立法會 Legislative Council

LC Paper No. CB(1)532/12-13 (These minutes have been seen by the Administration)

Ref: CB1/PL/CI/1

Panel on Commerce and Industry

Minutes of meeting held on Tuesday, 18 December 2012, at 2:30 pm in Conference Room 3 of the Legislative Council Complex

Members present: Hon Vincent FANG Kang, SBS, JP (Chairman)

Dr Hon CHIANG Lai-wan, JP (Deputy Chairman)

Hon Emily LAU Wai-hing, JP

Hon Jeffrey LAM Kin-fung, GBS, JP

Hon Andrew LEUNG Kwan-yuen, GBS, JP

Hon WONG Ting-kwong, SBS, JP Dr Hon LAM Tai-fai, SBS, JP Hon Steven HO Chun-yin Hon MA Fung-kwok, SBS, JP Hon Charles Peter MOK

Hon Dennis KWOK

Hon Christopher CHEUNG Wah-fung, JP

Hon SIN Chung-kai, SBS, JP

Hon Martin LIAO Cheung-kong, JP Ir Dr Hon LO Wai-kwok, BBS, MH, JP

Hon CHUNG Kwok-pan

Public officers attending

Agenda item IV

Miss Janet WONG, JP

Commissioner for Innovation and Technology

Dr Cecilia PANG

Biotechnology Director

Innovation and Technology Commission

Mr John HUNG Leung-bun Secretary-General (Testing and Certification) Hong Kong Council for Testing and Certification

Agenda item V

Mr Brian LO, JP

Deputy Director-General of Trade and Industry (Commercial Relations, Controls and Support)

Mr Raymond WU

Principal Assistant Secretary for Commerce and Economic Development (Commerce and Industry)2

Clerk in attendance: Ms Annette LAM

Chief Council Secretary (1)3

Staff in attendance: Miss Rita YUNG

Council Secretary (1)3

Ms May LEUNG

Legislative Assistant (1)3

Action

I. Confirmation of minutes of meeting

(LC Paper No. CB(1)292/12-13

-- Minutes of meeting held on 29 October 2012)

The minutes of the meeting held on 29 October 2012 were confirmed.

II. Information paper issued since last meeting

2. <u>Members</u> noted that no information paper had been issued since last meeting held on 20 November 2012.

III. Date of next meeting and items for discussion

(LC Paper No. CB(1)299/12-13(01) -- List of outstanding items for discussion

LC Paper No. CB(1)299/12-13(02) -- List of follow-up actions)

- 3. <u>The Chairman</u> suggested and <u>members</u> agreed that the next regular Panel meeting originally scheduled for 25 January 2013 at 10:45 am be re-scheduled to 23 January 2013 at 9:00 am to discuss the following items proposed by the Administration:
 - (a) Briefing on relevant policy initiatives set out in the Chief Executive's 2013 Policy Address; and
 - (b) Promotion of inward investment.

IV. Research and development of Chinese medicines

(LC Paper No. CB(1)299/12-13(03) -- Administration's paper on research and development of Chinese medicines

LC Paper No. CB(1)299/12-13(04) -- Paper on research and development of Chinese medicines prepared by the Legislative Council Secretariat (background brief))

Presentation by the Administration

4. At the invitation of the Chairman, <u>Commissioner for Innovation and Technology</u> (CIT) gave a video presentation on the Government's efforts in promoting research and development (R&D) of Chinese medicines (CM) in Hong Kong. Details of the CM-related work including strengthening of R&D, promoting testing and certification, and facilitating collaboration among stakeholders were set out in the Administration's paper (LC Paper No. CB(1)299/12-13(03)).

Discussion

Testing of CM

5. <u>Ir Dr LO Wai-kwok</u> declared that he was a member of the Hong Kong Council for Testing and Certification (HKCTC) although he was not a member of its Panel on Promoting Testing and Certification Services in Chinese Medicine Trade. <u>Ir Dr LO</u> said that the Mainland market promised huge business opportunities for CM made in Hong Kong in view of the wide acceptance of CM in the Mainland. However, the Mainland and Hong Kong

- 4 -

Action

Admin

applied different reference standards in respect of the testing of Chinese materia medica and registration of proprietary CM (pCm). He enquired whether the Administration would consider co-ordinating the different standards in the two places so as to facilitate Hong Kong-made CM's entry into the Mainland market. Sharing a similar concern, the Deputy Chairman requested the Administration to advise whether the Committee on Research and Development of Chinese Medicines (the R&D Committee) would explore issues on developing a common standard of CM testing and also on the registration of Hong Kong manufactured pCm in other economies.

6. In response, <u>CIT</u> and <u>Secretary-General</u> (<u>Testing</u> and <u>Certification</u>), HKCTC advised that the Mainland set standards for Chinese materia medica in the Pharmacopoeia of the People's Republic of China (the Chinese Pharmacopoeia). Under the management and co-ordination of Department of Health (DH), Hong Kong had been developing the Hong Kong Chinese Materia Medica Standards (HKCMMS) which provided detailed references for testing laboratories in providing authentication services for Chinese materia medica. Laboratories in Hong Kong had the capability of providing testing services for Chinese materia medica according to both HKCMMS and the Chinese Pharmacopeia. As for testing for registration of pCm, Hong Kong had to seek Mainland laboratories' assistance in providing services since local laboratories were not ready at the time of introduction of statutory Nowadays, local laboratories had built up registration requirement. capability in providing safety and quality testing for registration of pCm. The Administration would discuss with the Mainland authorities through the Mainland and Hong Kong Closer Economic Partnership Arrangement to seek acceptance of testing reports for pCm registration issued by laboratories accredited by the Hong Kong Accreditation Service. At present, over 10 laboratories in Hong Kong were accredited for providing testing services for Chinese materia medica and pCm, thus helping the CM trade in product quality assurance.

Clinical trial for CM

7. <u>Ir Dr LO Wai-kwok</u> observed that while 16 public Chinese medical clinics (CMCs) had been established so far, there was presently no public Chinese medicine hospital in Hong Kong and internship placement positions were not enough for graduates of local Chinese medicine degree programmes. He enquired whether the Administration had any plan to establish a public Chinese medicine hospital to promote the development of "evidence-based" Chinese medicine and to facilitate the conduct of clinical trials for CM. <u>CIT</u> and <u>Biotechnology Director</u>, <u>Innovation and Technology Commission</u> (BD, ITC) responded that policy and regulatory matters relating to the overall

development of CM, including the establishment of Chinese medicine hospital, the standard of practice and conduct of Chinese medicine practitioners and CM traders as well as the safety, quality and efficacy of pCm were under the purview of the Food and Health Bureau (FHB)/DH. On the other hand, ITC played a significant role in the promotion of testing and certification, as well as R&D of CM. It was also eager to assist the industry. The long-term goal of the Administration in promoting the development of CM was to develop, through an evidence-based approach, a model of collaboration between Chinese and Western medical practitioners that could meet the actual circumstances and needs of Hong Kong. ITC had encouraged local universities and relevant organizations to apply for funding under the Innovation and Technology Fund (ITF) to support evidence-based CM R&D projects in the areas of pre-clinical and clinical evaluation of CM as well as R&D of integrative Chinese and Western medicines.

Intellectual property protection of CM

- 8. Mr Martin LIAO pointed out that the existing intellectual property (IP) laws in Hong Kong in respect of trademarks and patents did not offer enough legal protection for traditional CM, and hence the CM industry was reluctant to invest in R&D and in manufacturing pCm. Highlighting the importance of setting up an IP protection system for CM to promote the development of CM industry, Mr LIAO called on the Administration to consider exploring IP issues in relation to CM in both Hong Kong and the Greater China region. Ms Emily LAU and Mr Dennis KWOK concurred with Mr Martin LIAO. Ms Emily LAU remarked that where necessary, the Administration should consider including legal personnel and representatives of the IP industry in the membership of the R&D Committee to take forward the issue.
- 9. <u>CIT</u> noted members' views and suggestions. She explained that the Intellectual Property Department (IPD) was responsible for matters pertaining to IP protection in Hong Kong. IP protection for CM was a complex issue that required the co-operation of various government bureaux/departments. <u>BD, ITC</u> supplemented that in accordance with the Chinese Medicine Ordinance (Cap. 549), all kinds of pCm must first be registered by the Chinese Medicines Board under the Chinese Medicine Council of Hong Kong before they could be imported, manufactured and sold in Hong Kong. If the subject medicine was sold or manufactured in Hong Kong on 1 March 1999, the relevant traders might also apply for registration under transitional arrangements.

The R&D Committee

- 10. Dr LAM Tai-fai and Ms Emily LAU enquired progress/achievement had been made after disbandment of the former Hong Kong Jockey Club Institute of Chinese Medicine (HKJCICM) and whether the R&D Committee would be more conducive to the sustainable long-term development of R&D of CM in Hong Kong compared with the defunct Ms Lau also enquired whether the development of CM in Hong Kong was hindered by the domination of medical professionals of Western medicine. Pointing out that the development of CM in Hong Kong required the co-operation of various government bureaux/departments and integration of Chinese and Western medicines, she hoped that the R&D Committee would focus its work on removing the barriers between Chinese and Western medicines.
- 11. In response, <u>CIT</u> advised that the membership of the R&D Committee included representatives from the Government, CM and pharmaceutical trade/industry, medical professionals of Chinese and Western medicines, relevant public organizations and advisory bodies as well as local universities with significant R&D of CM. It provided a good platform for all to identify R&D collaboration potentials of Chinese and Western medicines in areas where Hong Kong had strengths. Since the representation and scope of work of the R&D Committee were broader than those of HKJCICM, the Administration believed that it would be more effective in co-ordinating collaboration among various parties. <u>CIT</u> highlighted that while ITC focused on promoting R&D of CM and providing support to the CM industry, the regulation of the practice of Chinese medicine practitioners and the use, manufacture and trading of pCm were under the purview of FHB and DH.
- 12. <u>Mr WONG Ting-kwong</u> enquired about the difference between the R&D Committee and the Chinese Medicine Development Committee (the Development Committee) in respect of their terms of reference and composition, as well as the co-operation between the two Committees.
- 13. <u>CIT</u> explained that the Chief Executive, in his election manifesto, had committed to setting up a Development Committee to study and put forward proposals on policies and measures to further the development of CM. In this connection, a Preparatory Task Force, chaired by Secretary for Food and Health, had been established in mid-August 2012 to advise the Administration on the composition, terms of reference, and areas of work of the Development Committee. On the other hand, the R&D Committee under ITC was established to provide a platform to gauge views from various stakeholders, facilitate sharing of R&D outcome and collaboration, and to

- 7 -

better co-ordinate efforts in promoting R&D and testing of CM to meet the future needs of Hong Kong. As R&D and technology upgrading were important elements in the overall development of CM, the R&D Committee together with ITC would render full support to the Development Committee when it was established.

14. Highlighting the importance of demand and market needs in driving the development of the CM industry in Hong Kong, the Deputy Chairman said that the membership of the R&D Committee should in particular include representatives from the commerce and industry sectors who possessed relevant knowledge and experience in sales and marketing to help promote the commercialization of R&D results and manufacturing of pCm. She requested the Administration and the R&D Committee to consider exploring the impact arising from regulation of health food products, and how overseas Hong Kong Economic and Trade Offices might help in promoting Hong Kong's strengths in CM.

Development of the pCm manufacturing industry

- 15. Referring to the Good Manufacturing Practice (GMP) requirement in respect of pCm in Hong Kong, Dr LAM Tai-fai noted that to date, only 10 pCm manufacturers had been awarded GMP Certificates. He asked about the total number of pCm manufacturers in Hong Kong, and the number of those who were in the process of applying for GMP Certificates. Chairman, Dr LAM Tai-fai, and Mr WONG Ting-kwong expressed concern about the difficulties faced by pCm manufacturers in becoming GMP-compliant, such as financial constraints, lack of technical know-how, and shortage of suitable land space for establishing GMP facilities. These members were particularly concerned about the lack of Government support and assistance to pCm traders/manufacturers, worrying that most of the local pCm manufacturers, which were small and medium enterprises (SMEs), would be forced to cease operation upon the implementation of the mandatory GMP requirements. Dr LAM Tai-fai enquired about the Administration's support and assistance to the pCm manufacturing industry, as well as whether the Administration would set a target of assisting a certain number of pCm manufacturers to obtain GMP Certificates within a specified period of time.
- 16. Relaying the grave concerns of the pCm manufacturing industry about the lack of suitable plants and the substantial capital outlay needed for setting up production lines that could meet the pCm GMP standards, the Chairman enquired whether the Administration would consider setting aside sites at existing industrial estates (IEs) for the development of the pCm

Admin

manufacturing industry and taking the lead in setting up a traditional Chinese medicine science and technology industrial park with GMP facilities for use by the pCm manufacturing industry, especially SME manufacturers.

- CIT and BD, ITC responded that there were currently some 290 licensed pCm manufacturers in Hong Kong, mostly SMEs. GMP requirement in respect of pCm in Hong Kong was not mandatory. ensure the quality and safety of pCm, it was announced in the 2010-2011 Policy Address that a timetable for mandatory GMP compliance for manufacture of pCm would be worked out, to keep up with international trends of developing GMP for medicines. While FHB/DH were responsible for regulatory matters relating to the implementation of pCm GMP in Hong Kong, the R&D Committee would make every effort to support and facilitate technology upgrading of the industry. Mindful of the local pCm manufacturers' difficulties in complying with the GMP requirements, the R&D Committee had explored the future mandatory requirements of pCm GMP, and had formed a Working Group on Chinese Medicines Manufacturing (the Working Group) to discuss the GMP issue in greater detail. It would also address other important R&D and technical issues of CM manufacturing to facilitate industry upgrading in the long run. Working Group was of the view that local pCm manufacturers' lack of proper understanding of GMP was one of the factors deterring them from setting up The Working Group recommended that relevant training GMP production. in a systematic manner should be organized to help local pCm manufacturers get prepared for the future implementation of mandatory GMP requirements. As agreed at the Working Group, ITC was currently in discussion with GMP consultants (e.g. the Hong Kong Institute of Biotechnology (HKIB), a Company Limited by Guarantee wholly controlled by the Council of The Chinese University of Hong Kong) to organize different types of training activities to suit the needs of different target groups, such as top management, middle management and front-line staff, according to their skill levels and roles in the companies.
- 18. <u>CIT</u> and <u>BD, ITC</u> supplemented that the R&D Committee was also aware of the industry's concern about the provision of hardware support, especially for SMEs that lacked the financial capacity, technical knowledge and expertise to support the building of GMP facilities and their subsequent operation. In this connection, the R&D Committee was considering the possibility and options of GMP consultancy service and contract manufacturing arrangements. The R&D Committee was in discussion with HKIB which had been offering GMP consultation services to the pharmaceutical industry and had a GMP-compliant production facility which could offer contract CM manufacturing services to local companies. They

- 9 -

Action

would explore whether the present GMP facilities in HKIB could be expanded to help address the increasing industry demand for pCm GMP manufacturing. As local CM manufacturers varied widely in their technical knowledge and scale of operation, <u>CIT</u> highlighted that the R&D Committee and ITC, in conjunction with relevant stakeholders, needed to examine the overall potential demand, the size and the needs of each subsector for better planning of the support to the industry.

- 19. On financial support, <u>CIT</u> said that the \$5 billion ITF provided funding support for applied R&D projects of various technology areas including CM. Since its establishment in late 1999, ITF had supported over 70 CM-related projects with a total funding of about \$170 million. The nature of these projects included development of new CM, clinical studies, and technologies related to manufacturing and quality control of CM. As for infrastructure, in addition to the existing three IEs, the Hong Kong Science Park (the Park) managed by the Hong Kong Science and Technology Parks Corporation provided the industry with R&D infrastructure, including two laboratory buildings with central facilities located in Phase Two of the Park to support companies in the Park engaging in R&D of CM.
- 20. <u>Mr WONG Ting-kwong</u> and <u>Ms Emily LAU</u> cautioned against the contract manufacturing arrangements which in their view might result in market domination by large companies at the expense of SME manufacturers. They said that caution should be exercised to protect local pCm SMEs from being acquired and merged by the large companies. <u>The Administration</u> took note of Mr WONG's and Ms LAU's concerns.
- 21. <u>Dr LAM Tai-fai</u> expressed disappointment at the slow progress of the development of the CM industry in Hong Kong and criticized the Administration for the lack of concrete proposals to support pCm manufacturers and address their problems in complying with the GMP requirements. At the request of the Deputy Chairman, the Administration agreed to provide information on the plan or strategy, as well as the timetable, for supporting the development of CM manufacturing industry in Hong Kong.

Admin

22. The Chairman suggested and members agreed that issues on the support and assistance to the pCm manufacturing industry to facilitate their compliance with the implementation of GMP requirements and promote the development of the CM industry in Hong Kong should be discussed at a future Panel meeting with the Administration, including the Commerce and Economic Development Bureau/ITC and FHB/DH as well as the R&D Committee. The Panel would also receive views from relevant stakeholders on the subject.

V. Proposed adjustment to fees and charges under the purview of the Trade and Industry Department

(LC Paper No. CB(1)299/12-13(05)

-- Administration's paper on proposed adjustment to fees and charges under the purview of the Trade and Industry Department

LC Paper No. CB(1)299/12-13(06)

-- Paper on proposed adjustment to fees and charges under the purview of the Trade and Industry Department prepared by the Legislative Council Secretariat (background brief)

Presentation by the Administration

23. At the invitation of the Chairman, <u>Deputy Director-General of Trade and Industry (Commercial Relations, Controls, and Support)</u> (DDGTI) briefed members on the proposals to adjust fees and charges in respect of the certification and licensing services related to strategic commodities under the purview of the Trade and Industry Department (TID). <u>DDGTI</u> advised that subject to members' views, the Administration planned to introduce the necessary legislative amendments to implement the proposed fee adjustments for two strategic commodities-related items, namely Delivery Verification Certificate (DVC) and International Import Certificate (IIC) under the Import and Export (Fees) Regulations (Cap. 60B) in January 2013. Details of the proposals were set out in the Administration's paper (LC Paper No. CB(1)299/12-13(05)).

Discussion

Strategic trade control system in Hong Kong

24. The Chairman enquired about the definition of strategic commodities and the annual trade statistics on these commodities. DDGTI responded that strategic commodities were broadly classified into two categories. One of which was munitions such as firearms, ammunition, explosives, bombs and rockets, tanks and toxicological agents, equipment and technology for the

production of these weapons, etc. The other category was dual-use goods that were capable to be developed into weapons of mass destruction. These industrial dual-use goods were grouped into various categories including, among other things, chemicals, electronics, telecommunications and information security.

- 25. <u>DDGTI</u> further said that the Import and Export Ordinance (Cap. 60) (the Ordinance) was the legal basis for strategic trade control in Hong Kong. It was aimed at preventing Hong Kong from being used as a conduit for the proliferation of weapons of mass destruction and guaranteeing Hong Kong's access to high technology products. The Ordinance required strategic commodities to be covered by import/export licences issued by TID before they were imported into/exported from Hong Kong. TID issued about 80 000 to 90 000 import licences and about 330 000 export licences each year, mostly covering import/export of high technology dual-use goods such as integrated circuit, telecommunications equipment and components, etc.
- 26. Responding to the Deputy Chairman's enquiry about the strategic trade control system in Hong Kong, DDGTI said that in view of Hong Kong's status as a regional trading and distribution centre, the Administration was committed to maintaining an effective and efficient import and export control system which could guard against illegal flow of strategic commodities and at the same time facilitate legitimate business. The strategic trade control system was underpinned by the licensing system administered by TID and the enforcement system under the purview of the Customs and Excise Department (CED). The Hong Kong strategic trade control lists were based on the controls adopted by the various international export control regimes and conventions. TID would continue to update the control lists to reflect changes agreed by the international export control regimes. would also co-operate closely with other enforcement agencies and relevant international organizations in combating unlicensed transshipment and in-transit cargoes.

Proposed adjustments to fees and charges

27. The Chairman and Mr WONG Ting-kwong expressed support for the proposed fee increase for DVC and IIC in 2012-2013. Noting that the proposed fee adjustments would result only in a net increase of around \$970 in revenue per annum, the Chairman and Mr WONG opined that the increase in revenue was not commensurate with the administrative cost and the legislative process involved.

- 28. <u>DDGTI</u> responded that under the "user-pays" principle, fees charged by the Government for various goods and services should be regularly reviewed and updated, and in general be set at levels adequate to recover the full cost of providing these goods and services. Based on the outcome of the recently completed annual costing review of fee items, and in accordance with the guidelines issued by the Financial Services and the Treasury Bureau, the Administration suggested to adopt a gradual approach to achieve full-cost recovery in respect of DVC and IIC through a fee increase by about 10% in 2012-2013.
- **DDGTI** advised that for the purpose of ascertaining the actual 29. destination or controlling exports of specific types of strategic commodities, overseas exporting licensing authorities might require their exporters who, in turn, requested Hong Kong importers to obtain a DVC or IIC respectively. On the IIC, the Hong Kong importer undertook that the goods concerned would be imported into Hong Kong and would not be diverted, transshipped or re-exported unless he/she obtained an export licence issued by TID. In 2011, TID had issued less than ten DVCs and about 80 IICs. The fees for DVC and IIC were specified in the Schedule to the Import and Export (Fees) Section 29A of the Interpretation and General Regulations (Cap. 60B). Clauses Ordinance (Cap. 1) provided that the Financial Secretary might vary fees which had previously been set by subsidiary legislation made by the Chief Executive in Council. Although the proposed fee adjustments were not significant in dollar terms, the relevant subsidiary legislation to implement the proposed adjustments was subject to the Legislative Council (LegCo)'s scrutiny under the negative vetting procedure, and the Panel should be consulted first before the legislative proposals were introduced into the DDGTI said that it was up to the Panel to decide whether members could be consulted by circulation on a proposal to adjust statutory fees with insignificant financial implication in the future.
- 30. Mr WONG Ting-kwong was concerned that increase in fees and charges under the purview of TID would have adverse impact on business operating costs amid current difficult trading environment. He enquired whether the Administration would propose to increase other fees and charges under the purview of TID in the near future.
- 31. <u>DDGTI</u> responded that TID had recently completed the annual review exercise regarding 24 fee items under its purview. Apart from the fees for DVC and IIC, increase in two other items relating to printing charge and registration fee were required. These two adjustments had been/were to be implemented through administrative measures and would not involve legislative amendments. There were no adjustments to the remaining 20 fee

items in 2012-2013.

Summing up

32. <u>The Chairman</u> concluded that the Panel supported in principle the proposed fee adjustments for DVC and IIC under the purview of TID.

VI. Any other business

33. There being no other business, the meeting ended at 4:12 pm.

Council Business Division 1
<u>Legislative Council Secretariat</u>
14 February 2013