



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

Our Ref : FHB/H/24/2
Your Ref : CB2/PL/HS

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20 April 2017

Ms Maisie LAM
Clerk to Panel
Legislative Council Panel on Health Services
Legislative Council Complex
1 Legislative Council Road
Hong Kong
(Fax : 2185 7845)

Dear Ms LAM,

Legislative Council Panel on Health Services
Issues relating to “Registration and Regulation of Health Food”

In response to the letter dated 8 March 2017 from Hon. CHAN Han-pan to the Chairman of the Legislative Council Panel on Health Services (HS Panel) on the issues relating to registration and regulation of health food, our detailed reply is as follows.

According to the Chinese Medicine Ordinance (Cap. 549) (CMO), Chinese herbal medicines (Chm) mean the toxic Chm specified in Schedule 1 of the CMO and the Chm specified in Schedule 2 of the CMO which are commonly used in Hong Kong. Chm specified in Schedule 1 must be dispensed in accordance with a prescription by a registered Chinese medicine practitioner and cannot be sold by retail. Besides, any products which fulfil the definition of proprietary Chinese medicines (pCm) must be registered by the Chinese Medicines Board (CMB) under the Chinese Medicine Council of Hong Kong (CMCHK) before they can be imported, manufactured or sold in Hong Kong. To be registered in Hong Kong, all pCm must meet the registration requirements regarding safety, quality and efficacy as prescribed by the CMB.

The CMO stipulates that Chinese medicines traders who wish to carry on a business in the retail of Chm, wholesale of Chm, wholesale of pCm or manufacture of pCm shall first obtain a licence issued by the CMB and comply with the relevant practicing guidelines, which include ensuring that Chinese medicines traded by them are of good quality.

There is no international standard on the definition of and regulation for “health food”. The Government has imposed specific control by adopting a multi-pronged approach to regulate through a series of legislation based on the nature, composition, content of claims made, method of usage, dosage and packing specification, etc. of individual products. To protect public health, we have also adopted various targeted measures to monitor the products in the market with a view to ensuring their safety and that their functional claims and composition are true.

Products composed solely of Chinese medicines as active ingredients with therapeutic or health-preserving effect are regulated by the CMO. Products containing medicinal ingredients or presented as having properties for treating or preventing disease in human beings or animals are regulated by the Pharmacy and Poisons Ordinance (Cap. 138) (PPO). The Department of Health (DH) will exercise the power imposed by relevant ordinances to regulate the concerned medicines. In sum, the above products are subject to the following control –

- (a) Products that fall within the definition of pCm or pharmaceutical products under the CMO and the PPO respectively must fulfil the relevant requirements in respect of safety, quality and efficacy and be registered according to the relevant regulations before they can be sold legally in the market;
- (b) According to the PPO, pharmaceutical products must be properly labelled with information about the composition and the manufacturer etc. Moreover, over-the-counter medicines must also be labelled with dosage and usage directions. All registered pharmaceutical products shall bear the Hong Kong registration number in the format of “HK-XXXXX” on their package. The public can search the details of the registered pharmaceutical products by entering the English name of the products concerned or their Hong Kong registration numbers into the “Search Drug Database” at the website of the DH’s Drug Office (http://www.drugoffice.gov.hk/eps/do/tc/consumer/search_drug_database.html).
- (c) According to the CMO, pCm must be labelled with the stipulated particulars, which include the name of the holder of the certificate of registration, ingredients, dosage and method of usage, etc. The

package insert of pCm must also include the name of the holder of the certificate of registration or the name of the manufacturer who produces the pCm. Registered pCm shall also bear the Hong Kong pCm registration number in the format of “HKC-XXXXXX” or “HKP-XXXXXX”. The public can check the details of the registered pCm in the website of the CMCHK (http://www.cmchk.org.hk/pcm/chi/#main_listpcm.htm).

The Public Health and Municipal Services Ordinance (Cap. 132) (PHMSO) provides general protection to purchasers of food and drug. Section 54 of the PHMSO stipulates the basic regulation that food and drug unfit for human consumption/use shall not be sold. With respect to food safety, products fall within the definition of “food” under the PHMSO are regulated by that ordinance. The main provisions of the PHMSO cover offences related to sale of food unfit for consumption and adulteration of food, composition and labels of food, seizure and destruction of food unfit for consumption, etc. The subsidiary legislation of PHMSO provides regulations in specific areas (including individual food categories, specific harmful substances and food industry).

To protect the public from being induced by advertisements or health claims and thereby seeking improper self-medication that may result in delay in seeking medical treatment, the Undesirable Medical Advertisements Ordinance (Cap. 231) (UMAO) amended in 2005 prohibits/restricts the publication of any advertisement likely to lead to the use of any medicine, surgical appliance or treatment for the purpose of prevention or treatment of certain diseases or conditions specified in schedule 1 and 2 of the UMAO. The UMAO also prohibits/restricts the use of six types of health claims as specified in schedule 4 of UMAO in advertising orally consumed products (irrespective to whether the product is a medicine but does not include a product which is customarily consumed as food or drink). In addition, the DH has established a system to regularly screen advertisements. Actions would be taken in accordance with the law if the content of the advertisement violates the UMAO. The claims of orally consumed products including health products are also subject to regulation by relevant provisions or codes under the Trade Descriptions Ordinance (Cap. 362), Broadcasting Ordinance (Cap. 562) and Broadcasting (Miscellaneous Provisions) Ordinance (Cap. 391). The Customs and Excise Department and the Communications Authority will take enforcement and regulatory actions in accordance with the relevant provisions and codes.

Fructus Psoraleae is a Chm specified in Schedule 2 of the CMO. In this regard, a retailer licence in Chm is required for retailing or dispensing of Fructus Psoraleae. To address the adverse events related to the purchase and consumption of medicines by the public without seeking advice from

healthcare professionals, the DH has been attaching great importance to the publicity and education for the general public. This includes strengthening efforts in issuing safety alerts and announcements on drugs or pCm which do not comply with the relevant requirements, updating the DH's website to enhance information dissemination, and providing more health information on different categories of drugs and pCm. It has also disseminated messages about the safe use of medicines to the general public, the trade and other stakeholders through various channels. Members of the public who feel unwell should seek advice from healthcare professionals. In addition, they are advised not to self-medicate or consume products with therapeutic or health-preserving claims without seeking advice from healthcare professionals.

In addition, before purchasing Chinese medicines, members of the public are advised to have a general understanding of their constitution, cause of disease, clinical condition or consult the Chinese medicine practitioners. They should not self-prescribe Chinese medicines. Medical advice should be sought for those who are having persistent and deteriorating conditions, or feeling unwell after consumption of Chinese medicines. Members of the public may visit the website of Chinese Medicine Division of the DH for educational information about Fructus Psoraleae (Chinese only):
http://www.cmd.gov.hk/html/b5/health_info/publication/AdverseEvents22.html

The Government will continue to closely monitor the regulatory measures of other regions and the situation of the local market, and conduct risk assessment. Having balanced public safety and the trade's concerns, the Government will review the relevant legislation and regulatory arrangement in due course, which includes considering the need to formulate specific legislation to impose more targeted control on different products. Before formulating more targeted regulation, the Government will continue to enforce prevailing relevant legislation with a view to regulating products sold in the market which contain non-Chinese medicine ingredients.

We thank Members of the HS Panel for expressing concerns about this matter.

Yours sincerely,



(Mr James LAM)
for Secretary for Food and Health

c.c. Director of Health
(Attn: Assistant Director (Traditional Chinese Medicine))