

**立法會**  
**Legislative Council**

LC Paper No. CB(2)699/17-18  
(These minutes have been  
seen by the Administration)

Ref : CB2/BC/6/16

**Bills Committee on Chinese Medicine (Amendment) Bill 2017**

**Minutes of the first meeting**  
**held on Monday, 17 July 2017, at 8:30 am**  
**in Conference Room 1 of the Legislative Council Complex**

**Members present** : Hon Alice MAK Mei-kuen, BBS, JP (Chairman)  
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  
Hon SHIU Ka-fai  
Dr Hon Pierre CHAN

**Member attending** : Hon WU Chi-wai, MH

**Members absent** : Hon Mrs Regina IP LAU Suk-ye, GBS, JP  
Dr Hon Junius HO Kwan-yiu, JP

**Public Officers attending** : Mr Howard CHAN, JP  
Deputy Secretary for Food and Health (Health) 1  
Food and Health Bureau  
  
Miss Fiona CHAU  
Principal Assistant Secretary for Food and Health  
(Health) 1  
Food and Health Bureau

Dr Edwin TSUI  
Assistant Director (Traditional Chinese Medicine)  
Department of Health

Mr Stephen YUNG  
Senior Pharmacist (Traditional Chinese Medicine) 2  
Department of Health

**Clerk in attendance** : Ms Maisie LAM  
Chief Council Secretary (2) 5

**Staff in attendance** : Mr Bonny LOO  
Assistant Legal Adviser 4

Ms Jasmine TAM  
Senior Council Secretary (2) 8

Miss Maggie CHIU  
Legislative Assistant (2) 5

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**I. Election of Chairman**

Ms Alice MAK was elected Chairman of the Bills Committee.

2. Members considered it not necessary to elect a Deputy Chairman for the Bills Committee.

**II. Meeting with the Administration**

[File Ref.: FHB/H/24/24, LC Paper Nos. LS75/16-17, CB(2)1883/16-17(02) to (05) and CB(3)630/16-17]

3. The Bills Committee deliberated (index of proceedings attached at **Annex**).

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4. The Bills Committee requested the Administration to provide:

Regulation of Chinese medicines traders

(a) the respective lists of holders of the four types of Chinese medicines trader licences issued by the Chinese Medicines Board

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("CMB") of the Chinese Medicine Council of Hong Kong ("CMCHK") (i.e. retailer licence in Chinese herbal medicines, wholesaler licence in Chinese herbal medicines, manufacturer licence in proprietary Chinese medicines ("pCms"), and wholesaler licence in pCms);

- (b) a copy of the recall guidelines for Chinese medicine products issued by CMCHK for the reference of Chinese medicines traders;

Regulation of Chinese herbal medicines

- (c) the membership list of the International Advisory Board ("IAB") established under the Hong Kong Chinese Materia Medica Standards project, and the work undertaken and advice given by IAB in relation to the reference standards (in particular, the maximum permitted limits of heavy metals and pesticide residues) for the testing of Chinese Materia Medica to ensure their safety and quality;
- (d) details of the market surveillance mechanism put in place by the Department of Health ("DH") to monitor the quality and safety of Chinese herbal medicines, including (i) the number of Chinese herbal medicines samples collected per month from the market for testing over the past two years, the sources from which such samples were taken and the Chinese herbal medicines covered by such samples; (ii) the testing items, methods, procedures and standards adopted for human risk assessment; and (iii) the results of the tests conducted on the Chinese herbal medicines samples taken in (i) above;
- (e) in respect of the requirement set out in the Practising Guideline for Wholesalers of Chinese Herbal Medicines promulgated by CMCHK that herbal medicines or processed herbal medicines should only be purchased from reputable suppliers, information on the suppliers from which the licensed wholesalers of Chinese herbal medicines imported/procured their Chinese herbal medicines, including the number of such suppliers which had complied with the Good Manufacturing Practice ("GMP") requirements in respect of Chinese herbal medicines in the Mainland;

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Regulation of proprietary Chinese medicines

- (f) the membership list of the working group established under CMB to review the definition of pCms;
- (g) details of the market surveillance mechanism put in place by DH to monitor if there are any unregistered pCms sold on the local market, including (i) the number of routine inspections of the premises of local Chinese medicine traders conducted per month; (ii) whether only the premises of licensed Chinese medicine traders would be inspected or whether other retail outlets would also be covered; and (iii) how such inspections were carried out (e.g. whether they were announced or unannounced inspections);
- (h) a comparison of the GMP requirements in respect of pCms adopted respectively in Hong Kong and the Mainland; and

Public and trade consultation

- (i) details of the public and trade consultation conducted by DH in early 2017 on the legislative amendments proposed under the Chinese Medicine (Amendment) Bill 2017 ("the Bill"), including the name list of the Chinese medicines traders/associations which had been consulted.

**III. Any other business**

Invitation of public views

5. Members agreed to receive public views on the Bill at the next meeting to be scheduled for late September 2017. The Chairman said that members would be consulted on the proposed date(s) for holding the next meeting and she would decide on the meeting date and time having regard to members' replies. The Chairman further said that members who wished to invite any parties to give views on the Bill at the meeting might forward the proposed list of deputations to the Clerk. Members noted that in line with usual practice, a general notice would also be posted on the Legislative Council website and invitation letters would be issued to the 18 District Councils for the purpose.

*(Post-meeting note: Members were consulted on the proposed dates for holding the next meeting vide LC Paper No. CB(2)1967/16-17 on 26 July 2017. Members were subsequently informed vide LC Paper*

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No. CB(2)2009/16-17 on 9 August 2017 that in the light of Members' replies, the Chairman had decided that the next meeting would be held on Thursday, 28 September 2017, at 2:30 pm.)

6. There being no other business, the meeting ended at 10:24 am.

Council Business Division 2  
Legislative Council Secretariat  
12 January 2018

**Proceedings of the first meeting of  
the Bills Committee on Chinese Medicine (Amendment) Bill 2017  
held on Monday, 17 July 2017, at 8:30 am  
in Conference Room 1 of the Legislative Council Complex**

| Time marker  | Speaker  | Subject(s)/Discussion   | Action required |
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| <i>Agenda item I: Election of Chairman</i>             |  |   |                 |
| 000413 -<br>000558                                     | Mr CHAN Han-pan<br>Dr Elizabeth QUAT<br>Mr SHIU Ka-fai<br>Ms Alice MAK | Election of Chairman  |                 |
| <i>Agenda item II: Meeting with the Administration</i> |  |   |                 |
| 000559 -<br>001230                                     | Chairman<br>Admin  | Briefing by the Administration on the Chinese Medicine (Amendment) Bill 2017 ("the Bill").  |                 |
| 001231 -<br>001944                                     | Chairman<br>Mr CHAN Han-pan<br>Admin                                   | <p>Mr CHAN Han-pan's remark that apart from conferring power on the Director of Health ("DoH") to issue Chinese medicine safety orders ("CMSO") to prohibit the sale, or to direct the recall, of Chinese medicines or related products under the Chinese Medicine Ordinance (Cap. 549) ("the Ordinance"), the Administration should proactively review the Ordinance in a holistic and comprehensive manner to address the trade's concerns over, among others, the existing definition of proprietary Chinese medicines ("pCms") under the Ordinance and the low success rate of applications for registration of pCms.</p> <p>The Administration's response as follows:</p> <p>(a) as the judgment of a judicial review case handed down by the Court of First Instance, High Court, in May 2015 ("the court judgment in question") concluded that DoH had no lawful power under the Ordinance to order recall of Chinese medicines or products which might pose threats to public health, it was necessary to introduce the proposed amendments to the Ordinance in a timely manner to fill the lacuna in the law; and</p> <p>(b) the Chinese Medicines Board ("CMB") under the Chinese Medicine Council of Hong Kong ("CMCHK") had set up a working group comprising Chinese medicine experts, and representatives from the Chinese medicines industry and the Government Laboratory to examine possible amendments to the definition of pCms ("the CMB working group").</p> <p>Mr CHAN Han-pan's view that the CMB working group should comprise representatives from a wide cross-section of the Chinese medicine industry and solicit the views of Legislative Council ("LegCo") Members in the course of the review. At the request of the Chairman, the Administration agreed to provide in writing the membership list of the working group and details of the public and trade consultation conducted by the Department of Health ("DH") in early 2017 on the legislative proposals under the Bill.</p> | <b>Admin</b>    |

| Time marker     | Speaker                             | Subject(s)/Discussion  | Action required |
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| 001945 - 002611 | Chairman<br>Dr Helena WONG<br>Admin | <p>Dr Helena WONG's indication of in-principle agreement to the legislative proposals. Echoing Mr CHAN Han-pan's view on the need for a comprehensive review of the Ordinance, Dr WONG enquired about the Administration's plan in this regard and its understanding of the key concerns of the trade on the Ordinance.</p> <p>The Administration's advice that DH had maintained close communication with representatives from the Chinese medicine practice and the trade, who had different views on the definition of pCms. There was also a suggestion that the duration of the licences issued under the Ordinance, which currently lasted for not more than two years, should be extended. DH would study these views and suggestion in detail with CMB.</p> <p>In reply to Dr Helena WONG's enquiry, the Administration advised that any person who wished to import Chinese herbal medicines or pCms into Hong Kong was required to first obtain from CMB a wholesaler licence in Chinese herbal medicines or a wholesaler licence in pCms, as the case might be.</p> <p>Dr Helena WONG's request for the Administration to provide the respective lists of holders of the four types of Chinese medicines trader licences issued by CMB, namely, retailer licence in Chinese herbal medicines, wholesaler licence in Chinese herbal medicine, wholesaler licence in pCms and manufacturer licence in pCms.</p>   | <b>Admin</b>    |
| 002612 - 003630 | Chairman<br>Mr SHIU Ka-fai<br>Admin | <p>Mr SHIU Ka-fai's remark that while members of the trade supported in principle the legislative proposals, they had concerns about various operational issues such as which party would be held liable if a supplier of Chinese medicines or products served with a CMSO had requested the retailers concerned to return the recalled medicines or related products but the latter had failed to do so; the time to be given for a supplier to recall the Chinese medicines or related products concerned; the criteria or standards to be adopted by DoH for assessing whether a supplier had complied with the requirements of the CMSO; and the maximum penalty for non-compliance which was proposed to be a fine at level 6 (i.e. \$100,000) and imprisonment for two years under the proposed new section 138K of the Ordinance.</p> <p>The Administration's response as follows:</p> <p>(a) wholesalers of Chinese herbal medicines, wholesalers of pCms and manufacturers of pCms had already been required under the relevant practising guidelines promulgated by CMCHK to set up a system for recalling Chinese medicine products for public health purposes. CMCHK had issued a set of recall guidelines for traders' reference. A copy of such guidelines would be provided after the meeting for members' reference;</p> <p>(b) in the past two years, there were 10 cases of recall actions carried out by licensed traders. Given that the quantity of the Chinese medicine products concerned and the sale or distribution network involved were different, each recall action was considered as a unique exercise. DH had assisted</p> | <b>Admin</b>    |

| Time marker     | Speaker                              | Subject(s)/Discussion  | Action required |
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|                 |                                      | <p>the traders concerned in deciding on the appropriate manner of recall. The traders concerned were required to report to DH the progress of recall, and the effectiveness of each recall action was assessed by DH on a case-by-case basis having regard to, among others, the quantity of the Chinese medicine products concerned which had been distributed, sold and recalled. In these 10 cases, the traders concerned were generally able to recall the Chinese medicine products concerned within one or two weeks; and</p> <p>(c) under the proposed new section 138F of the Ordinance, a CMSO made by DoH would be binding on a person to whom the CMSO was addressed only from the time the CMSO was served on the person. DH had explained to the trade that the proposal would not impose additional compliance burden on licensed traders since there would be no procedural difference between the recall action in future and that under the existing recall system set up by the trade. However, the proposed new sections 138B and 138D of the Ordinance would enable DoH to direct any person, including unlicensed traders, to recall from the market any Chinese medicine product which was dangerous or injurious to health or unfit for use by human beings, or otherwise might pose threats to public health.</p> <p>Mr SHIU Ka-fai's reiteration of the trade's worry about inadvertent violation of the requirements set out in a CMSO given the lack of uniform standards for assessing whether a trader had complied with the order and the proposed heavy penalty for non-compliance. He suggested that the Bills Committee should receive views from interested parties on the Bill at a future meeting.</p> |                 |
| 003631 - 004359 | Chairman<br>Mr CHAN Han-pan<br>Admin | <p>On Mr CHAN Han-pan's concern about whether traders who had been instructed by DH to recall Chinese medicine products from the market would make claims against the Government for compensation following the delivery of the court judgment in question, the Administration advised that DH had in the past requested traders to carry out recall actions through administrative means. So far, the traders concerned were willing to recall the products concerned to safeguard public health. The Administration did not anticipate that any claims would arise from the past recall actions.</p> <p>Mr CHAN Han-pan's enquiries about whether products which were composed mainly of Chinese medicine materials and adulterated with other materials or substances would be regulated by the Bill; the way forward for the review of the definition of pCms being carried out by the CMB working group; and the Administration's timetable for conducting a comprehensive review of the Ordinance.</p> <p>The Administration's response as follows:</p> <p>(a) no change had been proposed to the existing definition of pCms under the Ordinance and only products falling within such definition would be caught by the Bill. Subject to the recommendations to be made by the CMB working group and the view of CMB in this regard, extensive consultations</p>   |                 |



| Time marker     | Speaker                             | Subject(s)/Discussion  | Action required |
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|                 |                                     | <p>would need to be conducted on any proposed amendment to the definition of pCms. The Administration would, if considered necessary and appropriate, propose amendments to the definition of pCms in a separate legislative exercise;</p> <p>(b) it would need to further discuss with the Chinese medicine industry to understand the industry players' views on the current provisions of the Ordinance before a concrete timetable could be drawn up for the review of the Ordinance.</p> <p>Mr CHAN Han-pan's view that the Bills Committee should receive views from interested parties on the Bill at a future meeting.</p>   |                 |
| 004400 - 005547 | Chairman<br>Dr Helena WONG<br>Admin | <p>In response to Dr Helena WONG's call for the Administration to strengthen the monitoring of the quality and safety of pCms and Chinese herbal medicines at the import level, the Administration advised that apart from requiring traders who wished to import pCms or Chinese herbal medicines into Hong Kong to obtain wholesaler licences, importation and exportation of pCms and 36 types of Chinese herbal medicines (including 31 Chinese herbal medicines specified in Schedule 1 and five Chinese herbal medicines specified in Schedule 2 to the Ordinance) had to be covered by an import or export licence issued by DH. In addition, products that fell within the definition of pCms had to be registered by CMB before they could be imported, manufactured or sold in Hong Kong. To be registered, pCms had to meet the requirements in respect of safety, quality and efficacy prescribed by CMB.</p> <p>Dr Helena WONG's view that DH should regularly take samples of Chinese herbal medicines at the import, wholesale and retail levels for testing of pesticide residues and heavy metal contents to safeguard public health; and her enquiry about the standards currently adopted by DH for assessing the quality and safety of Chinese herbal medicines under the market surveillance system.</p> <p>The Administration's explanations as follows:</p> <p>(a) since February 2017, DH had increased the targeted number of market surveillance samples from 30 to 45 per month, and had extended the sampling scope to include wholesalers in addition to retailers. The regular testing items included pesticide residues, heavy metal contents and morphological identification. The standards currently used for the testing of pesticide residues and heavy metal contents in Chinese herbal medicines, which covered 37 pesticide residues and four heavy metal contents, were formulated by CMCHK with reference to other international standards. Relevant information had been uploaded onto CMCHK's website for the reference of traders and the public. This apart, the Hong Kong Chinese Materia Medica Standards ("HKCMMS") project was launched in 2002 to develop reference standards for commonly used Chinese herbal medicines in Hong Kong and set objective standards for safety testing of Chinese medicines; and</p> <p>(b) the testing for pesticide residues and heavy metal contents in Chinese herbal medicines consisted of two stages. The first</p> |                 |

| Time marker     | Speaker                             | Subject(s)/Discussion  | Action required |
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|                 |                                     | <p>stage involved tests on the Chinese herbal medicines samples in their raw state to check whether they contained the aforesaid 37 pesticides and four heavy metals and the respective residue levels/contents. If pesticide residues or heavy metals existed at a level exceeding the prescribed standards, the second-stage test would be conducted to assess the level of pesticide residues or heavy metal contents in the decoctions of the Chinese herbal medicines concerned, which was a closer simulation of the condition during human consumption and was considered more appropriate for human risk assessment. The procedures and scope of tests were recognized by both CMB and the international expert group of the Scientific Committee set up under the HKCMMS project. None of the Chinese herbal medicines samples taken by DH were found to have exceeded the prescribed limits of pesticide residues and heavy metals after decoction.</p>  |                 |
| 005548 - 010614 | Chairman<br>Mr SHIU Ka-fai<br>Admin | <p>Mr SHIU Ka-fai expressed concern that products which were composed mainly of Chinese medicine materials and adulterated with other materials or substances (e.g. vitamins) were currently regarded as health products and would not be regulated by the Ordinance or the Bill. The lack of regulation on the sale of such products which were not required to meet the stringent registration requirements applicable to pCms had created unfairness to pCm traders which had devoted much effort and resources to apply for registration. In his view, pCms and other health products should be required to bear the label of "pCms" and "health products" respectively on their packages so as to facilitate differentiation by consumers.</p> <p>The Administration's response as follows:</p> <p>(a) orally consumed products sold on the market that fell within the definition of pCms under the Ordinance and the definition of pharmaceutical products or medicines under the Pharmacy and Poisons Ordinance (Cap. 138) were regulated by these two Ordinances respectively. The labels and advertisements of products with health claims were regulated by the Undesirable Medical Advertisements Ordinance (Cap. 231). The claims of health products were also subject to regulation by the Trade Descriptions Ordinance (Cap. 362) and by the relevant provisions or codes of practice under the Broadcasting Ordinance (Cap. 562) and the Broadcasting (Miscellaneous Provisions) Ordinance (Cap. 391). The CMB working group would study issues relating to the regulation of products which were not composed solely of Chinese medicines as active ingredients; and</p> <p>(b) the Ordinance required that the label on a package of registered pCm should include, among other information, the registration number issued by DH. DH had put in place a market surveillance system to monitor if there was any sale of unregistered or counterfeit pCms on the market. Efforts had been and would continuously be made by DH to educate the public to check whether a pCm had been registered when purchasing pCms for treatment of diseases.</p> |                 |



| Time marker     | Speaker                            | Subject(s)/Discussion   | Action required |
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|                 |                                    | <p>approval for applications for formal registration of pCms.</p> <p>The Administration's response that it would continue to discuss with the trade on matters relating to possible amendments to the Ordinance and report the progress of its work to the Panel on Health Services.</p>  |                 |
| 012403 - 013059 | Chairman<br>Mr WU Chi-wai<br>Admin | <p>Mr WU Chi-wai's enquiries as follows:</p> <p>(a) whether health products claimed to be composed solely of natural ingredients would be regulated by the Bill and whether they were subject to any requirement for registration; and</p> <p>(b) whether DH would proactively conduct inspections to ascertain whether individual health products sold on the market were required to be registered under the laws of Hong Kong and if so, how such inspections were conducted and the frequency of conducting such inspections.</p> <p>The Administration's reiteration that products that fell within the definition of pCms under the Ordinance would be subject to a CMSO made under the Bill and had to be registered with CMB under the Ordinance before they could be imported, manufactured or sold in Hong Kong; and its advice that DH had been monitoring under its market surveillance system whether individual health products sold on the local market were required to be registered under the laws of Hong Kong. Regarding the monitoring of the sale of pCms, DH would conduct inspections of the premises of each licensed Chinese medicines trader at least once a year to ensure their compliance with the Ordinance and practising guidelines, and when the traders applied for licence renewal or change of the address of premises or other information specified in their respective licences. All inspections were unannounced and would cover, among others, examination as to whether there was any unregistered pCm or sale of the same on the traders' premises. DH would also conduct investigations and carry out enforcement actions upon receipt of complaints and intelligence.</p> |                 |
| 013100 - 014011 | Chairman<br>Dr KWOK Ka-ki<br>Admin | <p>Dr KWOK Ka-ki's view that DH should enhance its market surveillance by increasing the number of samples of Chinese herbal medicines drawn from the market for testing and consider requiring traders who wished to import Chinese herbal medicines into Hong Kong to provide relevant test reports issued by local accredited laboratories to prove the quality and safety of the imported Chinese herbal medicines. As regards pCms, DH should increase the number of routine inspections of the premises of licensed Chinese medicines traders and extend the scope of inspections to cover other retail outlets.</p> <p>The Administration's advice that licensed wholesalers of Chinese herbal medicines were currently required under the relevant practising guidelines to purchase herbal medicines/processed herbal medicines only from reputable suppliers, and 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/processed herbal</p>   |                 |

| Time marker     | Speaker                             | Subject(s)/Discussion  | Action required |
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|                 |                                     | <p>medicines purchased where necessary. At present, most of the Chinese herbal medicines supplied in Hong Kong were Chinese medicine decoction pieces imported from the Mainland, where the production of which had to meet the relevant Good Manufacturing Practice ("GMP") requirements. The Administration would need to consult the trade on the suggestion to require traders to provide relevant test reports when importing Chinese herbal medicines into Hong Kong. Due regard would also need to be given to the capacity of the local testing and certification industry in coping with the increase in demand for such testing services.</p> <p>In response to Dr KWOK Ka-ki's view that the proposed maximum fine for not complying with a CMSO made by DoH (i.e. \$100,000) should be increased to achieve greater deterrent effect, the Administration advised that the proposed penalty level was the same as the existing penalty level applicable to conviction of most other offences under the Ordinance. The Administration could, where necessary, review the penalty level after the passage of the Bill for a period of time.</p> <p>Dr KWOK Ka-ki's request for the Administration to provide details of the market surveillance mechanism put in place by DH to monitor if there were any unregistered pCms sold on the local market, including (i) the number of routine inspections of the premises of local Chinese medicine traders conducted per month; (ii) whether only the premises of licensed Chinese medicine traders would be inspected or whether other retail outlets would also be covered; and (iii) how such inspections were carried out (e.g. whether they were announced or unannounced inspections).</p> | <b>Admin</b>    |
| 014012 - 015434 | Chairman<br>Dr Helena WONG<br>Admin | <p>In reply to Dr Helena WONG's enquiries about the GMP requirements in respect of Chinese herbal medicines and pCms in Hong Kong and the Mainland, the Administration advised that there were established GMP standards and GMP factories for the manufacture or processing of Chinese herbal medicines and the manufacture of pCms in the Mainland. Locally, there was no GMP factory for the manufacture or processing of Chinese herbal medicines. While compliance with the GMP requirements in respect of pCms was not mandatory, 18 local licensed manufacturers of pCms had been awarded the GMP Certificates for Manufacturer.</p> <p>Dr Helena WONG's view that the Administration should consider requiring, as an additional licensing condition for the issuance or renewal of wholesaler licence in Chinese herbal medicines, wholesalers of Chinese herbal medicines to purchase Chinese herbal medicines from suppliers which had complied with the relevant GMP requirements in the Mainland; and her request for the Administration to provide information on the suppliers from which local licensed wholesalers of Chinese herbal medicines imported/procured their Chinese herbal medicines, including the number of such suppliers which had complied with the GMP requirements in respect of Chinese herbal medicines in the Mainland; and a comparison of the GMP requirements in respect of pCms adopted respectively in Hong Kong and the Mainland.</p>  | <b>Admin</b>    |

| <b>Time marker</b>                         | <b>Speaker</b>                      | <b>Subject(s)/Discussion</b>   | <b>Action required</b> |
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| 015435 -<br>015711                         | Chairman<br>Mr SHIU Ka-fai<br>Admin | Mr SHIU Ka-fai's reiteration of his request that DH should address the problem of lack of regulation on the sale of health products which resembled pCms in their packaging and ingredients. |                        |
| <i>Agenda item III: Any other business</i> |                                     |  |                        |
| 015712 -<br>015738                         | Chairman                            | Date of the next meeting for receiving public views on the Bill  |                        |

Council Business Division 2  
Legislative Council Secretariat  
12 January 2018