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Panel on Health Services

Background brief prepared by the Legislative Council Secretariat for the meeting on 28 February 2017

Regulation of pesticide residues and heavy metal in Chinese herbal medicines

Purpose

This paper provides background information and summarizes the concerns of members of the Panel on Health Services ("the Panel") on the regulation of pesticide residues and heavy metal in Chinese herbal medicines.

Background

2. At present, the Chinese Medicine Ordinance (Cap. 549) ("the Ordinance") provides the statutory framework for the regulation of the practice, use, trading and manufacturing of Chinese medicines in Hong Kong. According to the Ordinance, Chinese herbal medicines means Chinese herbal medicines specified in Schedules 1 and 2 to the Ordinance. At present, Schedule 1 contains 31 Chinese herbal medicines which are known to be potent, whereas Schedule 2 contains 574 other Chinese herbal medicines commonly used in Hong Kong.

3. All Chinese medicines traders who engage in a business of retail and wholesale of these Chinese herbal medicines are required under the Ordinance to obtain relevant licence from the Chinese Medicines Board. In addition, those Chinese herbal medicines specified in Schedule 1 may only be sold or dispensed based on prescription by registered Chinese medicine practitioners. Separately, according to the Import and Export Ordinance (Cap. 60), any person who wish to import or export any of the 31 Chinese herbal medicines specified in Schedule 1 and five Chinese herbal medicines specified in Schedule 2 to the Ordinance (namely, Flos Campsis, processed Radix Aconiti, processed Radix

Aconiti Kusnezoffii, Radix Clematidis and Radix Gentianae) must first apply for an import or export licence from the Department of Health ("DH").

4. Separately, to safeguard public health and promote the development of Chinese medicine, DH developed the Hong Kong Chinese Materia Medica Standards ("HKCMMS") aiming to provide applicable and adoptable reference standards for the Chinese medicine industry. HKCMMS cover, among others, indicators relating to the safety and quality of Chinese herbal medicines, such as contents of pesticide residues, heavy metals and aflatoxin. So far, the research on 236 Chinese herbal medicines commonly used in Hong Kong[1] has been completed, and seven volumes of HKCMMS have been published.

5. To monitor the quality and safety of the Chinese herbal medicines regulated under the Ordinance, DH will collect samples of Chinese herbal medicines from the market for testing by the Government Laboratory on a regular basis. Testing items include pesticide residues, heavy metals and morphological identification.

Deliberations of the Panel

6. The subject of regulation of pesticide residues in Chinese herbal medicines was discussed by the Panel of the Fifth Legislative Council. The deliberations and concerns of members are summarized in the following paragraphs.

Number of samples taken for testing

7. Noting that there were more than 6 000 licensed retailers and wholesalers of Chinese herbal medicines in Hong Kong, some members were concerned about whether the taking of some 30 Chinese herbal medicines samples for testing was adequate. Questions were raised about the setting of the number of samples and the international standard in this regard.

8. The Administration explained that a two-pronged approach had been adopted by DH in testing Chinese herbal medicines. Through its routine market surveillance system, DH collected around 30 samples of Chinese herbal medicines each month for testing based on the risk-based approach, which was

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[1] According to the Administration, the criteria for selection of Chinese herbal medicines include (a) popularity in the local community; (b) international concern in respect of their safety and quality; (c) high economic value in the local market; and (d) priority being accorded to the Chinese herbal medicines listed in the two schedules to the Ordinance.

commonly adopted internationally, with the emphasis on those Chinese herbal medicines commonly used by the general public or prone to adverse events. Based on the information gathered from various channels which included the adverse events reporting system, complaints lodged by members of the public and referrals from other Government departments, special follow-up tests would be conducted on those Chinese herbal medicines suspected of dubious quality. About 220 special follow-up tests were conducted each year.

9. On members' concern about the regulatory control over those Chinese herbal medicines not listed in Schedules 1 and 2 to the Ordinance, such as honeysuckle, the Administration advised that some commonly-used Chinese herbs were classified as food and were regulated under other relevant food legislation such as the Public Health and Municipal Services Ordinance (Cap. 132), which sought to ensure that food for sale was fit for human consumption. Under the Food Surveillance Programme, food samples including, among others, commonly-used Chinese herbs, would be taken by the Centre for Food Safety for microbiological, chemical and radiation testing.

Testing methods and standards

10. Members noted that the samples of Chinese herbal medicines would be subject to, among others, 37 tests for pesticide residues by the Government Laboratory. If pesticide residues were found in the samples during the first stage of testing, the Government Laboratory would proceed to test for pesticide residues in the decoctions of the Chinese herbal medicines concerned in order to simulate the circumstance of human consumption. Some members considered that the Administration should publicize the results of the first-stage tests to remind the public of the safe use of the Chinese herbal medicines concerned.

11. According to the Administration, it was inappropriate to publicize the results of the first-stage tests as this might deter some patients from taking the Chinese herbal medicines concerned and hence affecting their treatment. The Administration stressed that since Chinese herbal medicines should only be consumed after decoction, it was more appropriate to adopt the results of the second-stage testing for human risk assessment. Hence, the Chinese herbal medicines concerned would be considered suitable for human intake if its test result of pesticide residues in the decoction was satisfactory.

12. On members' concern about the health risk assessment of Chinese herbal medicines, the Administration advised that the safety reference values of Acceptable Daily Intake ("ADI"), which was established by the Joint Food Agricultural Organization/World Health Organization Meeting on Pesticide Residues, were adopted as a reference standard for assessing the health risk of

pesticide residues in Chinese herbal medicines. The ADI of a pesticide was the estimate of the amount of a pesticide in food or drinking water, expressed on a body-weight basis, that could be ingested daily over a lifetime without appreciable health risk to the consumer. It reflected the safety limits of pesticide intake by human.

Regulation of Chinese herbal powder

13. Concern was raised about the regulation of Chinese herbal powder for direct oral intake. Members were advised that Chinese herbal medicines grinded into powder by retailers for oral consumption were included in the market surveillance system for testing against pesticide residues and heavy metals. As regards proprietary Chinese medicines prescribed by Chinese medicine practitioners, including those in granule or powder form, they had to be registered before they could be imported, manufactured or sold in Hong Kong.

Relevant papers

14. A list of the relevant papers on the Legislative Council website is in the **Appendix**.

Council Business Division 2
Legislative Council Secretariat
23 February 2017

Appendix

Relevant papers on the regulation of pesticide residues and heavy metal in Chinese herbal medicines

Committee	Date of meeting	Paper
Panel on Health Services	16.12.2013 (Item V)	Agenda Minutes CB(2)1007/13-14(01)

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