的中药材不会产生严重的安全问题。

3 不过，下列人群严禁使用含有小檗碱的中成药或中药材：

- 婴儿
- 各年龄层的葡萄糖-6-磷酸脱氢酶缺乏症患者
- 孕妇
- 哺乳期妇女

更多有关详情，请参阅附录 A 的新闻发布。

4 吁请各位中医师，如果您发现任何怀疑由含有小檗碱的中成药或中药才引起的不良反应事件，请及时报告给卫生科学局的警戒及条例遵循组，电话：6866 3538/9，传真：6478 9069，电邮：HSA_productsafety@hsa.gov.sg 或上网：http://www.hsa.gov.sg/ae_online。

5 有关此议题，如果您还有任何疑问，请联络刘伟亮先生（电话 6304 5476）或柯思佳小姐（电话 6304 5475）或电邮：HSA_CHP@hsa.gov.sg。

谢谢！

许凤美
辅助医疗保健产品组组长
医疗保健产品管理司
卫生科学局

抄送： 中医管理委员会主席

(此为英文版翻译, 如有歧义, 请以英文版本为准。)

附件A

自2016年4月1日起, 卫生科学局将允许进口及销售含有小檗碱的中药材

自2016年4月1日起, 卫生科学局将允许含有小檗碱的中药材进口并在新加坡销售。这是卫生科学局分阶段逐步解除对小檗碱销售和使用限制的又一举措。自2013年1月起, 卫生科学局已经允许含有小檗碱的中成药(如胶囊、合剂、粉剂、颗粒剂)在本地销售和使用, 但是, 含有小檗碱的中药材还是禁用的。

2 小檗碱是一种生物碱, 天然存在于一些传统中医用于清热燥湿的中草药, 如黄连和黄柏。1978年, 由于小檗碱在本地被发现能引起患葡萄糖-6-磷酸脱氢酶(G6PD)缺乏症¹的新生儿严重的黄疸及脑损伤, 基于安全考量, 被列入《毒药法令》而禁止使用。

3 自2013年1月1日开始允许销售含有小檗碱的中成药以来, 卫生科学局已登记了超过140个此类中成药。至今, 卫生科学局未接获因服食含有小檗碱的中成药而直接导致的不良反应报告, 医学文献也没有报道新的有关使用小檗碱的安全问题。鉴于上述考量, 以及咨询了卫生部和专家委员会的意见后, 经评估认为, 适当地使用含小檗碱的中药材不会产生严重的安全问题。

4 这将让中医师们在行医和服务公众的时候有更多的治疗选择。卫生科学局将会提醒中医药从业人员以及业界, 注意有关小檗碱的安全信息, 婴儿、各年龄层的葡萄糖-6-磷酸脱氢酶缺乏症患者、孕妇、哺乳期妇女都应该避免使用小檗碱。

5 目前, 在本地, 中药材在进口及销售前不需要经过上市前的批准及领取执照。其安全和品质由经销商(包括进口商、批发商、分销商、包装商及零售商)负责。经销商必须确保他们所售卖的药材符合相关的管理规定, 如不得含有任何违禁成分或有毒重金属不得超过限量。

6 消费者在使用中药材时要谨慎, 与其它医疗保健产品一样, 中药材的效果也是因人而异的。如果不能确定含有小檗碱的中药材是否适合您使用, 请咨询医生或中医师。婴儿、葡萄糖-6-磷酸脱氢酶缺乏症患者、孕妇及哺乳期妇女应避免使用此类药材。

7 卫生科学局将继续密切监视含有小檗碱的中药材在本地的使用情况。如果有需要, 将会向公众通报其最新进展。

卫生科学局

新加坡

2016年3月21日

¹葡萄糖-6-磷酸脱氢酶缺乏症是一种遗传性红细胞酶缺乏病, 在正常情况下, 患者不会表现出贫血及症状。当患者被感染或服用某些特定药物, 如抗疟疾药物, 阿司匹林以及接触到化学物质如樟脑时, 红细胞有受到破坏的风险, 从而导致贫血。