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中華人民共和國香港特別行政區政府總部食物及衞生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

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Ms Maisie LAM
Clerk to Bills Committee on Chinese Medicine (Amendment) Bill 2017
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

Dear Ms LAM,

Bills Committee on Chinese Medicine (Amendment) Bill 2017

In response to the request of the Chairman of the Bills Committee on Chinese Medicine (Amendment) Bill 2017 at the meeting on 21 November 2017, the Government has set out the relevant reference materials in the Annex.

Yours sincerely,

(James LAM)
for Secretary for Food and Health

Encl.
c.c. Department of Justice (Attn: Ms Mandy NG)
Department of Health (Attn: Dr Edwin TSUI)

Annex

Bills Committee on Chinese Medicine (Amendment) Bill 2017

Purpose

This paper sets out the Government's response to the issues raised on the Chinese Medicine (Amendment) Bill 2017 at the Bills Committee meeting on 21 November 2017.

Regulation of the sale of herbal teas in Chinese herbal tea shops

2. Herbal teas containing Chinese medicines ingredients which are sold in Chinese herbal tea shops are not subject to the regulation of the Chinese Medicine Ordinance (CMO) (Cap. 549). At present, business operations involving the preparation of bottled drinks or herbal teas are required to obtain the relevant food factory licences or restricted food permits from the Director of Food and Environmental Hygiene under the existing legislation. Applicants for the relevant licences or permits are also required to submit to the Food and Environmental Hygiene Department (FEHD) the formula of each type of herbal tea to be sold on the premises and the quantity of each ingredient in the formula. The FEHD will then send the information to the Director of Health for vetting. The Department of Health (DH) is responsible for providing expert advice on the quantity of each ingredient in the formula in respect of the herbal teas containing Chinese medicines ingredients which are to be sold in these shops, so as to ensure that the formulae of these herbal teas are safe for consumption.

3. The Public Health and Municipal Services Ordinance (PHMSO) (Cap. 132) provides general protection for purchasers of food and drugs. Specifically, section 54 of the PHMSO stipulates the basic regulation that food and drugs unfit for human consumption/use shall not be sold. The FEHD and the DH may take prosecution action against any person who sells problem food or drugs by exercising the power conferred on them by the legislation mentioned above.

Regulation of intermediate products

4. According to the CMO, Chinese medicines traders who wish to carry on a business in the manufacture of proprietary Chinese medicines (pCms) shall obtain a licence issued by the Chinese Medicines Board (CMB) under the Chinese Medicine Council of Hong Kong (CMCHK). The manufacture of pCms means the whole process of producing a preparation for sale, using processed herbal medicines as major ingredients, together with appropriate excipients and in accordance with prescribed manufacturing process, and it is specialised work. During the process, intermediate products may be generated. An intermediate product means, according to the Chinese Medicines Regulation (CMR) (Cap. 549F), a substance or compound generated

in the course of manufacture of a pCm and which is to be used in further preparation or production process of the medicine. Regulatory provisions are stipulated in the CMR in respect of the storage, production and sale of intermediate products by licensed pCm manufacturers. The requirements are summarised as follows (see Appendix I for the provisions):

(i) section 16 of the CMR provides for the general duties of holders of manufacturer licences, including providing a suitable environment and adequate facilities for the storage of intermediate products, taking adequate steps to prevent contamination, conducting examinations on the products by a responsible person before they are sold, setting up and maintaining a system of recall, and retaining control samples; and

(ii) sections 18 and 19 of the CMR provide for other duties of holders of manufacturer licences, including the keeping of manufacturing and transaction records of intermediate products.

5. Apart from the above provisions concerning the regulation of intermediate products, sections 16 to 19 of the CMR also provide for the acquisition or receipt of ingredients, as well as the storage, production and sale of pCms by licensed pCm manufacturers. A person who contravenes section 18(1), 18(2), 19(1), 19(2) or 19(3) of the CMR commits an offence and is liable on conviction to a maximum penalty of a fine at level 6 (i.e. HK$100,000) for each contravention.

6. The *Practising Guidelines for Manufacturers of Proprietary Chinese Medicines* established by the CMCHK also set out guidelines for pCm manufacturers in respect of the requirements on the personnel, factory, fittings and equipment, scope of business, complaint and recall system of pCms/intermediate products, and keeping of records in order to enhance their practising standards. Contravention of the CMO and/or the practising guidelines by Chinese medicines traders may result in prosecution, disciplinary action by the CMCHK, and cancellation of licences in serious cases.

7. To sum up, every step of the manufacturing process of pCms is already subject to comprehensive regulation under the existing legislation to ensure the manufacture of good pCms of which the quality and safety can be guaranteed to safeguard the public health.

Sections 16, 18 and 19 of the Chinese Medicines Regulation (Cap. 549F)

Section 16 General Duties of holders of manufacturer licences

A holder of a manufacturer licence shall ensure that-

(a) the premises to which the licence relates are maintained in sanitary condition;

(b) where ingredients or packing materials, or both, used for manufacturing proprietary Chinese medicines are stored in the premises-

(i) adequate space; and

(ii) adequate and suitable facilities,

(iii) for storing the ingredients or packing materials, or both, as the case may be, are provided in the premises;

(c) the facilities (if any) for storing ingredients or packing materials, or both, as the case may be, are maintained in good condition;

(d) where any Schedule 1 medicine is stored in the same premises with any Schedule 2 medicine or material of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, the Schedule 1 medicine is stored effectively separated from the Schedule 2 medicine or material;

(e) fittings and equipment suitable for use in the manufacturing process specified in the licence are provided in the premises;

(f) the fittings and equipment used in the manufacturing process are maintained in good condition;

(g) where intermediate products generated or proprietary Chinese medicines manufactured in the course of manufacture, or both, are stored in the premises-

(i) adequate space; and

(ii) adequate and suitable facilities,

(iii) for storing the products or medicines, or both, as the case may be, are provided in the premises;

(h) the facilities (if any) for storing intermediate products or proprietary Chinese medicines, or both, are maintained in good condition;

(i) the humidity, lighting, temperature and ventilation of the part of the premises provided for-

(i) storing ingredients or packing materials;

(ii) manufacturing proprietary Chinese medicines; or

(iii) storing intermediate products or proprietary Chinese medicines

are suitable for their respective purposes;

(j) where any ingredient is used in the manufacturing process, the ingredient is examined by a responsible person before it is used to ensure its identity and quality;

(k) no manufacturing process is carried out in the premises otherwise than under the supervision of a responsible person;
(l) adequate steps have been taken to prevent contamination of any ingredient or packing material used, any intermediate product generated or any proprietary Chinese medicine manufactured in the course of manufacture;
(m) each batch of intermediate product generated or proprietary Chinese medicine manufactured in the course of manufacture, or both, is examined by a responsible person before it is sold or distributed by the holder of the licence to ensure its quality;
(n) no proprietary Chinese medicine that he manufactures is sold or distributed by him after its expiry date;
(o) each container or package of intermediate product generated or proprietary Chinese medicine manufactured in the course of manufacture is sufficiently stout to prevent leakage and contamination arising from the ordinary risks involved in handling the products or medicines, as the case may be;
(p) no intermediate product generated or proprietary Chinese medicine manufactured in the course of manufacture is consigned for transport unless suitable arrangements have been made to prevent leakage and contamination arising from the ordinary risks involved in the delivery and transport of the product or medicine, as the case may be;
(q) a system of control is set up and maintained, which will enable the rapid and, so far as practicable, complete recall of any intermediate product generated or proprietary Chinese medicine manufactured in the course of manufacture which has been sold or distributed in the event of the product or medicine, as the case may be, being found to be dangerous, injurious to health or unfit for human consumption;
(r) a control sample of each batch of intermediate product (if any) generated in the course of manufacture which has been sold is retained, under suitable conditions of storage, in the premises from the date on which the batch of product is generated until the expiry of 2 years from the date of the last transaction in the batch of product; and
(s) a control sample of each batch of proprietary Chinese medicine (if any) manufactured in the course of manufacture is retained, under suitable conditions of storage, in the premises from the date of the manufacture until the expiry of 2 years from the expiry date of the batch of medicine.

Section 18 Other duties of holders of manufacturer licences - keeping of manufacturing records

(1) A holder of a manufacturer licence shall ensure that the following particulars in respect of eachmanufacturing process of a proprietary Chinese medicine carried out by him are recorded-
(a) the name of the intermediate product generated or proprietary Chinese medicine manufactured from the manufacturing process, or both, as the case may be;

(b) the quantity of the batch of product or medicine, or both, as the case may be;
(c) the expiry date and batch number of the batch of medicine (applicable only where a proprietary Chinese medicine is manufactured from the manufacturing process);
(d) the name and quantity of each ingredient or packing material used in the manufacturing process;
(e) a description of each manufacturing method used; and
(f) the date on which the manufacturing process-
(i) begins; and
(ii) is completed.

(2) The licence holder shall also ensure that-
(a) the particulars mentioned in subsection (1) (other than those referred to in subsection (1)(b) and (f)(ii)) are recorded within 72 hours after the manufacturing process begins;
(b) the particulars mentioned in subsection(1)(b) and (f)(ii) are recorded within 72 hours after the manufacturing process is completed; and
(c) subject to subsection (3), the record prepared pursuant to subsection (1) is retained in the premises to which the licence relates from the date of preparation of the record until the expiry of 2 years-
(i) in the case where the record relates to a batch of intermediate product, from the date of the last transaction in the batch of product or the date when the batch of product is used up by the licence holder, whichever is later; or
(ii) in the case where the record relates to a batch of proprietary Chinese medicine, from the expiry date of the batch of medicine.

(3) Where the record prepared pursuant to subsection (1) relates to a batch of intermediate product and proprietary Chinese medicine, the record shall be retained until the expiry of 2 years from the latter of the dates referred to in subsection (2)(c)(i) or (ii).

Section 19 Other duties of holders of manufacturer licences – keeping of transaction records

(1) A holder of a manufacturer licence shall ensure that the following particulars in respect of every transaction whereby a batch of intermediate product generated or a batch of proprietary Chinese medicine manufactured in the course of manufacture is sold or distributed by him are recorded -
(a) the date of the transaction;
(b) the name and quantity of the batch of product or medicine sold or distributed, as the case may be;
(c) the name, address and telephone number of the person to whom he sells or distributes the batch of product or medicine, as the case may be;
(d) the batch number of the batch of medicine (applicable only where the

transaction relates to a proprietary Chinese medicine); and

(e) the reference number of the invoice or other document evidencing the transaction.

(2) The licence holder shall ensure that -

(a) the particulars mentioned in subsection (1) are recorded within 72 hours after the completion of the transaction; and

(b) the record prepared pursuant to subsection (1) is retained in the premises to which the licence relates from the date of preparation of the record until the expiry of 2 years-

(i) in the case where the transaction relates to a batch of intermediate product, from the date of the transaction; or

(ii) in the case where the transaction relates to a batch of proprietary Chinese medicine, from the expiry date of the batch of medicine.

(3) The licence holder shall also ensure that

(a) every transaction mentioned in subsection (1) is evidenced by an invoice or other document which contains the particulars mentioned in that subsection; and

(b) the invoice or other document evidencing the transaction is retained in the premises to which the licence relates from the date of the transaction until the expiry of 2 years from the dates referred to in subsection (2)(b)(i) or (ii), as the case may be.