

For information

On 14 May 2012

**Legislative Council Panel on Health Services
Control over Proprietary Chinese Medicines
Containing Ingredients from Bear Gall Bladders**

Purpose

This paper briefs Members on the source of bear gall bladders, their medicinal value and the existing controls over proprietary Chinese medicines (pCm) containing ingredients from bear gall bladders in Hong Kong.

Background Information

2. Bear gall bladders are a rare and precious item of herbal medicine of animal origin with more than a thousand years' history of medicinal use in China. According to Zhonghua Bencao (《中華本草》)(the Chinese Materia Medica) compiled by the State Administration of Traditional Chinese Medicine, bear gall bladders are obtained from black bears (*Selenarctos thibetanus* G. Cuvier) and brown bears (*Ursus arctos* Linnaeus) of the Ursidae family. Included in the Appendix to the Pharmacopoeia of the People's Republic of China (《中華人民共和國藥典》), bear bile powder is a dehydrated product made from bile extracted from black bears (*Selenarctos thibetanus* Cuvier) of the Ursidae family through a surgical procedure performed on their gall bladders for the purpose of biliary drainage.

3. According to Zhonghua Bencao, the medicinal effects of bear gall bladders include heat-clearing and detoxicating, calming the liver and improving acuity of vision, destroying parasites and stanching. They are primarily indicated for jaundice with

damp-heat pathogen, summer heat dampness, diarrhea and dysentery, fever and convulsive epilepsy, red eyes and partial blindness, pharyngitis, furunculosis, anal fistula, malnutrition, ascarid and various types of bleeding. Modern pharmacological studies show that they have antispasmodic and anticonvulsant effects.

4. It is commonly viewed in the Chinese medicine field that bear gall bladders have significant efficacy in the treatment of critical, acute, serious and rare or complex illnesses, playing an important role in Chinese medicine clinical treatment. Medicines made with bear gall bladders have been widely used for treatment of various diseases such as liver and gall bladder diseases, cardiovascular and cerebrovascular diseases and acute infectious diseases.

Existing statutory controls over pCm containing ingredients from bear gall bladders in Hong Kong

5. In Hong Kong, the import and export of Chinese herbal medicines, pCms and related products that contain ingredients from bear gall bladders are subject to control under the Protection of Endangered Species of Animals and Plants Ordinance (PESAPO) (Cap. 586), which aims to give effect in Hong Kong to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). The objective of CITES is to strengthen trade controls through adoption of effective measures among governments of the contracting parties, so as to effectively protect the endangered species of wild fauna and flora and to ensure that the sustainable use of wild fauna and flora will not be affected by international trade.

6. The import, introduction from the sea, export, re-export or possession of specimens of species listed in Appendix I and Appendix II to CITES are subject to control under PESAPO irrespective of whether they are alive, dead, parts or derivatives (including medicines) of the species.

7. At present, bears of all species are endangered species listed in the Appendices to CITES, with some listed in Appendix I, and others listed in Appendix II. Under PESAPO, a total ban is generally imposed on the import and export of specimens of Appendix I species irrespective of whether they are alive, dead, parts or derivatives (including medicines) of the species. Where Chinese herbal medicines, pCms and products containing ingredients of species listed in Appendix II are to be imported into Hong Kong, they must be accompanied by a CITES permit issued by the exporting country for inspection by an authorised officer at the time of their arrival in Hong Kong. For such items to be exported from Hong Kong, an export permit must be obtained in advance from the Agriculture, Fisheries and Conservation Department.

8. Besides, it is stipulated in the Chinese Medicine Ordinance (CMO) (Cap. 549) that all products that fall within the definition of pCm must be registered before they can be imported, manufactured or sold in Hong Kong. In order to register, all pCms must meet the registration requirements prescribed by the Chinese Medicine Board under the Chinese Medicine Council regarding their safety, quality and efficacy.

9. As for Chinese herbal medicines, CMO has listed in its Schedules 1 and 2 Chinese herbal medicines which are more commonly used in Hong Kong; the import/export, possession, wholesale and retail sale of these herbal medicines are subject to control under CMO. "Bear gall bladders" and "bear bile powder" are seldom sold in the form of Chinese herbal medicine in Hong Kong, and therefore not included in the Schedules.

Controls over pCms containing ingredients from bear gall bladders

10. In the Chinese medicine arena, bear gall bladders have been used for more than a thousand years. Their clinical effects cannot be substituted by the use of other herbal medicines, and no artificially synthesised substitutes have been found through technological

research so far. Having considered the uniqueness of the medicinal properties, functions and usage of bear gall bladders and the balance between animal rights and utilisation of natural resources, the Chinese Medicines Board accepted the use of bear gall bladders as an active ingredients of pCm where the pCm product used for medical treatment meets the requirements laid down in CMO, PESAPO and CITES.

Use of bear gall bladders in Hong Kong

11. According to the records of the Chinese Medicines Board, there are currently 21 registered pCm products containing bear gall bladders as active ingredients, involving a total of three local pCm manufacturers, two mainland manufactures and three overseas manufacturers. These 21 products are primarily for strengthening heart functions, boosting resuscitation, invigorating blood circulation and removing blood stasis, etc. They all have therapeutic effects.

Advice Sought

12. Members are invited to note the contents of the paper.

Food and Health Bureau

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