立法會
Legislative Council

LC Paper No. CB(2)2493/01-02
(These minutes have been
seen by the Administration)

Ref : CB2/PL/HS

LegCo Panel on Health Services

Minutes of meeting
held on Monday, 10 June 2002 at 8:30 am
in Conference Room A of the Legislative Council Building

Members Present	:	Hon Mrs Sophie LEUNG LAU Yau-fun, SBS, JP (Chairman) Dr Hon LO Wing-lok (Deputy Chairman) Hon Cyd HO Sau-lan Hon CHAN Kwok-keung Hon Andrew CHENG Kar-foo Hon LAW Chi-kwong, JP Dr Hon TANG Siu-tong, JP Hon LI Fung-ying, JP Hon Tommy CHEUNG Yu-yan, JP Hon Michael MAK Kwok-fung
Members Absent	:	Hon CHAN Yuen-han, JP Dr Hon YEUNG Sum
Public Officers Attending	:	All items Mr Thomas YIU Deputy Secretary for Health and Welfare Miss Angela LUK Principal Assistant Secretary for Health and Welfare

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Dr P Y LAM, JP
Deputy Director of Health

Dr Constance CHAN
Assistant Director (Health Administration and Planning)
Department of Health

Dr Monica WONG
Principal Medical Officer
Department of Health

Mr Peter KWOK
Assistant Secretary for Health and Welfare

Clerk in Attendance : Ms Doris CHAN
Chief Assistant Secretary (2) 4

Staff in Attendance : Ms Janet SHUM
Senior Assistant Secretary (2) 9

I. Confirmation of minutes of meeting held on 13 May 2002
(LC Paper No. CB(2)2212/01-02)

The minutes were confirmed.

II. Date of next meeting and items for discussion
(LC Paper Nos. CB(2)2213/01-02(01) and (02))

2. Members agreed to discuss the following items at the next meeting to be held on 8 July 2002 at 8:30 am -

(a) General Out-patient Clinic Transfer - Progress Report; and

(b) Amendments to Smoking (Public Health) Ordinance.

3. Mr Michael MAK was of the view that the Administration should continue

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to provide members with information papers during the recess so as to keep members informed of the progress of the items to be followed up or discussed. In addition, Mr MAK suggested that the following outstanding items should be given priority for discussion early in the next legislative session -

(a) Chinese medicine;

(b) Proposed regulatory system for unregulated health care personnel; and

(c) Regulation of health claims.

4. Deputy Secretary for Health and Welfare (DSHW) agreed that the Administration would provide members with information papers during the recess when it was in a position to do so.

III. Draft report of the Panel for submission to the Legislative Council
(LC Paper No. CB(2)2213/01-02(03))

5. Members endorsed the above report for submission to Legislative Council on 3 July 2002.

IV. Proposal on the regulation of medical devices
(LC Paper No. CB(2)2213/01-02(04))

6. At the invitation of the Deputy Chairman, Deputy Director of Health (DDH) took members through the Administration's paper which detailed the proposal on the regulation of medical devices.

7. Mr Michael MAK requested the Administration to conduct direct consultations with the professions which might be affected by the proposed regulatory system so as to clear their doubts and address their concerns. In addition, Mr MAK raised the following questions -

(a) What standard had been adopted in classifying the risk levels of the medical devices as proposed in paragraph 9 of the Administration's paper;

(b) Whether the Administration would consider strengthening existing regulations as an alternative to introducing new mandatory legislation on medical devices; and

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(c) How would the administrative control system operate as an interim measure before the enactment of the new ordinance which might take some time to formulate.

8. DDH clarified that the earlier survey jointly conducted by the Department Health (DH) and the Electrical and Mechanical Services Department sought to obtain an overview of the sale and use of medical devices in Hong Kong. The survey was aimed at collecting information on the types of products being marketed in Hong Kong and opinion on the regulation of medical devices from traders, including manufacturers, importers and selected operators in the trade. DDH said that after finalizing the proposed regulatory framework in the coming months, the Administration would conduct consultation exercises which would include customers representatives, healthcare and engineering professionals, the industry and other stakeholders of the trade.

9. In response to Mr MAK's first question, DDH said that the proposed regulatory framework was largely formulated in line with the recommendations made by the Global Harmonisation Task Force (GHTF), including the definition and classification of medical devices, essential principles of quality and safety, vigilance system requirements, and the use of international standards. GHTF was a voluntary consortium with representatives from the trade and regulatory authorities from U.S.A., Canada, Australia, Japan and the European Union. DDH said that although different countries might vary in setting standards regarding the regulation of medical devices, GHTF had developed reference standards and recommended regulatory authorities to adopt such standards when devising control over medical devices. For examples, injection needle, contact lens disinfectants and laser were items of medium level of risk while heart valve and implantable pacemaker were of high level of risk.

10. In response to Mr MAK's second question, DDH said that regulation for medical devices containing radioactive substances or pharmaceutical products were provided in current legislation such as the Radiation Ordinance (Cap. 303) and the Pharmacy and Poisons Ordinance (Cap 138). DDH further said that the implementation of regulatory control on medical devices would involve consequential amendments to existing legislation but details of the amendments were not available at this stage.

11. In response to Mr MAK's third question, DDH said that an administrative control system would be put in place before the enactment of the new ordinance. The administrative control system would follow the same principles as the proposed legislative system. Manufacturers, importers, and operators of selected medical equipment would be invited to list their medical devices with DH on a

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voluntary basis and an adverse incident reporting system would also be set up. DDH understood that an administrative control system on voluntary basis might not be fully effective but the Administration would work out details of the implementation of the system and report to members in future meetings.

12. Referring to paragraph 15 (C) (b) and (e) of the Administration's paper, Dr TANG Siu-tong wished to clarify the requirement regarding the recall of defective products by manufacturers or their representatives. He also expressed concern that the report of any adverse incidents or serious complications arising from the use of medical devices by non-healthcare professionals might not be effective. For example, non-healthcare professions such as beauty parlours might not report cases under this system.

13. DDH said that it was proposed that manufacturers or their representatives would be required by law to report any adverse incidents, provide investigation report and recall defective products. As regards the report of adverse incidents, DDH said that the reporting system served to identify and collect information on the incorrect use of medical devices, and users were encouraged to report adverse incidents under this system. DDH said that it would be difficult to enforce legislation to penalize the users for not reporting cases of adverse incidents in using medical devices.

14. Dr TANG Siu-tong was of the view that as serious complications arising from the use of the devices might not emerge until after a period of time, it was not easy to detect immediate defects of some medical devices. DDH said that a mechanism would be set up to monitor and investigate serious incidents caused by the use of medical devices such as those which had caused damages to the users. He pointed out that similar mechanisms were available in other countries such as the United States who had often issued medical alerts to the Administration about defects of medical devices. DDH said that with the setting up of a mechanism in reporting defective products, DH would be able to collect information for investigation and inform healthcare professionals or the public of the defects so that re-occurrence of incidents could be prevented.

15. Ms LI Fung-ying was of the view that the definition of medical devices must be clear and the classification of their risk levels objective. Ms LI pointed out that GHTF which harmonized the standards and principles of regulating medical devices might not have specifications regarding the application of Chinese medical devices. In addition, Ms LI enquired whether there was any information on the size of the workforce which needed to use medical devices in daily operation and whether the implementation of the regulatory system would have any impact on the workforce.

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16. DDH agreed that while international standards had been set for most of the Western medical devices, it might be less easy to define and set the risk levels of Chinese medical devices. DDH pointed out that apart from regulation of medical devices, it was equally important that the public should be provided with information to facilitate their choices in using medical devices. As regards the impact of the proposed regulation on the workforce, DDH said that the Administration would conduct an assessment of such impact prior to the implementation of the regulatory system. As a case in point, DDH said that according to the result of the recent survey, 80% of the traders who responded to the survey agreed that there should be some form of control on medical devices to ensure public safety.

17. Mr Michael MAK enquired whether the Administration had any record of past figures showing the number of complaint cases about medical devices such as the use of laser. As regards the definition of Chinese medical devices and the classification of their risk levels, Mr MAK suggested that the Administration should conduct research to study whether there was any mechanism in the Mainland which defined or regulated Chinese medical devices. In addition, Mr MAK said that the consultation to be conducted should include traders, operators and other professionals who would be affected by the regulatory system.

18. DDH said that the Administration had no record of the total number of cases of adverse incidents or serious complications arising from the use of medical devices but he understood that there should not be too many cases save the earlier complaints about misuse of lasers by beauty parlours. DDH further said that a basic definition of medical devices was that they should perform certain medical functions. As regards the workforce in businesses involving the use of medical devices, DDH pointed out that according to the analysis based on the recent survey on traders and selected operators, it was estimated that there were around 600 importers of medical devices in Hong Kong importing some 20 000 types of devices and about 30 local manufacturers producing accessories or parts of medical devices. DDH further said the Administration would assess the number of people involved in the businesses relating to the trading and operation of medical devices and provide members with the information when available. DDH added that beauticians and optometrists would be included in the consultation.

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19. The Deputy Chairman expressed concern about the regulation of products with unproven medical claims such as magnetic pillows which might have misled the users. The Deputy Chairman considered that traders or manufacturers of such products should be required to comply with labeling requirement before approval was given for registration and sale of such products. An appeal mechanism should be set up in case of disputes arising from regulatory actions against persons held responsible for adverse incidents.

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20. In response, DDH said that the Administration might consider setting up an alternative category under which unproven medical devices would be listed. DDH pointed out that regulatory control should be proportional to the level of risk associated with the device and it should not place an unnecessary burden on the regulators, the trade and industry nor delay the introduction of new products that would benefit patients. DDH said that the Administration had not yet decided on the setting up of an appeal system at this stage but assured members that the products would be assessed in accordance with criteria relating to safety, quality and efficacy. A panel comprising biomedical engineering and healthcare experts would carry out the assessment of the technical documents.

21. In response to the Deputy Chairman's enquiry about the timetable in implementing such regulation, DDH said that details of the regulatory system would be developed by early next year after consultation with consumers representatives, healthcare and engineering professionals, the industry, the operators and other stakeholders who would be affected by the regulatory system. DDH further said that the first phase of the regulatory system would focus on medical devices of high and medium risk levels. DSHW said that the Administration would balance the interests of all parties concerned and conduct wide consultations before implementing the regulation. It would revert to the panel for further discussions on the matter in next legislative session.

V. Reorganisation of the Central Health Education Unit of Department of Health

(LC Paper No. CB(2)2213/01-02(05))

22. At the invitation of the Deputy Chairman, the Assistant Director (Health Administration & Planning) briefed members on the Administration's paper which detailed the reorganization of the Central Health Education Unit (CHEU) of DH.

23. In light of the functional change of CHEU, Ms LI Fung-ying enquired whether the reorganization would involve any additional costs or increase in resources. DDH responded that the reorganization of DH was aimed to strengthen the leadership and advisory role of DH in the formulation of health promotion strategy and programmes. For example, it would enhance provision of consultancy services to local community groups and assist the district health committees to draw up health promotion programmes targeting at the specific needs of local residents. DDH said that no additional costs were expected to be incurred in the reorganization.

24. Ms LI expressed concern that in view of DH's policy to emphasize its role

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in health promotion and delegate the tasks of health education to other organizations, those organizations might have problems in taking up the tasks without additional resources. Ms LI further enquired how DH would guarantee quality control of health educational programmes in this respect.

25. DDH responded that the reorganization of CHEU was in line with the policy objectives of the Administration to restructure and enhance health education and preventive programmes so as to provide lifelong holistic care for the public. Although no additional resources were involved in the reorganization of CHEU, DH had enhanced existing preventive services such as the setting up of a new Adolescent Health Programme to promote and improve the psychosocial health of adolescents. In addition, the four Regional Offices of DH were allocated with resources for health education programmes. DDH said that it was DH's policy to take a leadship role rather than monopolizing the work in health promotion and he understood that district health committees had expressed interests to run programmes on health education.

26. Mr Michael MAK considered that CHEU should take a more proactive role in promoting healthcare and asked for information on the staff composition of CHEU and the area of work of the Public Relations and Communication Branch. He further enquired how CHEU would interface with other departments to promote labour health and food health. ADDH responded that apart from medical and nursing expertise, the Public Relations and Communication Branch would include staff specializing in community development as well as staff responsible for creative design and information technology. The work of the Public Relations and Communication Branch was to enhance health promotion and disease prevention campaigns and give advice to other departments or organizations in promoting relevant programmes. As regards the Public Health Branch, ADDH said that it would include two research officers who would provide research and information support.

27. Mr MAK than asked how CHEU would execute its leadership role to promote health and whether it would put forward proposals to other departments for implementation. DDH replied that CHEU had worked closely with other departments such as the Labour Department (LD) and the Food and Environmental Hygiene Department as staff in those departments responsible for health promotion were deployed from DH. DDH said that with the application of social marketing skills, CHEU would enhance its work in community development and strengthen its communication with other departments in health promotion.

28. Referring to paragraphs 10 and 11 of the Administration's paper, Dr TANG Siu-tong enquired how far the Administration would resort to legislation as the

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measure in addressing established risk behaviours such as unhealthy diet and tobacco use and whether it would assess how legislative enforcement would impact on the established behaviours of the public.

29. DDH said that DH's goal was to advocate and support health-promoting public policies which should involve a combination of methods and approaches such as legislation, development of policy, organizational change, community development and education. As regards anti-smoking strategies, DDH said that apart from setting up regulations, the Administration would strengthen its services to help smokers refrain from smoking and would give careful considerations to all factors, such as the risk levels, established behaviour of the public, and results of consultations, before making decision for legislation.

30. In response to Dr TANG's further question on how legislation was to be implemented without infringing the right of the public in making their own health choices, DDH said that the Administration's anti-smoking strategies would be launched by phases taking into consideration the level of risk involved. In this connection, DSHW said that the Administration would ensure that legislation would be enforced only when necessary and concerns of all parties would be considered before taking any decisions. DSHW further said that the function of CEHU was not on policy-making but mainly to promote health preventive programmes and formulate strategies to support legislation.

31. Ms Cyd HO enquired whether patients' right and health concepts of Chinese medicine and alternative medicines such as homeopathy would be included in the work targets of CHEU and whether the new accountability system would bring along any changes to the authority designated for approving the allocation of funds and resources. DDH responded that CHEU would include the promotion of patients' right and give consideration to include alternative medicines in the programmes. DDH said that with the application of the concept of social marketing, the Administration would consult expertise in the community for advice on special health promotional programmes. As regards possible changes brought about by the implementation of the new accountability system, DSWH said that it was the policy of the Administration to provide lifelong holistic care to the public and he believed that the operation and services of DH would not be affected.

32. In response to Ms HO's further enquiry whether there was any mechanism at work to promote Chinese or alternative medicine, DDH said that DH had engaged a Chinese Medicine practitioner to give advice on matters related to Chinese medicine. CHEU would seek advice from experts in other fields such as alternative medicines and other specialists when needed.

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33. Mr Andrew CHENG was of the view that the Public Health Branch of CHEU should adopt a holistic concept in formulating strategy for health promotion and work closely with relevant departments such as the Education Department (ED), the LD and Home Affairs Department (HAD) to ensure that the objective of a lifelong holistic health care strategy had been consistently carried out. For example, apart from the Home Affairs Bureau which had recently formulated a policy on sports development, DH and ED should also participate in the policy-making process, particularly in formulating policy in student sports which was also a health and education issue.

34. DDH pointed out that rather than a policy-making body, CHEU was designated to formulate strategies related to health promotion. DDH further said that CHEU was currently working with LD, ED and HAD to prioritize promotional programmes for the control and prevention of diseases and regularly monitored the healthcare need of the labour sector and the public in general.

35. Mr Andrew CHENG considered that while CHEU had reorganized itself to strengthen its role in health promotion, there was a need of a higher authority empowered to formulate holistic and comprehensive health policy to be implemented by all relevant departments concerned. In response, DDH explained that DH had all along worked closely with the policy bureaux concerned and made suggestions in relation to health promotion strategy or health regulation based on studies of the risk levels of public health. For example, DH had worked with Home Affairs Department in launching health related programmes such as the promotion of sports culture and community-wide participation in sports.

36. The Deputy Chairman considered that the Administration should set up health targets to be achieved after assessing the health condition of the community and make provisions available for achieving such targets such as through healthcare education and medical care facilities. DDH explained that the Administration had strengthened the disease surveillance and control system and established a Public Health Information System so as to generate information and to identify key areas where maximum health impact could be achieved with public health intervention. DDH further said that despite the Administration's effort to enhance public health condition, results could not be assessed easily as effective interventions often took years to produce measurable health outcomes. DDH added that the Administration would keep in view overseas developments in conducting health impact assessment and staff would be provided with relevant training in this aspect.

37. Mr Andrew CHENG was of the view that CHEU should set up objective health indexes for different age groups so as to facilitate the public to make health-enabling personal choices and enhance the health culture. DDH said that the

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Administration should be able to formulate health indexes after the full implementation of the Public Health Information System.

VI. Any other business

38. There being no other business, the meeting ended at 10 :15 am.

Council Business Division 2
Legislative Council Secretariat
5 July 2002