For information
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Legislative Council Panel on Health Services

Regulation of Pesticide Residues in Chinese Herbal Medicines

PURPOSE

This paper aims to brief Members on the Administration's work in regulating Chinese herbal medicines and testing for pesticide residues in Chinese herbal medicines.

BACKGROUND

Regulatory framework for Chinese herbal medicines

2. Since the enactment of the Chinese Medicine Ordinance (Cap. 549) ("CMO") in 1999, we have strived to establish and improve the regulatory regime for Chinese medicines to ensure their safety, quality and efficacy, in order to safeguard the health of the general public and consumers' rights, as well as to enhance consumers' confidence in taking Chinese herbal medicines and proprietary Chinese medicines ("pCm"). The Chinese Medicine Council of Hong Kong ("CMC") is an independent statutory body established under the CMO. The Chinese Medicines Board set up under the CMC is responsible for formulating and implementing various regulatory measures for Chinese medicine, and the Department of Health ("DH") is responsible for carrying out relevant regulatory measures.

3. Currently, we have put in place a stringent regime for the regulation of Chinese herbal medicines and Chinese medicine traders. As for Chinese herbal medicines, since Chinese herbal medicines are sundry in types, they have been classified into different categories under the current regulatory mechanism according to their toxicity and degree

of popularity in Hong Kong. Having regard to the need of regulatory control, a total of 605 types of Chinese herbal medicines have been included in the CMO and listed respectively in Schedules 1 and 2 of the CMO. In general, the CMO imposes the following regulatory controls on the Chinese herbal medicines listed respectively in its Schedules 1 and 2 –

(i) The 31 types of Chinese herbal medicines in Schedule 1 and the 574 types of Chinese herbal medicines in Schedule 2 can only be sold by licensed retailers or wholesalers in the premises specified in their licences;

(ii) Control for the 31 types of Chinese herbal medicines listed in Schedule 1 is more stringent as they are toxic. In this regard, no medicine traders shall possess or sell the Chinese herbal medicines listed in Schedule 1 unless specified in their licences;

(iii) Chinese herbal medicines listed in Schedule 1 must be dispensed in accordance with a prescription given by a registered Chinese medicine practitioner and cannot be sold by retail. In addition, retailers and wholesalers of Chinese herbal medicines have to keep a record of dispensation/sales of Chinese herbal medicines listed in Schedule 1; and

(iv) All Chinese herbal medicines in Schedule 1 and five Chinese herbal medicines in Schedule 2 (namely Radix Clematidis, Flos Campsis, processed Radix Aconiti, processed Radix Aconiti Kusnezoffii and Radix Gentianae) are subject to import and export control.

4. Regarding the regulation of Chinese medicine traders, any person who is engaged in the business of the retail and wholesale of Chinese herbal medicines must obtain a relevant licence from the Chinese Medicine Board and comply with the relevant practising guidelines which include ensuring the quality of Chinese herbal medicines. The DH conducts regular inspections to the premises of licensed retailers and wholesalers of Chinese herbal medicines to ensure their compliance with the requirements of the law and the practising guidelines. As at October 2013, CMC has issued licences to around 4 440 retailers and 880 wholesalers of Chinese herbal medicines, and around 290 manufacturers and 1 070 wholesalers of pCm.

Testing of Chinese herbal medicines

5. To monitor the quality and safety of the Chinese herbal medicines regulated under the CMO, the DH has put in place a market surveillance system under which samples of Chinese herbal medicines would be collected from the market for testing on a regular basis. To safeguard public health, the DH has also established a mechanism for reporting adverse incidents relating to Chinese medicines to collate information through various channels, so as to conduct risk assessment, management and reporting. If any substandard Chinese herbal medicines are found, the DH may take actions such as ordering the Chinese medicine traders concerned to recall the products and referring the cases to the CMC for follow-up actions (in cases of violating the CMO or relevant practising guidelines), and issuing relevant press statements. To further enhance the capability of Hong Kong in handling problems related to the safety and quality of Chinese medicines, the DH has maintained close liaison and established a communication mechanism with the relevant Mainland regulatory authorities.

6. Currently, the DH draws samples of around 30 Chinese herbal medicines every month for testing by the Government Laboratory ("GL"). Testing items include pesticide residues, heavy metals and morphological identification. The daily testing work of the GL is carried out in accordance with international standard ISO/IEC 17025[1]. At present, samples of Chinese herbal medicines taken will be subject to 37 tests for pesticide residues[2]. The GL will first conduct tests on the samples of Chinese herbal medicines for pesticide residues. If pesticide residues are found in the above samples, the GL will proceed to the next stage of testing, i.e. testing for pesticide residues in the decoctions of the Chinese herbal medicines concerned, so as to simulate the circumstances of human consumption. The Scientific Committee on Hong Kong Chinese

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[1] The "General requirements for the competence of testing and calibration laboratories" jointly formulated by the International Organization for Standardization ("ISO") and the International Electrotechnical Commission ("IEC") contains both management system requirements and technical requirements.

[2] In addition to fulfilling the requirements of ISO/IEC 17025, the tests for pesticide residues in Chinese herbal medicines are also accredited by the Hong Kong Accreditation Service. The GL is subject to periodic assessments by local and overseas experts. Since 2005, the GL has been representing the Hong Kong Special Administration Region as a designated institute in the field of metrology in chemistry under the Mutual Recognition Arrangement of the International Committee for Weights and Measures.

Materia Medica Standards ("HKCMMS") also considers that the testing for pesticide residues in the decoctions of Chinese herbal medicines is a closer simulation of the circumstances of actual consumption/exposure, hence it is more appropriate to adopt the results of the second-stage testing for human risk assessment.

7. At present, the standards for raw materials of herbs or natural plant preparations set out by the World Health Organization ("WHO") and other countries or regions (e.g. the US Pharmacopoeia and the European Union Pharmacopoeia) are adopted for testing the pesticide residues in the Chinese herbal medicines sold in Hong Kong. As mentioned in paragraph 6 above, if the test results reveal the presence of excessive pesticide residues in the decoctions of the Chinese herbal medicines concerned, the DH may take a series of follow-up actions accordingly, including the issue of press statements. Thus far, the tests conducted by the DH on the decoctions of Chinese herbal medicines have not found any pesticide residues which exceed the safety standards.

Results of a test on Chinese herbal medicines conducted by a green group

8. A green group conducted a test on samples of Chinese herbal medicines of Hong Kong and the Mainland in June 2013 and alleged that a high level of toxic pesticide residues was found in many of the Chinese herbal medicines tested. The Government was very concerned about the matter. The DH immediately requested the green group to provide detailed information such as the testing methods, the standards adopted and the testing institute, with a view to taking follow-up actions and conducting appropriate risk assessments. According to the supplementary information provided to the DH by the green group, the test had made reference to the Maximum Residue Limits ("MRLs") recommended by the European Union ("EU"), i.e., the maximum concentration of pesticide residues legally permitted in food under the EU's Good Agricultural Practice ("GAP"). In general, MRL reflects the quality of food and is not an absolute standard for assessing the level of food safety. The green group also did not conduct tests on the amount of pesticide residues in the decoctions of the Chinese herbal medicines concerned. Moreover, if the safety reference values of Acceptable Daily Intake ("ADI") are taken as the testing standard, the DH has found that the pesticide residues as measured in their maximum consumption quantity for the Chinese herbal medicines purchased in Hong Kong, with pesticide residues exceeding the EU's MRL as alleged by the green

group's test results, **do not exceed** the safety reference values of ADI for pesticide as developed by the Joint Food and Agriculture Organisation / WHO Meeting on Pesticide Residues.

9. When promoting the safe use of Chinese herbal medicines, the DH has emphasized that Chinese herbal medicines must be used according to one's own body constitution and illness. Hence, members of the public should consult a Chinese medicine practitioner before taking Chinese herbal medicines, and follow the instructions of Chinese medicine practitioners (e.g. soaking, "cooked first" or "added later" etc.) when preparing decoctions of Chinese herbal medicines.

10. The DH will continue ensuring the safety of Chinese herbal medicines through the existing regulatory and surveillance mechanism. It will also continue to conduct relevant tests for pesticide residues and heavy metal. In addition, it will maintain close liaison with the Mainland authorities and enhance the exchange of information on Chinese herbal medicines in accordance with the established communication mechanism.

HKCMMS

11. The DH established the Hong Kong Chinese Materia Medica Standards Office in 2001 to co-ordinate and manage the HKCMMS project, with a view to providing a stronger evidence-based reference on the safety and quality of Chinese herbal medicines and addressing the safety and quality issues such as contamination with heavy metals and other contaminants.

12. Since 2001, the HKCMMS project has developed standards for commonly used Chinese herbal medicines in phases. The criteria for selection of Chinese herbal medicines include: (i) popularity in the local community; (ii) international concern in respect of their safety and quality; (iii) high economic value in the local market; and (iv) priority being accorded to the Chinese herbal medicines listed in the two schedules of the CMO.

13. The Chief Executive highlighted in his 2009-10 Policy Address and 2011-12 Policy Address the importance of expediting the setting of standards for Chinese herbal medicines commonly used in Hong Kong. The objective is to extend to the Chinese Materia Medica coverage to about 200 Chinese herbal medicines by 2012. The DH has already

completed the research work of setting standards for around 200 Chinese herbal medicines as at the end of 2012. We hope that the HKCMMS will set objective standards for the testing on the safety of Chinese medicines in future.

ADVICE SOUGHT

14. Members are invited to note the content of this paper.

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