

	Question	Answer
1.	When is the effective date that Chinese herbs containing berberine will be allowed for import and sale? 什么时候开始允许进口及销售含有小檗碱的中药材?	<ul style="list-style-type: none"> <li>Chinese herbs containing berberine will be allowed for import and sale from 1 April 2016.</li> <li>含有小檗碱的中药材将于 2016 年 4 月 1 日起允许进口及销售。</li> </ul>
2.	After 1 Apr 2016, am I still required to apply for Poisons Licence for the import of Chinese herbs containing berberine? 2016 年 4 月 1 日之后, 进口含有小檗碱的中药材, 是否需要申请毒药执照?	<ul style="list-style-type: none"> <li>No, companies would no longer be required to apply for Poisons Licence for the import and wholesale of Chinese herbs containing berberine with effect from 1 April 2016.</li> <li>2016 年 4 月 1 日之后, 进口及批发含有小檗碱的中药材将不再需要申请毒药执照。</li> </ul>
3.	What are the Chinese herbs containing berberine? 含有小檗碱的中药材有哪些?	<ul style="list-style-type: none"> <li>Some common examples are Rhizoma coptidis (黄连) and Cortex phellodendri (黄柏). Companies may wish to refer to reference books such as "A Dictionary of Chinese Pharmacy" &lt;&lt;中药大辞典&gt;&gt;, or submit an enquiry to the Complementary Health Products Branch (email: HSA_CHP@hsa.gov.sg) for any clarification.</li> <li>常用的有黄连、黄柏。请查阅中药参考书, 如《中药大辞典》, 或有任何疑问, 请咨询辅助医疗保健产品组, (电邮至: HSA_CHP@hsa.gov.sg)</li> </ul>
4.	Is there any pre-market approval needed for the import and sale of raw herbs containing berberine? 进口含有小檗碱的中药材需要上市前的批准吗?	<ul style="list-style-type: none"> <li>Currently, raw herbs are not subjected to pre-market approval for importation and sale. Dealers of raw herbs (including CPM manufacturers, importers, wholesale dealers, distributors, re-packers and retailers) are responsible for the safety and quality of the herbs with which they are dealing. Effective 1 April 2016, importers of Chinese herbs containing berberine will no longer need to apply for the Poisons Licence.</li> <li>目前, 中药材在进口和销售前不需要经过上市前的审批。中药材经销商(包括中成药制造商、进口商、批发商、分销商、包装商及零售商)需要对其经销的中药材的品质和安全负责。自 2016 年 4 月 1 日起, 进口含有小檗碱的中药材不再需要申请毒药执照。</li> </ul>

5.	<p>Are CPM containing berberine still allowed for use? Any changes to the regulatory requirements for such CPM?</p> <p>含有小檗碱的中成药仍然允许使用吗？对这类中成药的管理要求有变化吗？</p>	<ul style="list-style-type: none"> <li>• CPM containing berberine have been allowed for use since 1 January 2013, and such CPM which have been listed by the Health Sciences Authority will continued to be allowed for use, subject to current listing requirements.</li> <li>• Companies who wish to import Chinese herbs containing berberine for local manufacturing of such CPM will no longer need to apply for the Poisons Licence from 1 April 2016.</li> <li>• 含有小檗碱的中成药自 2013 年 1 月 1 日起允许使用，这类符合目前中成药的登记要求要求并已经由卫生科学局登记的中成药将继续允许使用。</li> <li>• 自 2016 年 4 月 1 日起，公司进口含有小檗碱的中药材用于生产中成药，将不再需要申请毒药执照。</li> </ul>
6.	<p>Is there a limit on the level of berberine allowed in such CPM?</p> <p>此类中成药产品对小檗碱的含量有限制吗？</p>	<ul style="list-style-type: none"> <li>• There is no legal limit of berberine allowed in CPM.</li> <li>• 法律上对中成药中的小檗碱含量没有限量要求。</li> <li>• However, the dosing of the herb containing berberine in the CPM has to follow that stipulated in references such as the Chinese Pharmacopoeia.</li> <li>• 但是，含有小檗碱的中药的用量必须以如中国药典等相关 资料作为参考。</li> </ul>
7.	<p>Would applicants be required to send their CPM for testing of berberine?</p> <p>申请者会被要求检测其产品中的小檗碱吗？</p>	<ul style="list-style-type: none"> <li>• According to current practices, first-time applicants (new importers, new local manufacturers) as well as applicants of imported CPM involving new overseas manufacturers will be required to send the product for screening of common poisons during the evaluation process.</li> <li>• 依据当前的管理要求，第一次的申请者（新的进口商、新的本地制造商）以及申请者进口的中成药是由新的海外制造商生产的，在产品的审评过程中，都将被要求进行不含毒药的检测。</li> <li>• CPM containing berberine are subject to the current listing requirements as with other CPM, For details on listing requirements, please refer to:</li> <li>• 含有小檗碱的中成药与目前其它中成药的登记要求相同，详情请参阅网站： <a href="http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Complementary_Health_Products/Chinese_Proprietary_Medicines/Overview/Guidelines_for_CPM/guidelines-on-cpm-product-listing-.html">http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Complementary_Health_Products/Chinese_Proprietary_Medicines/Overview/Guidelines_for_CPM/guidelines-on-cpm-product-listing-.html</a></li> </ul>

8.	<p>My company has listed CPM which are “amended formulas” (“修改方”) where the berberine herb was removed from a classical formula. Can I apply for the product with the original formula now?</p> <p>我公司已经登记了将含有小檗碱的中药成分去除后的“修改方”，现在，我能不能以原配方申请？</p>	<ul style="list-style-type: none"> <li>• Yes, but the original formula has to be submitted as a new application and not an amendment.</li> <li>• 可以。但是，原配方产品必须作为新产品呈交申请，而不是修改已经登记的现有产品。</li> </ul>
9.	<p>How can I advise my consumers on the appropriate use of raw herbs containing berberine?</p> <p>我应该如何建议消费者合理使用含有小檗碱的中药材？</p>	<ul style="list-style-type: none"> <li>• Chinese herbs and Chinese proprietary medicines (CPM) containing berberine should be avoided by individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency, children less than 1 year old, pregnant and breastfeeding women. If in doubt, your consumers should be advised to consult a doctor or TCM practitioner before consumption of the herbs and products. 葡萄糖-6-磷酸脱氢酶缺乏症患者、一岁以内的儿童、孕妇及哺乳期妇女应避免使用含有小檗碱的中药材和中成药。如有任何疑问，在使用前，消费者应咨询医生或中医药专业人员。</li> <li>• Possible side effects of such herbs include nausea and vomiting, fever, allergic reactions, skin irritation (for topical preparations).</li> <li>• 这类中药材可能引起的副作用有：恶心、呕吐、药热、过敏、皮肤红疹（外用）等。</li> <li>• If your consumer suspects that the Chinese herb is making him unwell or is causing side effects, please advise him to stop taking it immediately and consult a doctor or TCM practitioner who can help to inform HSA of the side effects experienced. 如果您的消费者怀疑所服用的中药材导致了不适或引起不良作用，请建议他立即停止服用，并咨询医生或中医师，他们会将引发的不良反应通知卫生科学局。</li> <li>• You can also direct consumers to the health advisory on HSA's website for more information:</li> <li>• 您也可建议消费者参考卫生科学局网站的消费者指南，以获取更多信息： “Advisory on Chinese Proprietary Medicines Containing Berberine &amp; Special Warning for Children Less than 1 Year Old, Glucose-6-Phosphate Dehydrogenase (G6PD) Deficient Individuals, Pregnant and Breastfeeding Women”</li> </ul>