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Report of the Bills Committee on
Chinese Medicine (Amendment) Bill 2017

Purpose

This paper reports on the deliberations of the Bills Committee on Chinese Medicine (Amendment) Bill 2017 ("the Bills Committee").

Background

2. The Chinese Medicine Ordinance (Cap. 549) ("the CM Ordinance"), enacted in July 1999, provides a statutory framework for the regulation of the practice, use, trading and manufacturing of Chinese medicines in Hong Kong. The Chinese Medicine Council of Hong Kong ("CMCHK") is established under the CM Ordinance to develop and implement these regulatory measures. The Chinese Medicines Board ("CMB") is one of the two boards[1] established under CMCHK, as the board responsible for regulatory measures for Chinese medicines.

3. Under the CM Ordinance, all products falling within the definition of proprietary Chinese medicine ("pCm")[2] must be registered with CMB before they can be imported, manufactured and/or sold in Hong Kong. To get registered in Hong Kong, a pCm must fulfil the registration requirements regarding safety, quality and efficacy as prescribed by CMB. Separately, all Chinese medicines traders who engage in a business of retail and wholesale of Chinese herbal

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[1] The other board is the Chinese Medicine Practitioners Board.

[2] Under section 2(1) of the CM Ordinance, "proprietary Chinese medicine" refers to any proprietary product composed solely of any Chinese herbal medicines and/or any materials of herbal, animal or mineral origin customarily used by the Chinese as active ingredients; formulated in a finished dose form; and known or claimed to be used for the diagnosis, treatment, prevention or alleviation of any disease or any symptom of a disease in human beings, or for the regulation of the functional states of the human body.

medicines[3], or manufacture or wholesale of pCms are required under the CM Ordinance to apply to CMB for a relevant Chinese medicines traders licence before the commencement of their business. Manufacturers holding a pCm manufacturer licence may apply to CMB for a certificate for manufacturer to certify that they follow the requirements of good practices in manufacture and quality control of pCms (i.e. the Good Manufacturing Practice ("GMP") Certificate).

4. Under the Chinese Medicines Regulation (Cap. 549F) ("the Regulation"), licensed wholesalers of Chinese herbal medicines, licensed manufacturers of pCms and licensed wholesalers of pCms are required to set up and maintain a system of control to enable the rapid and, so far as practicable, complete recall of any Chinese herbal medicine, intermediate product [4] generated or pCm manufactured in the course of manufacture which has been sold or distributed by the traders concerned in the event that the products or medicines are found to be dangerous, injurious to health or unfit for human consumption.

5. The judgment of a judicial review case handed down by the Court of First Instance ("CFI") on 21 May 2015[5] concluded that the the Director of Health ("Director")[6] had no lawful power under the CM Ordinance to instruct the licensed wholesaler concerned to recall the two suspected unregistered pCms in question on 27 March 2014 and the decision to issue the instruction to recall was ultra vires. Upon a review of the CM Ordinance and its subsidiary legislation, the Administration has also found that there is currently no provision providing that an unlicensed trader must carry out recall actions regarding pCms or Chinese herbal medicines which may pose threats to public health.

The Bill

6. The Administration introduced the Chinese Medicine (Amendment) Bill 2017 ("the Bill") into the Legislative Council ("LegCo") on 14 June 2017 to amend the CM Ordinance and its subsidiary legislation to confer power on the Director to make a Chinese medicine safety order ("CMSO") to prohibit the sale of Chinese medicines and other substances or compounds generated in the course

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[3] Under section 2(1) of the Ordinance, "Chinese herbal medicine" means any of the substances specified in Schedule 1 or 2 to the CM Ordinance.

[4] Under section 2 of the Regulation, "intermediate product" means 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.

[5] *Man Hing Medical Supplies (International) Ltd v Director of Health* [2015] 3 HKLRD 224

[6] Under section 2(1) of the CM Ordinance, "Director" also includes a Deputy Director of Health.

of manufacture of pCm and/or to recall such products in specified circumstances; and to provide for related matters.

The Bills Committee

7. At the House Committee meeting on 16 June 2017, Members agreed to form a Bills Committee to study the Bill. The membership list of the Bills Committee is in **Appendix I**.

8. Under the chairmanship of Ms Alice MAK, the Bills Committee has held five meetings with the Administration. The Bills Committee has also received oral representations from 15 organizations and two individuals at two of these meetings. A list of organizations and individuals which/who have given views to the Bills Committee is in **Appendix II**.

Deliberations of the Bills Committee

Chinese medicines and related products covered under CMSO

9. Members are in principle supportive of the legislative proposal to confer power on the Director to make a CMSO to prohibit the sale of a Chinese medicine or related product and/or to recall such product in specified circumstances in order to further protect public health. They note that under the proposed new section 138A of the CM Ordinance, Chinese medicine or related product means a Chinese herbal medicine or a pCm (as currently defined in the CM Ordinance), or an intermediate product (the definition of which is proposed to be amended in the Bill[7]). Some members including Mr CHAN Han-pan, Dr KWOK Ka-ki and Mr SHIU Ka-fai have pointed out that registration of pCm is subject to a set of stringent registration requirements in respect of the safety, quality and efficacy of the product concerned. They are, however, concerned about the public health risk that might arise from the various orally consumed products composing mainly of Chinese herbal medicines but added other materials or substances (e.g. vitamins) as active ingredients being sold in the market and bottled drinks containing Chinese herbal medicines, such as Spica Prunellae bottled drinks or herbal teas claiming to have heat-clearing effect. Members note that these products are currently not regulated under the CM Ordinance and, if the Bill is passed, would not be subject to CMSO as they do not fall within the definition of pCm under the CM Ordinance.

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[7] Please see paragraphs 14 and 15 below for details.

10. The Administration has advised that the Public Health and Municipal Services Ordinance (Cap. 132) provides general protection for purchasers of food and drugs that do not fall within the definition of pCm under the CM Ordinance but fulfill the definition of "food" under the Public Health and Municipal Services Ordinance.[8] This apart, the labels and advertisements of products with health claims are regulated by the Undesirable Medical Advertisements Ordinance (Cap. 231), whereas the claims of health products are subject to the regulation of the Trade Descriptions Ordinance (Cap. 362). Separately, 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 required to submit to the Food and Environmental Hygiene Department ("FEHD") the formula of each type of herbal tea containing Chinese medicines ingredients to be sold on the premises and the dosage of each ingredient in the formula. FEHD will send the information to the Department of Health ("DH") for vetting to ensure that the formulae of these products are safe for human consumption. As at the end of December 2017, there were 398 valid Chinese Herb Tea Permits issued by FEHD. In 2017, the Centre for Food Safety took eight samples in these permitted premises for testing of plasticisers, pathogens, etc. All testing results were satisfactory.

11. Members have enquired about whether a licensed pCm manufacturer could manufacture health products (i.e. non-pCm products) in their licensed premises. According to the Administration, a pCm manufacturer licence only authorizes its holder to conduct the business of manufacturing pCms in the premises specified. A licensed pCm manufacturer who plans to manufacture non-pCm products in the licensed premises should make a declaration to CMB and provide objective justifications for the measures taken to prevent cross contamination as well as the effectiveness of these measures in order to ensure that the Chinese medicine products manufactured therein will be free from contamination.

12. The Administration has informed the Bills Committee that notwithstanding the safeguards set out in paragraphs 10 and 11 above, it is exploring amendments to the definition of pCm in the CM Ordinance so as to strengthen the regulation. CMB under CMCHK has established a working group, which comprises Chinese medicine experts, Chinese medicines industry representatives and representative

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[8] Under the Public Health and Municipal Services Ordinance, "food" includes drink; ice; chewing gum and other products of a similar nature and use; smokeless tobacco products; and articles and substances used as ingredients in the preparation of food, but does not include live animals or live birds, other than live aquatic products; fodder or feeding stuffs for animals, birds or aquatic products; or medicine as defined by section 2(1) of the Pharmacy and Poisons Ordinance (Cap. 138) or Chinese herbal medicine or pCm as defined by section 2(1) of the CM Ordinance.

from the Government Laboratory, to examine the issue and provide advice on the way forward. Subject to the recommendations to be made by the working group and the view of CMB, extensive consultations would be conducted on any proposed amendments to the definition of pCm in the CM Ordinance. The Administration would, as and when appropriate, propose the relevant legislative amendments in a separate legislative exercise.

13. While agreeing with the need to amend the definition of pCm in the CM Ordinance to cast the net wider for the protection of public health, some members including the Chairman, Mr CHAN Han-pan, Dr Helena WONG and Mr SHIU Ka-fai have urged for a holistic review of the CM Ordinance within the term of the Sixth Legislative Council. In particular, Mr CHAN Han-pan considers that there is an imminent need to introduce more classification categories of pCms with different levels of safety and quality testing requirements. The Administration has advised that it would need to further discuss with the Chinese medicine industry to understand the stakeholders' views on the current provisions of the CM Ordinance before a concrete timetable could be drawn up for a review of the CM Ordinance. In view of members' strong views, the Administration has undertaken that it would keep the Panel on Health Services informed of the way forward in this regard.

14. Members share the concern of some deputations about what will constitute "intermediate product" under the regulatory regime for Chinese medicine products. They note that the term is currently defined in section 2 of the Regulation as "a substance or component that is generated in the course of manufacture of a pCm and *which is to be used* in the further preparation or production process". Clauses 4 and 7 of the Bill seek to amend the above definition to "a substance or component that is generated in the course of manufacture of a pCm and *that is intended for use* in the further preparation or production process" for the respective purposes of the making of a CMSO and the regulation of the storage, production and sale of intermediate products by licensed pCm manufacturers. They have raised queries over the difference in meaning of the phrases "is to be used" and "is intended for use".

15. The Administration has advised that the proposed amended definition of "intermediate product" as currently drafted in the Bill would introduce a mental element requiring proof of the trader's subjective intention to use the product for the stated purpose. Since it has no intention to change the policy intent regarding what will constitute "intermediate product", the Administration has agreed to move an amendment to replace the words "intended for use" in the definition of "intermediate product" as provided for in the proposed new section 138A of the CM Ordinance with "to be used" as currently appears in section 2 of the Regulation so that the question as to whether the product is to be used for the

stated purpose would continue to be determined objectively having regard to all relevant circumstances.

Principles of the making of a CMSO

Grounds for prohibiting sale and directing recall

16. The proposed new sections 138C and 138D of the CM Ordinance provide for the grounds on which the Director may make a CMSO to prohibit the sale and/or to direct a recall of a Chinese medicine or related product. It is proposed that the Director may make a CMSO when he or she has reasonable grounds to believe that (a) a Chinese herbal medicine, a pCm and/or an intermediate product is dangerous or injurious to health, or unfit for use by human beings; (b) the CMSO is necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health; or (c) the medicine has been sold, dispensed, distributed or manufactured in contravention of the CM Ordinance, such as Chinese herbal medicines being sold or distributed without licence, unregistered pCms being sold, pCms being sold without a package insert in contravention of the prescribed requirements, and pCms being sold in a package not labelled in the prescribed manner.

17. Members in general welcome the proposed amendments which would enable the Director to direct any person, including an unlicensed trader and a shell company, to stop selling and/or to recall from the market any Chinese medicines or related products with public health risk. They have sought information about the circumstances under which a Chinese medicine or related product would be regarded as being "dangerous or injurious to health" or "unfit for use by human beings", and a CMSO is considered necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health. Some members take the view that the making of a CMSO has to be supported by objective evidence, such as laboratory report proving that the products concerned contain harmful substances and consumption by members of the public may be dangerous or harmful to their health.

18. The Administration has advised that examples whereby a Chinese medicine or related product would be regarded as being "dangerous or injurious to health" include wrongly labelled products (e.g. Unprocessed Radix Aconiti Lateralis being labelled as Processed Radix Aconiti Lateralis) and deficient products deviating from the quality specifications which would result in serious health consequences. A Chinese medicine product containing industrial dye is an example of products that are "unfit for use by human beings". A product with incorrect dosage labelling and an improper storage of products which will cause a danger to public health (e.g. asbestos-containing Chinese medicines) are

respective examples whereby a CMSO is necessary in order to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health. The Administration has advised the Bills Committee that all previous recall cases which might relate to public health were supported by sufficient objective evidence before DH took the appropriate action (e.g. issuance of a press release and initiation of prosecution). If the Bill is passed, DH would process the recall cases based on the same criteria.

19. The Legal Adviser to the Bills Committee has enquired about the reason why the proposed new sections 138C(a)(ii), (b)(iv) and (c)(i) and 138D(a)(iii), (b)(iv) and (c)(i) of the CM Ordinance refer to "unfit for use by human beings", rather than "unfit for human consumption" as currently referred to in sections 11(i), 16(q) and 20(g) of the Regulation. The Administration has explained that since the proposed new sections would apply to both external use (such as cream and plaster) and internal use (such as tablets and capsules), "unfit for use by human beings" would be wide enough to cover both scenarios.

Regulatory standards for Chinese herbal medicines available in the market

20. Members note that under DH's market surveillance system to monitor the quality and safety of the 605 types of Chinese herbal medicines regulated under the CM Ordinance[9], around 45 samples of these Chinese herbal medicines are collected every month from the market for testing. Items subject to regular testing include 37 pesticide residues (including 20 organochlorine pesticides[10] and 17 organophosphorus pesticides[11]), four heavy metals contents (namely lead, arsenic, cadmium and mercury[12]) and morphological identification. Separately, targeted tests are conducted on samples of Chinese herbal medicines obtained from other channels which include adverse drug reaction reporting system, public

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[9] There are 31 types of toxic Chinese herbal medicines and 574 types of commonly used Chinese herbal medicines listed in Schedule 1 and Schedule 2 to the CM Ordinance respectively.

[10] The 20 organochlorine pesticide items and the respective maximum residue limits are: sum of Aldrin and Dieldrin (0.05 milligrammes per kilogramme ("mg/kg")); sum of *cis*-chlordane, *trans*-chlordane and oxychlordane (0.05 mg/kg); sum of *p,p'*-DDT, *o,p'*-DDT, *p,p'*- DDE and *p,p'*-TDE (1.0 mg/kg); endrin (0.05 mg/kg); sum of heptachlor and heptachlor epoxide (0.05 mg/kg); hexachlorobenzene (0.1 mg/kg); sum of α-, β- and δ-isomers (0.3 mg/kg); lindane (0.6 mg/kg); and sum of quintozene, pentachloroaniline and methyl pentachlorophenyl sulphide (1.0 mg/kg).

[11] The 17 organophosphorus pesticide items that should not be detected are: Dichlorvos; Methamidophos; Trichlorphon; Omethoate; Diazinon; Dimethoate; Malathion; Isocarbophos; Triazophos; Parathion; Parathion-methyl; Monocrotophos; Phosphamidon; Chlorpyriphos; Acephate; Ethion; and Methidathion.

[12] The respective maximum limit (intake) of these heavy metals contents are: lead (179 microgram per day ("mcg/day")), arsenic (1 500 mcg/day), cadmium (3 500 mcg/dose) and mercury (36 mcg/day).

complaints and referrals from other government departments. Tests for targeted items may involve morphological identification, physiochemical testing and testing for adulteration with Western drug ingredients. Some members including Dr KWOK Ka-ki and Dr Helena WONG take the view that to ensure the effective implementation of CMSO after the passage of the Bill, DH should strengthen its market surveillance system such that sub-standard Chinese herbal medicines in the market could be identified and recalled in a timely manner to safeguard public health.

21. The Administration has advised that the number of samples of Chinese herbal medicines taken by DH for regular testing has increased from about 30 to 45 per month starting from February 2017. In the first half of 2017, DH collected a total of 289 samples of Chinese herbal medicines, of which 64.8% was taken from retailers of Chinese herbal medicines, 18.5% from wholesalers of Chinese herbal medicines and 16.7% from other channels (such as patients of Chinese herbal medicines poisoning and Chinese medicine clinics), for testing.

22. Given that the Director would in future decide on the need to issue CMSOs for Chinese herbal medicines in the light of the existing regulatory standards for routine surveillance if the Bill is passed, Dr Helena WONG is concerned about whether these standards are on par with the relevant international standards. In particular, she has queried about the difference in certain regulatory standards for routine surveillance and the quality reference limits set out under the Hong Kong Chinese Materia Medica Standards ("HKCMMS")[13], as well as the reason why sulphur dioxide residue is not a regular testing item. For the latter, it is specified under Part 1 of the Pharmacopoeia of the People's Republic of China (2015 edition) that except as otherwise provided in other provisions, the limit of sulphur dioxide residue in general Chinese herbal medicines and decoction pieces (except minerals) is no more than 150 parts per million. Referring to the Administration's plan to introduce a legislative proposal to, among others, update the standards of maximum permitted concentrations of metallic contaminants in food, she has

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[13] DH launched the HKCMMS project in 2002. An International Advisory Board is established under the project to, among others, give advice on the principles, methodologies, parameters and analytical methods for the development of HKCMMS. The standards cover the source, description, identification, assay and tests (namely on the limits of heavy metals, pesticide residues, mycotoxins, foreign matter, ash and determination of water). To date, eight editions of HKCMMS covering the reference standards of 275 types of commonly used Chinese herbal medicines in Hong Kong have been published. The quality reference limits of pesticide residues and heavy metal contents stipulated in HKCMMS are applicable to 267 out of these 275 types of Chinese herbal medicines, excluding the eight types of Chinese herbal medicines of mineral origin or certain types of Chinese herbal medicines otherwise specified.

enquired whether the Administration will in tandem review and update the relevant standards applicable to Chinese herbal medicines.

23. The Administration has informed the Bills Committee that the regulatory bodies around the world have not formulated a standardized set of maximum permitted limits of pesticide residues and heavy metals for Chinese herbal medicines. The current standards used by DH for testing of pesticide residues and heavy metal contents in Chinese herbal medicines sold in Hong Kong are formulated by CMCHK with reference to other international standards, including those of the World Health Organization and those set by different countries or regions on herbs or raw materials of natural plant preparations, such as the Pharmacopoeia of the People's Republic of China[14], the United States Pharmacopoeia[15] and the European Pharmacopoeia[16]. CMCHK has selected these 37 pesticide residues and four heavy metals for testing the Chinese herbal medicines regulated under the CM Ordinance after considering their toxicity, residual effect, popularity and prohibition or restriction in import, export and usage internationally. Given that it is proposed that the HKCMMS Volume 9 to be released in 2018-2019 will include the testing of sulphur dioxide residue, CMB will later consult the industry on the adoption of the testing method for sulphur dioxide residue promulgated by HKCMMS as a routine quality monitoring method of Chinese herbal medicines. As regards morphological identification of the Chinese herbal medicines, a standard will be formulated for each medicine, based on statutory pharmacopoeias and authoritative publications such as the Pharmacopoeia of People's Republic of China, the Chinese Materia Medica and the Chinese Materia Medica Standards in Guangdong Province.

24. The Administration has explained that the focus of the regulatory standards under DH's market surveillance system is on ensuring public safety to prevent causing injuries to health after use, whereas the HKCMMS standards are set as reference standards on the quality of individual Chinese herbal medicines. Separately, Chinese herbal medicines should be treated differently from food in that the use of the former and their medication are based on personal physical conditions and medical needs, and Chinese herbal medicines are normally not taken daily like food. The standards currently used for testing the limits of heavy metal and toxic element contents in Chinese herbal medicines are calculated on

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[14] The Pharmacopoeia of the People's Republic of China (2015 Edition) has set maximum residue limits ("MRLs") for up to 16 organochlorine pesticides for four types of Chinese herbal medicines. According to the Administration, these 16 organochlorine pesticides have already been included in the 37 pesticide residues that will be tested under DH's market surveillance system for Chinese herbal medicines.

[15] The United States Pharmacopoeia 39 has set MRLs for 106 pesticides (including both organochlorine pesticides and organophosphorus pesticides).

[16] The European Pharmacopoeia 8.6 has set MRLs for 105 pesticides.

the basis of maximum intake per day or dose to assess the impact on human beings. CMB will review the limits and scope of heavy metal contents in Chinese herbal medicines under the market surveillance system from time to time.

25. Members note that the testing of Chinese herbal medicines is carried out by the Government Laboratory, aiming to see if pesticide residues and heavy metal contents exist in the decoctions of the Chinese herbal medicines. In the first stage of the two-stage tests conducted by the Government Laboratory, preliminary tests are conducted on the Chinese herbal medicine samples in their raw state. If the test results are found in compliance with the limits set by CMB, no further testing will be conducted, otherwise the second stage tests will be conducted to see if pesticide residues and heavy metal contents exist in the decoctions of the Chinese herbal medicines concerned (not applicable if the Chinese herbal medicines concerned "can be directly taken after being grounded into powder", a condition as mentioned in Part 1 of the Pharmacopoeia of the People's Republic of China 2015). According to the Administration, 22 out of the 258 samples of Chinese herbal medicines collected for testing during DH's regular market surveillance in the first half of 2017 were found to contain pesticide residues in the first stage of testing and needed to be tested in the second stage.[17] Pointing out that not all Chinese herbal medicines are to be taken in the form of decoctions, Dr Helena WONG is of the view that results of the first-stage test, rather than that of the second-stage test as proposed by the Administration, should be adopted in assessing whether a Chinese herbal medicine may have public health risk and warrant the issuance of a CMSO. Some other members including Mr CHAN Han-pan and Mr SHIU Ka-fai, however, hold a contrary view. They consider that the current testing method is appropriate.

26. The Administration has advised that the testing of pesticide residues in the decoction of Chinese herbal medicines is considered to be a closer simulation of condition during human consumption which is more appropriate for human risk assessment. The procedures and scope of the tests are recognized by both CMB and the international expert group of the Scientific Committee set up under the HKCMMS research project. The Administration has stressed that the results of the first-stage test are for screening purpose only. It does not mean that the samples concerned will certainly have adverse effects on health. If the results of the second-stage tests show that the limits of pesticide residues are exceeded, DH

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[17] The 22 Chinese herbal medicines samples concerned include a sample of Fructus Corni; a sample of Fructus Cnidii; three samples of Rhizoma Alismatis; two samples of Herba Plantaginis; two samples of Fructus Aurantii Immaturus; two samples of Herba Artemisiae Scopariae; four samples of Rhizoma Chuanxiong; two samples of Herba Violae; two samples of Radix Asteris; a sample of Herba Leonuri; a sample of Folium Sauropi; and a sample of Flos Campsis.

will conduct investigations and carry out the associated risk management procedures. Results of the second-stage tests so far have proved that pesticide residues and heavy metal contents in all samples of Chinese herbal medicines concerned did not exceed the MRLs set by CMB.

Import requirements for Chinese herbal medicines

27. Some members including Dr KWOK Ka-ki and Dr Helena WONG are of the view that apart from putting in place a market surveillance system, it would be of paramount importance to monitor the quality and safety of Chinese herbal medicines at import level. While it is required under the Practising Guidelines for Wholesalers of Chinese Herbal Medicines issued by CMB that licensed wholesalers of Chinese herbal medicines should purchase herbal medicines or processed herbal medicines only from reputable suppliers, they are concerned about how the Administration could ensure that the above requirement has been complied with. Noting that the manufacturing process of those Chinese medicine products supplied to the Hospital Authority must meet the GMP standards, they consider that it should be made mandatory that the licensed wholesalers have to purchase herbal medicines or processed herbal medicines from suppliers meeting the GMP requirements. DH should also take samples of the imported herbal medicines or processed herbal medicines for testing, as is the case of the imported food. Alternatively, importers should be required to provide test reports issued by local accredited laboratories to prove the quality and safety of the imported medicines.

28. The Administration has advised the Bills Committee that at present, importation and exportation of 36 types of Chinese herbal medicines has to be covered by an import or export licence issued by DH.[18] It should be noted that the majority of the Chinese herbal medicines currently available in the market of Hong Kong are Chinese medicine decoction pieces imported from the Mainland. Under the Drug Administration Law of the People's Republic of China, the establishment of a drug manufacturer in the Mainland shall be subject to approval by the local drug regulatory department. Drug manufacturers shall conduct production according to the GMP for Pharmaceutical Products. The production of Chinese medicine decoction pieces in the Mainland shall also meet the requirements of GMP and be granted with the Drug GMP Certificate after passing the inspection by the local food and drug regulatory department of the respective

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[18] The 36 types of Chinese herbal medicines include all 31 types of toxic Chinese herbal medicines listed in Schedule 1 to the CM Ordinance and five types of Chinese herbal medicines listed in Schedule 2 to the CM Ordinance (namely Radix Clematidis, Flos Campsis, processed Radix Aconiti, processed Radix Aconiti Kusnezoffii and Radix Gentianae).

province, autonomous region or municipality under the China Food and Drug Administration. In addition, the establishment of a wholesaler or retailer of processed herbal medicines in the Mainland shall be granted with the Drug Supply Certificate by the local drug regulatory department, while the wholesaling and retailing of Chinese medicine decoction pieces in the Mainland shall put in place rules and regulations to ensure the quality of drugs.

29. The Administration has further advised that licensed wholesalers of Chinese herbal medicines are currently required under the Practising Guidelines for Wholesalers of Chinese Herbal Medicines to keep the relevant purchase records and transaction documents for a period of not less than two years from the date of transaction to enable the tracing of the source of herbal medicines or processed herbal medicines purchased where necessary. DH will conduct inspections on the premises of licensed retailers and wholesalers of Chinese herbal medicines on a regular basis to ensure their compliance with the requirements of the law and the practising guidelines. Contravention of the CM Ordinance and/or the practising guidelines by Chinese medicines traders may result in prosecution, disciplinary action by CMCHK, and cancellation of licences in serious cases. In the first half of 2017, a total of 3 677 inspections, covering 3 115 retailers and 562 wholesalers[19], were conducted.

Manufacturing standards for pCms

30. Dr KWOK Ka-ki and Dr Helena WONG are of the view that the GMP requirements for pCms should be made mandatory to ensure the safety of pCms and enhance their quality. The Administration has advised that the Chinese medicines industry, in particular those small-and-medium-sized enterprises, is concerned about the financial resources involved, the availability of suitable manufacturing plants and the necessary technical support to be GMP-compliant. It will work out with the industry a practical timetable for the implementation of GMP in a progressive manner.

31. Members have asked about the regulatory measures to monitor the safety and quality of the intermediate products that may be generated in the course of the manufacture of pCms. According to the Administration, sections 16 to 19 of the Regulation have provided for the general duties of holders of pCm manufacturer licence in respect of the storage, production and sale of intermediate products. The Practising Guidelines for Manufacturers of pCm also set out, among others, guidelines for pCm manufacturers in respect of the requirements on the personnel, factory, fittings and equipment, scope of business, complaint and recall system of

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[19] As at 31 July 2017, there were a total of 4 688 licensed retailers and 937 licensed wholesalers of Chinese herbal medicines.

intermediate products, and keeping of records in order to enhance their practising standards.

Unregistered pCms being sold in the market

32. Under the Bill, the Director would be empowered to make a CMSO to prohibit the sale of and/or recall an unregistered pCm supplied in the market. Members note that DH has put in place a market surveillance system to check if there is any sale of unregistered pCms in the market. It also conducts unannounced inspections and checking of the premises of licensed local Chinese medicines traders at least once a year, as well as when the traders concerned apply for licence renewal or change of the address of premises or other information specified in their respective licences, to ascertain, among others, whether there is any unregistered pCm or the sale of the same on the traders' premises. In addition, investigations and enforcement actions will be carried out upon receipt of complaints and intelligence. Dr KWOK Ka-ki is of the view that DH should increase the number of routine inspections of the premises of the traders and expand the scope of inspections to cover other retail outlets.

33. As a related issue, members note that according to section 128 of the CM Ordinance, for any pCm which was, on 1 March 1999, manufactured, sold, or supplied for sale in Hong Kong, or manufactured outside Hong Kong and was sold or supplied for sale in Hong Kong, an application may be made to CMB for transitional registration with the issuance of a Notice of confirmation of transitional registration of pCm (i.e. HKP). Such registration will remain valid until the pCm concerned is formally registered and being issued with a Certificate of registration of pCm (i.e. HKC), or until the refusal of its application for formal registration, or until a date to be promulgated in the Gazette by the Secretary for Food and Health, whichever date is the earliest. Members including the Chairman and Mr CHAN Han-pan are concerned that when a pCm issued with HKP is approved for HKC by CMB, the product holder has to replace new labels and package inserts for the pCm within a specified period such that the particulars of the pCm concerned for sale on the market are identical to the registered particulars of that pCm. If the Bill is passed, those products with old packaging label and insert upon the expiry of the specified period would be subject to a CMSO under the proposed new sections 138C(b)(i) and 138D(b)(i). They consider that the Administration should allow the product holder to sell out the stocks bearing a HKP label and package insert to avoid unnecessary wastage arising from a product recall.

34. The Administration has explained that HKP and HKC could not co-exist for the same pCm under the law. A product holder who is granted HKC status has to indicate to CMB a preferred effective date for the HKC of the product, which

should be within 12 months after being notified of the granting of the HKC status. A product holder who fails to complete the replacement of old packaging label and insert for the product concerned before the effective date could apply to CMB for extending the deadline for up to another twelve months. CMB will consider such applications on a case-by-case basis.

Procedures for recalling a Chinese medicine or related product

35. Members note that under sections 11(i), 16(q) and 20(g) of the Regulation, the licensed wholesalers of Chinese herbal medicines, licensed manufacturers of pCms and licensed wholesalers of pCms have the duty to set up and maintain a system of control to enable the rapid and, so far as practicable, complete recall of the Chinese medicine products sold or distributed by the licence holder concerned in the event of such products being found to be dangerous, injurious to health or unfit for human consumption. CMB has published the Recall Guidelines for Chinese Medicine Products ("the Recall Guidelines") in 2005 to assist the licensed Chinese medicines traders concerned to set up the recall system. Dr Helena WONG is of the view that the recalling procedures should preferably be set out in the law. Mrs Regina IP and Mr SHIU Ka-fai have asked about whether there would be any difference in the recalling procedures after the passage of the Bill.

36. The Administration has advised that for enforcement of a CMSO in the future, DH would follow the current approach by discussing the details of the enforcement method and the timeframe with the person subject to the CMSO in each case. To minimize the risk that may arise from deficient products, recalls are usually carried out in the shortest time practicable. DH will handle each recall action as a unique exercise and formulate appropriate recall methods by taking into account the nature of the problem, the sales or distribution networks and the detailed assessment of deficient products concerned. The Administration has assured members that there would be no substantive procedural difference between the proposed and the existing recall actions, as the Bill, if passed, would not require licensed traders to adjust their recall systems already established.

37. This notwithstanding, the Administration has advised the Bills Committee that since the grounds for the making of a CMSO are set out in the proposed new sections 138C and 138D of the CM Ordinance, to avoid duplication with the requirements set out in these sections, consequential amendments would be made to sections 11(i) and 16(q) of the Regulation by removing the requirement that any product to be recalled must be " found to be dangerous, injurious to health or unfit for human consumption". After the passage of the Bill, CMB would amend the relevant practising guidelines and the Recall Guidelines to reflect the changes sought to be made by the Bill, including, among others, the circumstances and

grounds for product recall. It is expected that the administrative procedure for seeking endorsement from CMB to amend the Recall Guidelines would take a few weeks to complete.

Failure to comply with a CMSO

38. The proposed new section 138K of the CM Ordinance makes it an offence for a person bound by a CMSO (i.e. a person to whom the CMSO is addressed and on whom it is served under the proposed new section 138F(2) or 138H(4) of the CM Ordinance) to fail or refuse to comply with a requirement of the order. The person who commits such an offence would be liable to a fine at level 6 (i.e. $100,000) and to imprisonment for two years. Mr SHIU Ka-fai is concerned about the criteria or standards to be adopted by the Director for assessing whether a supplier has complied with the requirements of a CMSO. He has pointed out that there is possibility that the relevant Chinese medicine traders may not be able to recall all the Chinese medicines or related products concerned. For instance, there may be cases that a retailer to whom the CMSO is not specifically addressed refuses or fails without reasonable excuse to return the product concerned to the wholesaler or manufacturer.

39. The Administration has advised that given that the quantity of the Chinese medicine products concerned and the sale or distribution network involved are different, each recall action would be considered as a unique exercise. The trader served with a CMSO should maintain good communication with DH throughout the exercise. It would be a defence for a person charged under the proposed new section 138K of the CM Ordinance to establish that the person had a reasonable excuse for the failure or refusal. Separately, if a retailer to whom the CMSO is not specifically addressed refuses or fails without reasonable excuse to return the product concerned to the wholesaler or manufacturer, the Director may issue another CMSO to that particular retailer to prohibit the sale of and recall the product concerned.

40. Noting that the person charged is required to adduce sufficient evidence to raise an issue that he or she had a reasonable excuse for failing or refusing to comply with a CMSO under the proposed new section 138L(2) of the CM Ordinance, Mr SHIU Ka-fai has asked about what would constitute "a reasonable excuse" for the purposes of the defence.

41. The Administration has advised that what would constitute a reasonable excuse is to be considered on a case-by-case basis. Examples include cases where the product concerned has already been consumed by consumers; where the product concerned has been disposed of by the retailer due to damage; and where the product concerned was found in a retailer (who was not a customer of the

person bound by the CMSO) after the recall action was completed and the person bound by the CMSO can provide evidence showing that the product found in the above retailer is a counterfeit product.

42. The Legal Adviser to the Bills Committee has pointed out that the proposed new section 138L(2) seeks to impose an evidential (rather than legal or persuasive) burden on the person charged to adduce sufficient evidence to raise an issue that he had a reasonable excuse for failing or refusing to comply with a CMSO. This deviates from the formulation of the existing defences under section 156 of the CM Ordinance which requires the person charged "to prove" that he did not know, had no reason to suspect, and could not with reasonable diligence have discovered that the Chinese medicine was not supplied to him, or was not registered, in accordance with the CM Ordinance. Section 156 is couched in terms almost identical to the now repealed section 26(4) of the Trade Descriptions Ordinance which was read down by the Court of Final Appeal as imposing merely an evidential burden on the accused to raise an issue, with the prosecution retaining the persuasive burden as to each element of liability throughout: *Lee To Nei v HKSAR* [2012] 15 HKCFAR 162 at 179.

43. The Administration has advised that the statutory defences in the existing section 156 of the CM Ordinance fall outside the scope of the Bill. If it is considered necessary to review section 156, it would be taken forward in the context of a separate legislative exercise.

44. In the Chinese text of the Bill, "establish" and "established" in the proposed new section 138L of the CM Ordinance are rendered as "證明". The Legal Adviser to the Bills Committee has pointed out that this appears to run contrary to paragraph 6.2.18 of *Drafting Legislation in Hong Kong – A Guide to Style & Practices* (2012) which states that "prove" or "證明" should not be used for imposing an evidential burden. At the suggestion of the Legal Adviser to the Bills Committee, the Administration will move amendments to the proposed new section 138L to replace "證明" by "確立" in subsection (1) and replace "已證明" by "已確立" in subsection (2).

45. Mr SHIU Ka-fai is of the view that the proposed penalty for not complying with a CMSO or a variation order is heavy. Dr KWOK Ka-ki, however, takes the view that the proposed maximum fine for not complying with a CMSO or a variation order (i.e. $100,000) should be increased to achieve greater deterrent effect. The Administration has advised that the proposed penalty level is the same as the existing penalty level applicable to conviction of most other offences under the CM Ordinance. The Administration could, where necessary, review the

penalty level after the Bill has been passed and the new CMSO regime has been operated for a period of time.

Appeal mechanism

46. Under the proposed section 141(1A) and (1B) of the CM Ordinance, a person aggrieved by a CMSO or variation order would be able to appeal to CFI within one month from the date of service of the order on the person. The existing section 141(3) of the CM Ordinance provides that the decision of the CFI shall be final.

47. The Legal Adviser to the Bills Committee has raised queries as to whether the finality clause in section 141(3) of the CM Ordinance would satisfy the proportionality test referred to in *Mok Charles v Tam Wai Ho* [2010] 13 HKCFAR 762 at 781 insofar as section 141(3) purports to restrict or limit the power of final adjudication vested in CFA under Article 82 of the Basic Law.

48. The Administration has advised that the finality provision was modelled on the Pharmacy and Poisons Ordinance (Cap. 138) when the Chinese Medicine Bill was being drafted in 1999. Since the relevant finality provision in the Pharmacy and Poisons Ordinance has already been repealed in 2008, it will move an amendment to repeal the finality provision in section 141(3).

Commencement

49. Members note that the Bill does not contain a commencement provision. By virtue of section 20(2)(a) of the Interpretation and General Clauses Ordinance (Cap. 1), the Bill, if passed, would come into operation on the day on which the enacted Ordinance is published in the Gazette.

Amendments to the Bill

50. The Bills Committee does not object to the amendments to be moved by the Administration to the Bill as mentioned in paragraphs 15, 44 and 48 above.

51. The Bills Committee will not propose any amendments to the Bill.

Follow-up actions by the Administration

52. The Administration has undertaken to study if a comprehensive review of the CM Ordinance should be conducted and inform the Panel on Health Services of the way forward in this regard (paragraph 13 refers).

Resumption of Second Reading debate on the Bill

53. The Bills Committee raises no objection to the resumption of the Second Reading debate on the Bill, subject to the moving of the amendments to the Bill by the Administration. The Administration has informed the Bills Committee that it will resume the Second Reading debate on the Bill at the Council meeting of 28 March 2018.

Consultation with the House Committee

54. The Bills Committee reported its deliberations to the House Committee on 23 February 2018.

Council Business Division 2
Legislative Council Secretariat
21 March 2018

Appendix I

Bills Committee on Chinese Medicine (Amendment) Bill 2017

Membership list

Chairman	Hon Alice MAK Mei-kuen, BBS, JP
Members	Hon Mrs Regina IP LAU Suk-yee, GBS, JP Hon CHAN Han-pan, JP Dr Hon KWOK Ka-ki Hon KWOK Wai-keung, JP Dr Hon Helena WONG Pik-wan Dr Hon Elizabeth QUAT, BBS, JP Dr Hon Junius HO Kwan-yiu, JP Hon SHIU Ka-fai Dr Hon Pierre CHAN (Total : 10 members)
Clerk	Ms Maisie LAM
Legal Adviser	Mr Bonny LOO
Date	17 July 2017

Appendix II

Bills Committee on Chinese Medicine (Amendment) Bill 2017

A. Organizations and individuals which/who have made oral representation to the Bills Committee

1. Chinese Medicine Merchants Association Ltd.
2. Hong Kong Ample Love Society Ltd.
3. Hong Kong & Kowloon Chinese Medicine Association Limited
4. Hong Kong Chi Chun Tang Herbal Factory Limited
5. Hong Kong Chinese Medicine Industry Association
6. Hong Kong Chinese Medicine Manufacturers United Association
7. Hong Kong Medicine Workers General Union (Yee-Shing)
8. Liberal Party
9. Natural Health Care Development Ltd.
10. Natural Health Care (HK) Limited
11. Po Sau Tong Ginseng & Antler Association Hong Kong Limited and Hong Kong Yee Yee Tong Chinese Medicine Merchants Association Ltd.
12. The Democratic Party
13. The Hong Kong Medicine Dealers' Guild
14. The Hong Kong Society of Chinese Medicines
15. 香港《中醫藥條例》研究委員會
16. Mr Marcus MOK
17. Ms Karen TANG

B. Organizations which have provided written submissions to the Bills Committee only

1. Hong Kong Baptist University School of Chinese Medicine (Full Time) Alumni Association

2. Hong Kong Chinese Medicine Pharmacists Association

3. Hong Kong Chinese Patent Medicine Manufacturers' Association Ltd.

4. Modernized Chinese Medicine International Association Ltd.

5. The Hong Kong Federation of Chinese Medicine Sector Limited