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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 Joanne Mak
Clerk to Subcommittee on
Issues Relating to the Development of Chinese Medicine
Legislative Council Panel on Health Services
Legislative Council Complex
1 Legislative Council Road
Hong Kong

Dear Ms Mak,

Panel on Health Services
Subcommittee on Issues Relating to the Development of Chinese Medicine
Administration's responses on issues raised at the meetings held on 16 December 2014 and 26 January 2015

At the meetings of the Subcommittee on Issues Relating to the Development of Chinese Medicine held on 16 December 2014 and 26 January 2015, Members discussed the registration, testing and development of proprietary Chinese medicines (pCm) and the introduction of Good Manufacturing Practice (GMP) requirements to pCm, and listened to the views and suggestions of some deputations of Chinese medicine associations on the above issues. The supplementary information requested by Members is set out below.

Registration of pCm

2. According to the Chinese Medicine Ordinance (Cap. 549) (CMO), all applications for pCm registration must be made to the Chinese Medicines Board

(CMB) under the Chinese Medicine Council of Hong Kong, and the pCm must meet the requirements in terms of safety, quality and efficacy for safeguarding public health. The Department of Health (DH) provides professional and administrative support for the CMB and assists in implementing regulatory measures for Chinese medicines. In applying for pCm registration, information about the safety, quality and efficacy of the pCm must be submitted as required by the CMB. In the light of the sales history of pCm in Hong Kong, the CMO provides a transitional arrangement so that pCm with a long history will continue to be on sale as long as safety requirements are met.

3. The pCm registration system has been implemented since 19 December 2003. In vetting applications for pCm registration, the CMB mainly considers whether the pCm fulfil the prescribed registration requirements regarding safety, quality and efficacy. As at 31 January 2015, the CMB received about 17 980 applications for pCm registration, of which some 14 110 applications also applied for transitional registration at the same time. About 7 470 of the pCm registration applications were rejected by the CMB. The reasons for rejection and the numbers of rejected cases are set out below :

Reasons for rejection	**Number of applications for transitional registration**	**Number of applications for non-transitional registration**
Failed to furnish the required documents, information and / or samples for registration, including the three acceptable test reports for safeguarding public health [1]	3 810	1 350
Withdrawn by applicants	1 605	540
Not fulfilling the definition of pCm	125	25
Not fulfilling the application eligibility	15	0
Total	5 555	1 915

4. When formulating the registration requirements for pCm, the CMB already made reference to the regulatory requirements on pCm in other places, took into account the practical circumstances of the trade, and collated views of

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[1] The three test reports are: (1) heavy metals and toxic element test report; (2) pesticide residue test report; and (3) microbial limit test report.

the trade through extensive consultations. As long as the statutory requirements of the CMO are complied with, and the safety, quality and efficacy of the pCm are guaranteed, the CMB will from time to time review and update the requirements and arrangements on submitting registration documents or transitional registration particulars having regard to the circumstances of the trade and the factor of Chinese medicine development, with a view to expediting the processing procedures and responding to the aspirations of the trade. Individual applicants who have difficulties in complying with the registration requirements may approach the CMB for assistance.

5. To safeguard public health and uphold procedural integrity, the CMB is obliged to carefully vet each of the registration applications even if there are a large number of such applications. Given the uniqueness and complexity of the Chinese medicine prescription, the CMB will allow sufficient time for following up each case. In requesting applicants to submit the required registration documents, the CMB will allow a reasonable period of time for them to submit outstanding documents or test reports. Moreover, some applicants may fail to submit precise information about the prescription/manufacturing method due to such reasons as confidentiality, giving rise to inconsistencies in the registered particulars. In this case, the CMB will have to require the applicants to clarify and follow up.

6. Besides, some applicants, during the application process, may amend or correct product information (e.g. trade mark, packing specification, information about the manufacturer and information about the applicant) because of business needs or operational strategies. In this regard, the CMB will take some time for follow-up and require the applicants to submit the supplementary information for verification, so as to ensure that such amendments will not affect the safety, quality and efficacy of the products.

7. With the increasing popularity of the use of Chinese medicines, the CMB will from time to time review new scientific research findings, information regarding the safety of Chinese medicines and amendments to other local legislation (e.g. Protection of Endangered Species of Animals and Plants Ordinance (Cap. 586) and Air Pollution Control Ordinance (Cap. 311)), and where necessary, introduce additional registration requirements or update these requirements correspondingly so as to comply with the updating requirements of local legislation and protect public safety. The factors mentioned in paragraphs 5, 6 and this paragraph affect the progress of processing applications for pCm registration, thus lengthening the time for vetting these applications.

8. To assist the trade in applying for pCm registration, the CMB has issued guidelines on the requirements of registration applications, so as to help the trade understand clearly the specific requirements in respect of the reports required to be submitted. Moreover, the DH actively communicates with the trade through various channels such as sharing sessions, briefings or meetings with individual applicants. The Chinese Medicines Traders Newsletter published by the CMB informs the trade and applicants of the requirements of pCm registration and testing as well as other latest arrangements on pCm registration. In view of the difficulties faced by the trade in pCm testing, the DH regularly holds briefing sessions on "Technical Issues in Registration of pCm" to brief the trade on the issues of concern, in order to help them understand the requirements of pCm registration and the technical requirements for the establishment of quality specifications. The Government also provides technical support (such as information on laboratory testing) for the trade to facilitate their compliance with the registration requirements, and continues to maintain close contact with the trade. For details, please refer to LC paper No. CB(2)322/14-15(01).

9. On the support services for pCm registration and testing, currently nine local laboratories, as well as 17 Mainland laboratories recognised by the China Food and Drug Administration and the CMB, provide pCm testing services for the trade. Where necessary, we may request the relevant Mainland regulatory authorities to extend the list of recommended laboratories to cover more laboratories qualified for conducting pCm testing.

10. Besides, there are a number of non-governmental organisations providing technical support for pCm manufacturers. For instance, the Hong Kong Baptist University and the Hong Kong University of Science and Technology have each set up a research laboratory to provide the trade with technical support for Chinese medicine testing. The Hong Kong Institute of Biotechnology (HKIB) also provides the trade with various consultancy services, including those on pCm product registration. Moreover, the trade may apply for funding under various funding schemes and the Small and Medium Enterprise (SME) Funding Schemes currently administered respectively by the Innovation and Technology Fund (ITF) and the Trade and Industry Department (TID). These funding schemes are industry-neutral and enterprises / organisations meeting the relevant requirements, including those from Chinese medicine sector, are eligible to apply (see Annex IV of LC Paper No. CB(2)453/14-15(02) for details).

Transitional arrangements for holders of Notice of confirmation of transitional registration of pCm (HKP) issued with the Certificate of registration of pCm (HKC)

11. For cases of conversion from the HKP to the HKC, the CMB has decided to extend the deadline for replacing labels and package inserts from six months to 12 months. Individual product holders may apply to the CMB for further extension if they have such a need. The extension can allow product holders sufficient time to deal with the transitional/interfacing matters. The details are as follows :

(1) A product holder who is granted HKC status will receive from the CMB a notification letter with a return slip. He must complete the return slip and indicate in it a preferred effective date for the HKC of his product, which should be **within 12 months** after he is notified of the granting of HKC status. Product holders issued with the HKC must ensure that starting from the effective date, the particulars of the pCm for sale on the market are identical with the registered particulars of that pCm.

(2) If a product holder fails to complete the replacement of old packaging label and insert for his product before the effective date, he must apply to the CMB for extending the deadline. The CMB will consider such applications on a case-by-case basis. The extended period approved by the CMB will not be longer than **12 months**.

12. For products issued with HKP, they can still be sold legally on the market even if their quality specification and stability test reports cannot be submitted before 30 June 2015, until they are formally registered and issued with the HKC, or until their registration applications have been refused, or until such date to be promulgated by the Secretary for Food and Health in the Gazette, whichever date is the earliest. The CMB will continue to vet applications for conversion of transitional registration to formal registration according to the registration requirements set out in the Application Handbook for Registration of Proprietary Chinese Medicines. To date, the CMB has not discussed whether to extend the deadline for submitting the above reports.

Classification of pCm registration

13. The CMO provides a transitional registration arrangement in the light of the sales history of pCms and the practical circumstances in Hong Kong.

Under the arrangement, applications for transitional registration should be made within the specified application period (from 19 December 2003 to 30 June 2004) for pCm manufactured, sold or supplied for sale in Hong Kong on 1 March 1999. Those pCm assessed by the CMB as meeting the criteria will be transitionally registered in accordance with the CMO (please refer to LC Paper No. CB(2)322/14-15(01) for the relevant arrangement).

14. The pCm already on sale for decades in Hong Kong should be eligible for transitional registration application and be issued with the HKP for local sale according to the arrangements stated in paragraph 13 above. The CMB will only issue the HKC to HKP holders after the safety, efficacy and quality of the pCm have been substantiated.

15. Pursuant to the existing classification guidelines, the CMB has clearly set out the classification of pCm registration. For example, application for pCm registrationwith an ancient prescription (which is documented in Chinese medicines bibliography in or before the Qing dynasty) may be made under the category of "established medicines". There are a number of sub-categories (such as the modified ancient prescriptions) under the category of "established medicines". This gives sufficient flexibility to the CMB to consider granting a registration status to a pCm product which does not fulfil the definition of an ancient prescription but has long been sold in Hong Kong. The CMB conducts objective and professional assessments according to the standards or evidence set out in authoritative information on traditional Chinese medicines, including the impact of the pCm under application on the health of their users.

16. In summary, as the current pCm registration system developed by the CMB can ensure the safe use of drugs in the community, the Government does not see a need to change the pCm registration arrangement or impose a total ban on the sale of transitionally-registered pCm.

Introducing GMP requirements to pCm

17. In the interest of public safety, production of pCm must be enhanced in terms of both manufacturing technology and management to meet the latest pharmaceutical requirements stipulated in the GMP. When planning the introduction of GMP requirements to pCm, the Government will balance the actual capability of the trade with the intensity of regulation. To this end, the DH is consulting the trade through various channels and holding relevant briefings. With the premise that public interests will be safeguarded, the Government will consider carefully the views of the trade and their actual

circumstances in drawing up a timetable to progressively implement GMP requirements for pCm production. As a matter of fact, such policy is still at consultation stage and the Government has yet to fix an implementation schedule.

18. To further support the trade in implementing the GMP, the DH has conducted GMP briefings, attended meetings with Chinese medicine associations and met different pCm manufacturers. Also, the DH has invited local and Mainland experts to brief Chinese medicines traders on GMP requirements and relevant training and consultancy services, and share their experience in the implementation of GMP. The DH will meet with manufacturers who are interested in the implementation of GMP and already have preliminary proposal on the design of their factory premises, and explain to them the current requirements of GMP guidelines. In addition, the ITF has launched different funding programmes to support universities, research institutions and companies to conduct applied research projects relating to research and development and testing of Chinese medicines (see paragraph 10 above). For example, the General Support Programme (GSP) under the ITF provide support to various projects (including technical training) which would help promote the development of Chinese medicine industry. In June 2013, the GSP approved funding to support a one-year project conducted by the HKIB to provide basic GMP training for all local Chinese medicine manufacturers free of charge. The project includes a series of activities such as basic GMP training courses, GMP facility visits, surveys by questionnaires and on-site company interviews, which allow the participating Chinese medicine manufacturers to have a better grasp of the basic knowledge, expert advice and financial considerations involved in the implementation of GMP. All eligible organisations may apply for GSP funding to support activities organized to address the needs of the Chinese medicine industry, such as establishing GMP training platform.

19. Moreover, to tie in with the long-term development of relevant industries, the Government and the Hong Kong Science and Technology Parks Corporation are reviewing the effectiveness and long-term development direction of the Science Park and the industrial estates (IEs). The scope of this review includes formulating a new IE policy to enhance the value chain of the innovation and technology industries in Hong Kong, and to optimise the land use of the Science Park and further revitalise the IEs.

20. Regarding the GMP contract manufacturing arrangements under the three-year project carried out by the HKIB, the main focus of the project is to set up a GMP product development and technical support platform for oral solid

pCm products. Apart from providing support for participating manufacturers to help them comply with the requirements of GMP contract manufacturing, the project will also offer various technical support services to the local Chinese medicine industry, such as consultancy on GMP establishment, training platform for GMP personnel, and providing local pCm manufacturers with a turnkey solution through technology transfer for the manufacturing of GMP-complied pCm products. The project is expected to bring direct benefits and important support to the local Chinese medicine industry, particularly the SMEs, by helping them manufacture quality and safe pCm products, as well as strengthening their capability to comply with GMP requirements in the future. In addition, as mentioned in paragraph 10 above, the SME Funding Schemes launched by the TID provide funding to manufacturers for them to meet with various business needs.

Chinese Medicines Traders Licence

21. According to the CMO, Chinese medicines traders who carry on a business in the retail of Chinese herbal medicines, wholesale of Chinese herbal medicines, wholesale of pCm or manufacturing of pCm shall first obtain a licence issued by the CMB. The issue of licences to Chinese medicines traders is subject to their compliance with the requirements of the CMO regarding premises, hygiene, storage, facilities and personnel qualifications. Section 29 of the Chinese Medicines Regulation (CMR) (a subsidiary legislation under the CMO) also stipulates that Chinese medicines traders licences issued under the above-mentioned provisions shall be valid for two years.

22. Furthermore, licensed Chinese medicines traders may apply to the CMB for renewal of licence under the CMO. According to section 29 of the CMR, Chinese medicines traders licences renewed under the above-mentioned provisions shall be valid for two years or for such shorter period as considered appropriate by the CMB.

23. The CMB has developed the Chinese Medicines Traders Licence Application Handbook to provide applicants of Chinese medicines traders licences with guidelines and set out details of the relevant licensing system and licence application procedures to facilitate licence applications. In addition, the CMB has prepared a series of documents and information, such as the Guidance Notes of Application for Renewal of Chinese Medicines Trader Licences, the Documentation Checklist and the Licensing Arrangements of Chinese Herbal Medicines Tradeshow Licence for reference and use by the trade. Furthermore, the CMB will regularly update the industry on information about the Chinese Medicines Traders Licence through the Chinese Medicines Traders Newsletter.

The DH also helps the trade understand and comply with the relevant regulatory requirements through various means, such as sharing sessions and Health Ambassador visits.

Requirements on the batch number of Chinese herbal medicines

24. In accordance with sections 13 and 14 of the CMR, a holder of a wholesaler licence in Chinese herbal medicines shall ensure that an invoice or other document is kept for the Chinese herbal medicine acquired, received, sold or distributed by him for the purpose of recording the particulars of every transaction as specified in the CMR. Besides, it is stipulated in section 8 of the CMR that a holder of a retailer licence in Chinese herbal medicines shall ensure that every transaction whereby a Chinese herbal medicine is acquired or received by him is evidenced by an invoice or other document containing the specified particulars. The licence holder shall also ensure that the invoice or other document is retained on the premises to which the licence relates for a period of not less than two years from the date of the transaction.

25. These requirements are not new measures. In as early as 2003, the CMB already formulated practising guidelines in respect of all kinds of Chinese medicines traders licences (including the practicing guidelines for wholesalers and retailers for Chinese herbal medicines) listed in the CMO. The Practising Guidelines for Wholesalers of Chinese Herbal Medicines specify the particulars that should be contained in the transaction documents, including the batch number of the herbal medicine. Moreover, the Practising Guidelines for Retailers of Chinese Herbal Medicines require that retailers of Chinese herbal medicines, when carrying out inspection and acceptance of herbal medicines, should ensure that the batch number is specified on the purchase invoice.

26. In July 2014, the Chinese Medicines Traders Committee (CMTC) of the CMB discussed the issue on the failure to provide particulars which should be contained in the transaction invoices of wholesalers/retailers of Chinese herbal medicines. The CMTC noted that the practising guidelines had clearly specified that transaction invoices or other documents should contain the batch number of Chinese herbal medicines, which could help traders quickly trace the source of goods and date of supply. In case Chinese herbal medicines which fail to meet the safety and quality standards are found on the market, such information will also enable traders to accurately assess the scope of impact and quickly recall the problematic products. Where necessary, the DH may also notify the Mainland drug authority to curb the supply at source to safeguard public health.

27. Representatives of the DH held two meetings with representatives of the trade and stakeholders in January 2015 to have a clear picture of their business situation and listen to their opinions. The DH has relayed the concerns of the trade to the CMB for consideration. Furthermore, representatives of the DH visited the wholesalers of Chinese herbal medicines in Sheung Wan on 9 February 2015 to better understand the operation of the trade on-site.

28. The DH and the CMB will continue to maintain close communication with the trade, and will conduct extensive consultation before implementing any measures that might affect the trade.

29. In Hong Kong, there is currently no specific legislation for regulating health food products. Nevertheless, orally consumed products sold on the market are classified into two categories, namely medicine and food, according to their ingredients. They are also subject to more specific regulation under different legislation according to the content of their claims. At present, there is no uniform international standard for the term and definition of health food products. However, to protect public health, we have implemented various specific measures to monitor the relevant products on the market to ensure that they are safe and the claimed effects and ingredients are true. Relevant measures are set out in **Appendix I**.

Yours sincerely,

(Miss Fiona Chau)
for Secretary for Food and Health

Regulating Health Food Products

We have taken the following measures and put in place various legislation to ensure the safe use of health food products.

Undesirable Medical Advertisements Ordinance

2. In order to protect the public from being induced by therapeutic or health claims to seek improper self-medication, which may result in delay in seeking treatment, the Undesirable Medical Advertisements Ordinance (Cap. 231) (UMAO) prohibits the publication of any advertisement likely to lead to the use of any medicine, surgical appliance or treatment for prevention or treatment of certain diseases or conditions in human beings as specified in the Schedules to the UMAO. Starting from 1 June 2012, the UMAO also prohibits or restricts the advertising of six types of health claims as specified in the newly added Schedule for some orally consumed products.

3. In addition, the Department of Health (DH) has put in place a regular market surveillance mechanism, a mechanism for reporting adverse drug reactions and a complaint mechanism against any persons violating the above legislation. The DH will continue to keep close surveillance of the situation and take appropriate follow-up actions.

Food and Drugs (Composition and Labelling) Regulations

4. According to the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W), prepackaged food should be marked or labelled as appropriate. Besides, pursuant to section 61 of the Public Health and Municipal Services Ordinance (Cap. 132) (PHMSO), any person who sells any food which is presented with a label that falsely describes the food, or is calculated to mislead, will be guilty of an offence. The PHMSO also stipulates that any person who publishes an advertisement which falsely describes any food, or is likely to mislead, will be guilty of an offence. The Centre for Food Safety of the Food and Environmental Hygiene Department will take appropriate enforcement actions in respect of any non-compliant food products.

Publicity and Education

5. A major task of the Drug Office, established under the DH in September 2011, is to enhance publicity and public education. This includes strengthening the efforts to issue safety alerts and announcements on non-compliant drugs or health products, fully updating the Drug Office's website to enhance information dissemination, and providing more health information on different types of drugs and health products. Last year, the DH conducted four exchange sessions on the content of the UMAO and conveyed the message about the safe use of Chinese medicine to the general public, the trade and other stakeholders through various channels.

6. We will continue to step up enforcement actions under the existing legislation.