# 立法會
# *Legislative Council*

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(These minutes have been
seen by the Administration)

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**Bills Committee on Chinese Medicine Bill**

**Minutes of meeting**
**held on Tuesday, 25 May 1999 at 10:45 am**
**in Conference Room A of the Legislative Council Building**

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| **Members Present** | : | Prof Hon NG Ching-fai (Chairman)<br>Hon HO Sai-chu, JP<br>Hon LEE Kai-ming, JP<br>Dr Hon LUI Ming-wah, JP<br>Hon Mrs Selina CHOW LIANG Shuk-yee, JP<br>Hon Ronald ARCULLI, JP<br>Hon CHAN Yuen-han<br>Dr Hon LEONG Che-hung, JP<br>Dr Hon Philip WONG Yu-hong<br>Hon YEUNG Yiu-chung<br>Hon Ambrose LAU Hon-chuen, JP |
| **Members Absent** | : | Hon David CHU Yu-lin<br>Hon Cyd HO Sau-lan<br>Hon Michael HO Mun-ka<br>Dr Hon TANG Siu-tong, JP<br>Hon CHOY So-yuk<br>Hon SZETO Wah<br>Hon LAW Chi-kwong, JP |
| **Public Officers Attending** | : | Mr Gregory LEUNG Wing-lup, JP<br>Deputy Secretary for Health and Welfare (1)<br><br>Mr William TSUI<br>Assistant Secretary for Health and Welfare (Medical) 1 |

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| | | Mr Peter CHEUNG<br>Acting Director of Intellectual Property |
| | | Miss Miranda NG<br>Senior Assistant Law Draftsman, Department of Justice |
| | | Dr LEUNG Ting-hung<br>Assistant Director of Health (Traditional Chinese Medicine) |
| **Attendance by Invitation** | : | Hong Kong Baptist University<br>Professor YEUNG Hin-wing<br>Director, Institute for Advancement of Chinese Medicine |
| **Clerk in Attendance** | : | Ms Doris CHAN<br>Chief Assistant Secretary (2) 4 |
| **Staff in Attendance** | : | Mr LEE Yu-sung<br>Senior Assistant Legal Adviser |
| | | Mr Stephen LAM<br>Assistant Legal Adviser 4 |
| | | Ms Joanne MAK<br>Senior Assistant Secretary (2) 4 |

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## I. Meeting with the Administration

*Intellectual property protection*

At the Chairman's invitation, Acting Director of Intellectual Property (DIP(Atg)) briefed members on the existing measures under the intellectual property system used to protect medicinal products. He explained the concept of intellectual property and pointed out that intellectual property rights included trade marks, copyright, patents, designs, plant varieties and the lay-out design of integrated circuits. In addition, he introduced to members the Plant Varieties Protection Ordinance (Cap.490) which conferred intellectual property rights on breeders of plant varieties.

2. DIP(Atg) said that the intellectual property right in respect of Chinese medicinal products could be protected by keeping the relevant information (such as the

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ingredients or steps of preparation) as "undisclosed information". However, it entailed the risk that the medicinal products could still be reproduced by way of reversion. Nevertheless, he pointed out that the cases of "Coca-cola" and "Kentucky Fried Chicken" had shown that even if the ingredients that these products contained had been disclosed, the formulae of their production and the technical knowhow involved could not be found out by reversion. The information in respect of the formulae of these products and the knowhow of the manufacturing had been successfully protected by way of keeping it as trade secret.

3. DIP(Atg) considered that Chinese medicinal products were best protected by patent protection. He pointed out that patents could be granted to the following aspects of a Chinese medicinal product -

(a) the identity of specific ingredients of Chinese medicines contained;

(b) the weight ratios of the specific ingredients;

(c) the specific steps of the preparational process (such as crushing, evaporating, combining and so on); and

(d) the form (such as oral solution, injectable solution, capsule or tablet).

4. DIP(Atg) said that according to the International Patent Classification (IPC), pharmaceutical preparations fell under the classification A61K. Under this classification, the total number of granted patents was 2167, of which only one related to Chinese medicines. He explained that this was because of the fact that Chinese medicines were basically "products of nature" which were usually considered as not involving any "discovery" which was patentable.

5. DIP(Atg) said that patents registered in the Hong Kong Special Administrative Region (SAR) would only grant protection in the Hong Kong SAR. Its patent system was separate from the patent systems in other parts of the Mainland. Therefore, patents granted by the State Intellectual Property Office were not automatically protected in the Hong Kong SAR. There were two other designated patent offices, namely, the United Kingdom Patent Office and the European Patent Office, in respect of patents granted under European Patent Convention. He advised that depending on the length of the commercial life of the products concerned, manufacturers and businessmen might consider to obtain a short-term patent or a standard patent on products or processes. Their terms of protection were up to eight years and 20 years respectively.

6. Apart from the above ways, DIP(Atg) said that manufacturers of proprietary Chinese medicines could protect their goods by trade marks, which could be either registered or unregistered. He said that up to May 1999, there were about 14 000 registered trade marks for pharmaceutical preparations, of which less than 4% related

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to Chinese medicines. As to trade marks for services, there were presently about 3 600 registered trade marks. About seven of them related to medical treatment in Chinese medicine. DIP(Atg) stressed that a trade mark would be protected by the Trade Marks Ordinance in the Hong Kong SAR only if it was registered here.

7. In response to Dr LEONG Che-hung's question, DIP(Atg) confirmed that a western medicine which was granted patent in overseas countries was not automatically protected in the Hong Kong SAR. It should apply to the Patents Registry of the Hong Kong SAR for a standard patent. Dr LEONG said he noted that the current policy of the Pharmacy and Poisons Board in considering applications for registration of western medicines in Hong Kong "did not take the favour of patent right into consideration" as stated in the relevant regulations. It granted approvals to these applications mainly based on three factors: safety, efficacy and quality of the medicines concerned. Dr LEONG said therefore it was found that a patent granted to a drug in overseas countries could not prevent the sale of its generic drugs in Hong Kong and this problem had been much complained about since 1995 by pharmaceutical companies. He urged the Administration to take action to deal with the problem and suggested that the Administration should prevent similar problems in respect of Chinese medicines. DIP(Atg) advised that in this case, the owner of the patent should exercise his right and take legal action against the seller of the generic drug for infringement of the patent.

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8. Dr LEONG Che-hung commented that the hospitals or doctors using the generic drug should not be liable to infringement of the patent as they might not know anything about the patent. He considered that it was understandable for them to have used the generic drug since it had already been registered with the Pharmacy and Poisons Board. Regarding the possible penalty on conviction of the offence, DIP(Atg) said that as such a case would only involve civil proceedings, the doctor concerned would be subject to a fine only.

9. Mrs Selina CHOW said that the sector was very concerned about clause 121(1)(b) requiring the manufacturers of proprietary Chinese medicines to furnish the particulars of their medicines required to be registered in accordance with the prescribed requirements. In response, DIP(Atg) said that the officials involved in the process of handling the information should be obliged to keep it confidential. However, Mrs Selina CHOW pointed out that there were no such provisions made in the Bill to bind members of the Medicines Board to secrecy of the information provided by the manufacturers. In response, DIP(Atg) explained that trade secret was protected by common law. DS(HW)1 undertook to explore if it was possible to make provisions in the Bill to prohibit the disclosure of confidential information obtained by the Medicines Board in handling the applications for registration.

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10. Dr LUI Ming-wah considered that Chinese medicines by nature were not easy to obtain patents. He suggested that the Hong Kong SAR Government should establish a Chinese Medicines Patents Council to handle matters related to the

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intellectual property protection of Chinese medicines. In response, DIP(Atg) agreed that it was not easy to obtain patents for Chinese medicines. However, it was not impossible to do so as seen from the fact that the State Intellectual Property Office had already granted some 7 000 patents for Chinese medicines from 1985 up to now. Moreover, as explained before, several aspects of Chinese medicinal products could be patented such as the specific steps of the preparation process and the identity of specific ingredients contained. DIP(Atg) explained that the criteria for granting patents were universal and he doubted if it was necessary for Hong Kong to establish a Chinese Medicines Patents Council to process applications for patents based on some different criteria.

11. Dr LUI Ming-wah then asked what consideration criteria were adopted by the State Intellectual Property Office in granting patents for Chinese medicinal products.

Adm DIP(Atg) undertook to obtain the required information from the State Intellectual Property Office.

## II. Meeting with Professor YEUNG Hin-wing, Director of the Institute for Advancement of Chinese Medicine of the Hong Kong Baptist University

(LC Paper No. CB(2)2094/98-99(01))

12. Professor YEUNG Hin-wing informed members that the Hong Kong Baptist University had organized a Workshop on "Intellectual Properties and the Internationalization of Chinese Medicinal Products" from 17 to 19 May 1999. The abstracts of the essays presented at the Workshop had been compiled and copies could be provided to members upon request. A collection of the essays could also be provided to members for perusal when it was available.

13. Professor YEUNG said that the issue of intellectual property protection in respect of Chinese medicines was very complicated; but it was an important aspect in promoting Hong Kong as a centre of Chinese medicine. Addressing the concerns of the sector as conveyed by Mrs Selina CHOW, Professor YEUNG clarified that the Preparatory Committee on Chinese Medicine (PCCM) had never intended to require applicants for registration of Chinese medicinal products to disclose to the Medicines Board the manufacturing formulae of their medicines. He explained that for protection of public health, it was necessary for the manufacturers to reveal the ingredients of their products. However, the sector should not be too worried that their products could be copied, following the disclosure of their ingredients, because the formulae of the manufacture were not disclosed.

14. Mrs Selina CHOW considered that the Bill should specify what had to be furnished to the Medicines Board by the manufacturers/traders in applying for the registration of a proprietary Chinese medicine, and what information would be disclosed by the Board to the public. She also invited Professor YEUNG to comment on whether or not the Bill could give sufficient confidence to the sector to develop

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new proprietary Chinese medicine products. She pointed out that the requirements laid down under clause 129 regarding the conduct of clinical trials and medicinal tests would be beyond the affordability of the sector. She also referred to the fact that even the United States (US) did not impose such requirements on the manufacturers when importing their products. In response, Professor YEUNG explained that proprietary Chinese medicines were classified as "dietary supplements" in the US and it was therefore inappropriate to quote the case of the US for comparison. He emphasized that the PCCM was mainly concerned about the safety and efficacy of a proprietary Chinese medicine applying for registration and the PCCM did not stipulate that efficacy had to be proved by clinical trials. Rather, it had suggested that the future Medicines Board should consider other information made available to it by the traders/manufacturers concerned. He took the view that clause 129 was only an enabling provision to facilitate the conduct of clinical trials for proprietary Chinese medicines for the purpose of enhancing the competitiveness of the medicines in the market. It was not intended that all proprietary Chinese medicines had to undergo clinical trials when applying for registration.

15. DS(HW)1 pointed out that the Administration, in recognition of the financial constraints in the sector, had provided in the Bill some flexibility to enable gradual improvements be made to raise the overall standards of Chinese medicines. Assistant Director of Health (Traditional Chinese Medicine) (AD(TCM) ) added that the Administration had made reference to the experience of the Mainland in drafting the Bill. As an illustration of the flexibility allowed in the Bill, AD(TCM) pointed out that there were no requirements for all proprietary Chinese medicines applying for registration to undergo clinical trials. Instead, the Bill would only encourage the manufacturers/traders to do so as provisions had been made to enable the Medicines Board to issue certificates to those medicinal products which had passed through some quality control tests.

16. Mrs Selina CHOW was concerned about the way to prove the efficacy of a Chinese medicine. In response, Professor YEUNG said that it was difficult but possible to prove the efficacy of Chinese medicines. On the Mainland, the relevant authorities had laid down detailed guidelines on how to prove the efficacy of Chinese medicines and the suggested ways of proving it had been well supported by experts. Evidence-based methods and outcome research could be used to prove the efficacy of Chinese medicines. Professor YEUNG said that the PCCM also considered that it was comparatively more difficult to prove the efficacy of Chinese medicines. Therefore, the PCCM took the view that in relation to the registration of proprietary Chinese medicines, emphasis should be put on their safety and quality.

17. Miss CHAN Yuen-han noted that although the Mainland had much experience in conducting clinical trials and medicinal tests for proprietary Chinese medicines, from time to time some proprietary Chinese medicines had been found to contain a high level of heavy metal. She noted that in general overseas countries had more confidence in the Chinese medicinal products produced by South Korea and Japan.

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Miss CHAN asked what could be learnt from the experience of the Mainland to prevent occurrence of the same problems in Hong Kong. In response, Professor YEUNG said that the Mainland had very comprehensive guidelines on the testing and monitoring of the quality of Chinese medicines. However, the problems there were mainly due to their failures to stem the widespread sale of fake Chinese medicines. He believed that given its good law enforcement systems and better management, Hong Kong would be able to cope with the problem and ensure better control of the manufacturing process in the production of Chinese medicines.

18. Dr LUI Ming-wah considered that the Administration must not copy the same intellectual property protection system as adopted on the Mainland. Instead, more scientific approaches should be adopted to prove the dietary value, or the efficacy, of Chinese medicinal products and he gave an example of such approaches. In response, Professor YEUNG agreed that China was slow in implementing modernization of Chinese medicine. He considered that the scientific approach suggested by Dr LUI should be explored. He emphasized that Hong Kong should promote the development of Chinese medicine on the basis of traditional Chinese medicine and seek to modernize it.

19. Mrs Selina CHOW requested the Administration to explain in concrete terms the evidence required to be produced by manufacturers/traders of proprietary Chinese medicine to prove the efficacy of their products when they applied for registration. In response, AD(TCM) said that for those proprietary medicines which were manufactured based on traditional formulae, they would not be required to undergo clinical trials to prove their efficacy. Clinical trials might be considered necessary only for those medicines produced based on new formulae and when the manufacturers/traders concerned could not produce any evidence to prove the efficacy of the products.

*Visit to the Guangzhou University of Traditional Chinese Medicine*

20. The Chairman referred to the proposal made by Dr LUI Ming-wah at the last meeting of paying a visit to the Guangzhou University of Traditional Chinese Medicine and suggested that members' views on the proposal be sought at the next meeting.

## III. Date of next meeting

21. Members agreed that the next meeting be held on 27 May 1999 at 8:30 am to continue scrutiny of the Bill.

22. The meeting ended at 12:50 pm.

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Legislative Council Secretariat
3 December 1999