

	Question	Answer
1.	When is the effective date that Chinese Proprietary Medicines (CPM) containing <i>Corydalis yanhusuo</i> will be allowed for import and supply? 什么时候开始允许进口及销售含有延胡索的中成药?	<ul style="list-style-type: none"> • CPM containing <i>Corydalis yanhusuo</i> will be allowed for import and supply from 1 June 2018. • 含有延胡索的中成药将于 2018 年 6 月 1 日起允许进口及销售。
2.	Am I allowed to import and sell <i>Corydalis yanhusuo</i> raw herb? 是否允许进口及销售延胡索中药材?	<ul style="list-style-type: none"> • Yes, <i>Corydalis yanhusuo</i> raw herb will also be allowed for sale with effect from 1 June 2018. • 是。延胡索中药材也将于 2018 年 6 月 1 日起允许进口及销售。
3.	Will other raw herbs containing tetrahydropalmatine (THP) also be allowed for import and supply from 1 June 2018? 2018 年 6 月 1 日起, 是否也允许进口及销售其它含有延胡索乙素的中药材?	<ul style="list-style-type: none"> • Apart from <i>Corydalis yanhusuo</i> raw herb, other raw THP-containing herbs will only be allowed to be imported for the sole purpose of local manufacturing of CPM. • 除了延胡索中药材, 其它含有延胡索乙素的中药材只允许进口供本地生产中成药使用。
4.	Am I required to apply for Poisons Licence for the import of <i>Corydalis yanhusuo</i> herb and CPM containing <i>Corydalis yanhusuo</i> ? 进口延胡索中药材及含有延胡索的中成药, 是否需要申请毒药执照?	<ul style="list-style-type: none"> • No, companies will not be required to apply for Poisons Licence for the import of <i>Corydalis yanhusuo</i> herb and CPM containing <i>Corydalis yanhusuo</i> with effect from 1 June 2018. Poisons Licence is also not required for the import of other raw THP-containing herbs for the sole purpose of local manufacturing of CPM. • 2018 年 6 月 1 日之后, 进口延胡索中药材及含有延胡索的中成药不需要申请毒药执照。进口含延胡索乙素的中药材供本地生产中成药也不需要申请毒药执照。

<p>5.</p>	<p>Is there a limit on the level of THP allowed in such CPM? If yes, what are the corresponding additional requirements imposed on CPM dealers? 此类中成药产品对延胡索乙素的含量有限制吗？如果有，对中成药经销商相应的要求是什么？</p>	<ul style="list-style-type: none"> • As there is some evidence of an association between high levels of THP and liver toxicity, HSA has determined an acceptable daily intake for THP at 19 mg. To ensure the safe use of such CPM, the legal requirement imposed on these products is that they must deliver a THP dose not exceeding 19mg/day. • Companies dealing in such CPM will be required to ensure that every batch of the CPM delivers a THP dose not exceeding 19 mg/day. The product specifications should also include testing of THP as one of the quality parameters for the finished CPM. • 由于有证据显示，高剂量的延胡索乙素与肝毒性之间存在联系，卫生科学局确定延胡索乙素每日允许的用量为 19 毫克。为确保安全使用此类中成药产品，法律要求，其延胡索乙素的每日用量不得超过 19 毫克。 • 凡经销此类中成药的公司，必须确保其产品每批次中所含延胡索乙素的每日用量不得超过 19 毫克。同时，延胡索乙素的含量检测也需列入产品规格，作为成品质量控制的一部分。
<p>6.</p>	<p>Are there specific cautionary labelling required for CPM containing THP? 对含延胡索乙素的中成药标签有特殊的警示要求吗？</p>	<ul style="list-style-type: none"> • Yes, to safeguard public health and safety, such CPM are required to carry the following cautionary statements on their product labels: <ul style="list-style-type: none"> • Avoid use in individuals with liver diseases; and • Use according to the recommended dose and not to consume for more than two weeks. If symptoms persist, please consult a doctor. • 为确保公众的健康和安全，这类中成药产品的标签需标注： <ul style="list-style-type: none"> • 肝病患者避免使用；及 • 服用本品请勿过量或超过二周。如症状持续，请咨询医生。
<p>7.</p>	<p>My company has listed CPM which are “amended formulas” “修改方” where the THP-containing herb was removed from a classical formula. Can I apply for the product with the original formula now? 我公司已经登记了将含有延胡索乙素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"> • Yes, but the original formula has to be submitted as a new application and not an amendment. • 可以申请。但是，原配方产品必须呈交新的申请，而不是对已经登记的产品进行修改。