

立法會
Legislative Council

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LC Paper No. CB(2)484/10-11
(These minutes have been seen
by the Administration)

Panel on Health Services

Minutes of meeting
held on Monday, 8 November 2010, at 8:30 am
in Conference Room A of the Legislative Council Building

- Members present** : Dr Hon LEUNG Ka-lau (Chairman)
Dr Hon Joseph LEE Kok-long, SBS, JP (Deputy Chairman)
Hon Albert HO Chun-yan
Hon Fred LI Wah-ming, SBS, JP
Hon CHEUNG Man-kwong
Hon Andrew CHENG Kar-foo
Hon LI Fung-ying, SBS, JP
Hon Audrey EU Yuet-mee, SC, JP
Hon Cyd HO Sau-lan
Hon CHAN Kin-por, JP
Hon CHEUNG Kwok-che
Hon IP Kwok-him, GBS, JP
Dr Hon PAN Pey-chyou
Hon Alan LEONG Kah-kit, SC
Hon Albert CHAN Wai-yip
- Members attending** : Hon Vincent FANG Kang, SBS, JP
Hon WONG Kwok-hing, MH
- Members absent** : Ir Dr Hon Raymond HO Chung-tai, SBS, S.B.St.J., JP
Hon CHAN Hak-kan
- Public Officers attending** : Items III to VI
Prof Gabriel M LEUNG, JP
Under Secretary for Food and Health

Item III and IV only

Miss Gloria LO
Principal Assistant Secretary for Food and Health
(Health)2

Dr Su Vui LO
Director (Strategy & Planning)
Hospital Authority

Dr Nancy TUNG
Cluster Chief Executive, Kowloon West Cluster
Hospital Authority

Dr K K LAI
Hospital Chief Executive, Yan Chai Hospital
Hospital Authority

Mr Donald LI
Chief Manager (Capital Planning)
Hospital Authority

Item V and VI only

Ms Estrella CHEUNG
Principal Assistant Secretary for Food and Health
(Health)1

Dr Gloria TAM, JP
Deputy Director of Health

Dr Heston KWONG
Assistant Director of Health (Special Health Services)

Dr Teresa LI
Principal Medical & Health Officer
Department of Health

Item VI only

Dr HAU Kong-lung, JP
Consultant Forensic Pathologist in-charge
Department of Health

Clerk in attendance : Ms Elyssa WONG
Chief Council Secretary (2) 5 (Des)

Staff in attendance : Ms Maisie LAM
Senior Council Secretary (2)6

Ms Priscilla LAU
Council Secretary (2) 5

Ms Sandy HAU
Legislative Assistant (2)5

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I. Confirmation of minutes

(LC Paper No. CB(2)171/10-11)

The minutes of the meeting held on 14 October 2010 were confirmed.

II. Information paper(s) issued since the last meeting

2. No information paper was issued since the last meeting.

III. Discussion items for the next meeting

(LC Paper Nos. CB(2)183/10-11(01) to (02) and CB(2)376/10-11(01))

3. Members agreed to discuss the issue of "Healthcare Reform Second Stage Public Consultation - Health Protection Scheme" at the next regular meeting scheduled for 13 December 2010.

4. Referring to Mr Alan LEONG's letter dated 5 November 2010 (LC Paper No. CB(2)376/10-11(01)) tabled at the meeting in which the Panel was requested to discuss the issue of whether oral chemotherapeutic drugs could be introduced into the Drug Formulary of the Hospital Authority ("HA") for the benefits of cancer patients, Ms Audrey EU suggested to include the proposed item in the agenda of the meeting on 13 December 2010. Mr CHEUNG Man-
kwong also requested that arrangements be made for early discussion of the subject.

5. The Chairman said that the issue of "Drug Formulary of HA" had been scheduled for discussion at the regular meeting of the Panel in February/March 2011. The Administration would also address the issue concerning iron

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chelating therapy for Thalassaemia patients in public hospitals. The Chairman sought members' views on whether the subject of oral chemotherapy for cancer patients in public hospitals should be discussed separately in December 2010 or in the context of "Drug Formulary of HA" in February/March 2011.

6. While agreeing that it would be more conducive to discussing issues relating to the Drug Formulary of HA at one meeting, Ms Audrey EU held the view that the urgency for discussion of the subject would depend on whether the Drug Utilisation Review Committee of HA would only meet once a year and whether its meeting for finalizing its recommendation on the proposed changes to the Drug Formulary would be held in December 2010.

7. Under Secretary for Food and Health ("USFH") responded that he did not have the information in hand. He drew members' attention to the fact that the list of drugs in the Drug Formulary was under independent review through an established system. The HA Drug Advisory Committee and the Drug Utilisation Review Committee, comprising experts from relevant fields, would meet regularly and respectively to appraise new drugs and review existing drugs in the Drug Formulary. In addition, HA held annual consultation meetings since 2009 with patient groups to, among others, solicit their views and suggestions on introduction of new drugs and review of existing drugs in the Drug Formulary. USFH was of the view that discussion of the Panel on issues relating to the Drug Formulary should be confined to the policy aspect rather than the use of individual drugs. The Chairman advised that it would be for the Panel to decide the scope of discussion of an agenda item.

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8. At the request of the Chairman, USFH undertook to provide after the meeting information on the schedule of meetings of the Drug Advisory Committee and the Drug Utilisation Review Committee to facilitate the Panel's decision on the timing of discussion on the subject.

(Post-meeting note: The information provided by the Administration was circulated to members vide LC Paper No. CB(2)362/10-11 on 23 November 2010.)

9. As regards the special meeting to be held on 11 December 2010 from 9:00 am to 1:00 pm to receive public views on the Health Protection Scheme, Mr CHEUNG Man-kwong suggested inviting academics to give views on the subject. The Chairman asked members to inform the Secretariat if they intended to invite organizations/individuals, other than those set out in the list circulated to members vide LC Paper No. CB(2)226/10-11 on 5 November 2010, to give views on the subject. Depending on the number of deputations attending the meeting, the meeting might be extended to the afternoon. Ms Cyd HO suggested that consideration could be given to holding two half-day special

meetings if a large number of deputations indicated interest in giving views.

IV. Redevelopment of Yan Chai Hospital

(LC Paper Nos. CB(2)183/10-11(03) and (04))

10. USFH briefed members on the proposal to redevelop Blocks C, D, E and F of the Yan Chai Hospital ("YCH") into a community health and wellness centre, details of which were set out in the Administration's paper (LC Paper No. CB(2)183/10-11(03)).

Demand for services to be provided in the redeveloped YCH

11. Noting that Blocks C, D, E and F had a total gross floor area of about 22 210 square metres, Mr Vincent FANG asked about the total floor area of the new community health and wellness centre and whether the centre could meet the increasing demand of service from the growing population of the Kwai Tsing and Tsuen Wan districts.

12. Chief Manager (Capital Planning), HA advised that there would be an increase of around 20% in the total floor area of the redeveloped YCH to about 26 500 square metres. On the service demand of the Kwai Tsing and Tsuen Wan districts, USFH advised that the population in the two districts had increased by 14% between 1991 and 2009. According to the latest population projection of the Planning Department, the elderly population in the two districts would increase by 17% by 2016. As the increasing demand for healthcare services from the ageing community would further exert pressure on YCH, there was a need to redevelop YCH, in order to meet the increasing demand for comprehensive and integrated healthcare services in the community.

Service for the elderly

13. Mr CHEUNG Man-kwong enquired whether the new community health and wellness centre could address the service needs of the elderly in view of the ageing population of the two districts. Ms LI Fung-ying expressed similar concern and questioned why the new centre had not provided any specialist care services for the elderly.

14. USFH responded that the proposed community health and wellness centre would have a Health Resource Centre, a Primary Care Centre and a Specialist Care Centre. The Primary Care Centre would provide primary healthcare services for individuals at different stages of life including the elderly. The existing general out-patient clinic and community nursing services in YCH, of which the elderly was one of the main user groups, would also be reprovisioned

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in the Primary Care Centre. In addition, the Specialist Care Centre would provide, among others, assessment and stabilization services in an ambulatory setting for patients suffering from chronic diseases such as diabetes, hypertension and chronic obstructive airway disease which were common chronic diseases afflicting the elderly. The Administration considered that the proposed centre would be able to deliver comprehensive and integrated healthcare services for the elderly.

15. Dr PAN Pey-chyou maintained the view that primary healthcare was insufficient on its own to address the needs of the elderly and there was a need to enhance the specialist support in the provision of care for the elderly.

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16. The Chairman requested the Administration to provide in writing information on the increased service capacity for the elderly at the redeveloped YCH.

Urology service

17. Mr WONG Kwok-hing expressed his grave concern that with the cessation of the urology service at YCH, some urological cases in YCH had been referred to the Ha Kwai Chung General Out-patient Clinic, instead of a specialist out-patient clinic, for consultation. He asked whether HA would resume the provision of urology service at the redeveloped YCH and the interim arrangement that would be put in place to ensure that patients in need of the service would receive proper treatment.

18. Cluster Chief Executive, Kowloon West Cluster, HA ("CCE, KWC, HA") referred members to the letter dated 5 November 2010 from the Administration tabled at the meeting which addressed the same concern raised by Mr WONG at the special meeting of the Panel on 15 October 2010. She explained that services delivered by HA were on a cluster basis, with each cluster having a well-balanced mix of hospitals to provide comprehensive healthcare services to meet the needs of the community. The clustering arrangement enabled clear delineation of roles of different hospitals within each cluster and delivery of healthcare services in a cost effective manner. It also minimized duplication of services and allowed collaboration and complimentary support amongst hospitals. At present, the Princess Margaret Hospital ("PMH") was a Tertiary Referral Centre of Urology to support YCH. The Centre had established an expert team on urology with advanced technological support to manage all degrees of urology cases in Kwai Tsing and Tsuen Wan districts. Patients of non-urgent urological cases would receive consultation from family medicine doctors with additional training in urology, and they would provide early consultation for these patients. If any of these patients require subsequent urologist attention, they would receive consultations at the Centre within a

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reasonable period of time.

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19. The Chairman requested the Administration to provide in writing further information on the distribution of manpower and equipment for urology service among hospitals/clinics in KWC, as well as how those hospitals/clinics were able to meet the existing and expected demand for urology service of the Kwai Tsing and Tsuen Wan districts.

Mental health service

20. Ms Audrey EU asked whether the services to be provided in the proposed community health and wellness centre would include mental health service.

21. USFH responded that HA had started in October 2010 an Integrated Mental Health Programme to provide assessment and treatment services in the primary care settings for patients with common mental disorders. The programme would be expanded to cover all clusters in 2011-2012 in order to tackle more effectively the cases of mild mental illness in the community. The Primary Care Centre in the redeveloped YCH would provide such service.

22. Holding the view that the assessment and treatment services in primary care setting could hardly meet the needs of patients with serious mental health problems, Dr PAN Pey-chyou urged the Administration to consider providing ambulatory care facilities, such as psychiatric day hospital, in the redeveloped YCH to provide multidisciplinary assessment, continued care and rehabilitation to psychiatric patients.

23. CCE, KWC, HA supplemented that apart from the introduction of the Integrated Mental Health Programme, HA would also enhance co-operation with private medical practitioners to facilitate early identification and intervention of persons with signs of mental health problems. Under the cluster arrangement, community outreach services to persons with mental illness would be provided by the Kwai Chung Hospital, a psychiatric hospital in KWC. Psychiatric nurses are stationed at the Accident and Emergency Department of YCH, PMH and Caritas Medical Centre respectively to help handle patients with psychiatric conditions.

Obstetric service

24. Dr PAN Pey-chyou expressed concern at no mention being made of the provision of obstetric service at the redeveloped YCH, given that many young couples were residing in the Tsuen Wan district. Mr CHAN Wai-yip echoed similar view. He asked the Administration whether pre-natal assessment would be provided in the YCH.

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25. CCE, KWC, HA advised that obstetric service would be provided by PMH and Kwong Wah Hospital in KWC, and there was currently no plan to provide obstetric service at the redeveloped YCH. Yet, there is a Maternity and Child Health Centre provision in the proposed community health and wellness centre which would provide pre-natal assessment and post-natal care services to promote maternity health for mother and children.

Provision of service through the clustering arrangement

26. Ms LI Fung-ying asked whether the change of the focus of service of YCH from acute episodic illness to diseases of chronic disabling and relapsing nature would affect the provision of acute and emergency service in KWC. USFH replied in the negative, and pointed out that such service needs would be taken care of by other hospitals in KWC under the cluster arrangement.

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27. Mr Alan LEONG requested the Administration to provide information on the roles of the various hospitals in KWC in servicing the community in the Administration's paper to be submitted to the Finance Committee ("FC") for seeking funding approval for the redevelopment of YCH.

Environmental implications of the main works

28. Ms Audrey EU asked whether the redeveloped YCH would adopt an environmental-friendly building design and the measures which would be put in place to dispose of the construction waste generated.

29. Chief Manager (Capital Planning), HA responded that the design of the proposed community health and wellness centre had adopted various forms of energy efficient features, such as maximizing natural light penetration, installation of water-cooled air-conditioning system and automatic lighting on/off control system in office areas. On the disposal of construction waste, the contractors would be required to reuse inert construction waste (e.g. excavated rock and soil and demolished concrete) on site as far as possible, in order to minimize the disposal of inert construction waste at public fill reception facilities.

Completion time of the project

30. Mr Vincent FANG noted that the redevelopment project of YCH was expected to be completed in 2016. He urged the Administration to expedite the project so that the redeveloped YCH could come into service before 2016.

31. Chief Manager (Capital Planning), HA advised that subject to funding approval, HA planned to start the main works of the redevelopment project in July 2011. Having regard to various constraints of the site and the need for

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careful planning, it was expected that the main works would take about 55 months to complete. HA would endeavour to complete the project as soon as possible.

32. Ms Audrey EU sought clarification from the Administration as to whether the project had been expedited. USFH explained that the main works to be commenced in July 2011 would involve two phases. The first phase involved the demolition of Blocks C and D for construction of a new building to accommodate the proposed community and health wellness centre and ancillary facilities. Before the demolition of Blocks C and D, the existing services for patients provided in these two buildings would be decanted to Blocks A, B and E and subsequently reprovisioned in the community health and wellness centre upon the completion of the construction of the centre in mid 2014. The existing services in Blocks E and F, the out-patient clinics and pharmacy would also be reprovisioned in the centre by then. The second phase of the main works which involved the demolition of Blocks E and F and the provision of landscaped areas with car parking facilities at the sites of Blocks E and F was expected to complete in the first half of 2016.

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33. Mr CHAN Wai-yip urged HA to ensure that existing services for patients would not be affected by the redevelopment project. Hospital Chief Executive, YCH assured members that YCH would maintain its existing services for patients as those services in Blocks C and D would be decanted to Blocks A, B and E during the period of redevelopment. Ms Audrey EU requested HA to provide detailed information on how the existing services of YCH for patients would not be affected by the redevelopment project in the Administration's paper to be submitted to FC.

Project estimate

34. Mr CHEUNG Man-kwong enquired about the reason for the upsurge of the estimated cost of the main works of the redevelopment project by 170% from about \$420 million in December 2006 to \$715 million.

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35. Chief Manager (Capital Planning), HA explained that the increase in construction costs since early 2007 and the complexity of the redevelopment project being much higher than originally envisaged were the main reasons for the upsurge in the estimated cost of the project. At the request of Mr CHEUNG, Chief Manager (Capital Planning), HA agreed to provide detailed explanation on the increase in the estimated cost for the main works of the redevelopment project in the Administration's paper to be submitted to FC.

Conclusion

36. In closing, the Chairman said that members of the Panel were in support of the proposal to redevelop Blocks C, D, E and F of YCH into a community health and wellness centre.

V. Proposed regulatory framework of medical devices

(LC Paper Nos. CB(2)183/10-11(05) and (06); CB(2)221/10-11(01) and CB(2)241/10-11(01))

37. USFH briefed members on the proposed regulatory framework for medical devices, details of which were set out in the Administration's paper (LC Paper No. CB(2)183/10-11(05)). Assistant Director of Health (Special Health Services) then gave a PowerPoint presentation on the legislative proposal relating to the regulation of medical device, details of which were set out in the presentation materials tabled at the meeting (LC Paper No. CB(2)241/10-11(01)).

38. Members noted a joint submission dated 29 October 2010 from The Hong Kong Society of Professional Optometrists, The Hong Kong Association of Practicing Optometrists and The Hong Kong Optometric Association (LC Paper No. CB(2)221/10-11(01)) expressing views on the regulation of the distribution and sale of non-corrective contact lens.

Definition and classification of medical devices

39. Mr CHAN Kin-por noted that while corrective contact lens would be classified as Class II medical device (i.e. medium - low risk level) and subject to statutory control under the proposed regulatory framework for medical devices, non-corrective contact lenses would be included for regulatory control through listing in a Schedule of the proposed legislation. He asked for the reason for adopting a different approach to regulate the corrective and non-corrective contact lens, albeit that both were intended for use on human body and would potentially have similar adverse effect on human body.

40. Dr Joseph LEE expressed a similar concern and enquired whether the Administration had in mind a list of products which did not fall within the definition of medical device but would be designated in the Schedule for inclusion for regulatory control under the proposed legislation.

41. USFH explained that for the purpose of the proposed legislation, the definition of medical device would be based largely on the recommendation of the Global Harmonization Task Force. The experience of countries with

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regulatory control showed that, despite the attempt to provide a clear definition for medical device, a number of products appeared to be "borderline" cases. It was therefore proposed in the legislation that the Director of Health ("DoH") should be empowered to designate through a form of Schedule those products which were to be included for regulatory control taking into account the local situation and stakeholders' expectations.

42. Dr Joseph LEE pointed out that such an approach would cause confusion to the public and place unnecessary burden on the trade and industry. He suggested holding a special meeting to gauge views from the trade and industry. USFH remarked that in response to the recommendation of the Business Facilitation Advisory Committee, the Administration would conduct a business impact assessment ("BIA") at the detailed design stage.

43. Mr Alan LEONG sought information from the Administration on the factors which DoH would take into account in determining the products which should be included in the Schedule of the proposed legislation. He further asked whether consideration would be given to setting up an independent committee to advise DoH in this regard.

44. USFH advised that the Administration was in the process of preparing the proposed legislation and the details had yet to be worked out. However, similar to the arrangements under other ordinances, it was the regulatory authority, rather than another committee, which would be empowered to determine the products to be designated in the Schedule. In so doing, DoH might take into account factors such as the sale and use of the product in the local market; the risk of the product in causing adverse effect on human body; the frequency of adverse incidents arising from the use of the product; as well as the views of the sellers and users. In response to Mr LEONG's further enquiry as to whether the amendments made by DoH to the Schedule would be in the form of subsidiary legislation subject to the scrutiny of the Legislative Council, USFH replied that any amendments to the Schedule were subject to the negative vetting procedures under the scrutiny of the Legislative Council.

45. Ms Audrey EU remarked that the Administration should pay attention to the risk classification of the Chinese medicine medical devices as no international reference on their classification was available. Dr PAN Pey-chyou expressed a similar concern. He also urged the Administration to review the existing regulation for a registered Chinese medicine practitioner to adopt only treatment methods on the basis of traditional Chinese medicine in the use of traditional therapeutic apparatuses or other innovative therapeutic apparatuses that were developed with Chinese medicine theory, but not other therapeutic apparatuses such as X-ray.

Pre-market control

46. Dr PAN Pey-chyou said that it was of utmost importance for the regulatory authority to determine whether a medical device was safe and performed as intended before market entry. He urged the Administration to ensure that the Department of Health ("DH") would have adequate manpower and resources to effectively perform the assessment work.

47. USFH responded that the proposed legislation would empower DH to designate conformity assessment bodies ("CABs") to perform conformity assessment audits on medical devices, so as to provide third party conformity assessment services to manufacturers.

48. Ms Cyd HO urged the Administration to ensure the independence of the assessment conducted by CABs. USFH advised that DH had already accredited three CABs based on the quality standards adopted by the European Union in conformity assessment. USFH further said that there was no cause for concern about the independence of the assessment as the assessment teams of these CABs comprised a balanced mix of expertise in the various professional fields.

49. In response to Mr IP Kwok-him's enquiry about the regulation of the sale of medical devices on the internet, USFH responded that the Administration would look into the matter when preparing the proposed legislation.

Control over use of certain medical devices

50. Mr Vincent FANG sought clarification from the Administration on the following -

- (a) whether statutorily registered healthcare professionals would be required to undergo training before operating Class 3B and Class 4 high-power medical lasers; and
- (b) who were the business operators of such types of medical devices. According to the Administration, these business operators were required to apply for a licence to possess and operate the devices and undertake to comply with a set of licensing conditions.

51. Responding to Mr FANG's first question, USFH said that it was normal practice that statutorily healthcare professionals, such as medical practitioners, would receive training before operating any new medical device. The statutory regulation of certain healthcare professionals, through which the safe and appropriate treatment for patients could be ensured, also provided incidental control on the use of medical devices. USFH further said that the proposed

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legislation would allow personnel who were not statutorily registered healthcare professionals to operate the intense pulsed light ("IPL") equipment, provided that they had undergone training and passed the pulsed light trade test run by reputable institutions such as the Vocational Training Council.

52. As regards Mr FANG's second question, USFH advised that hospitals as well as commercial entities, such as beauty parlours, were examples of business operators of such types of medical devices. Mr FANG considered that the Panel should invite views from the trade in this regard, as the beauty trade had raised concern over the proposal of controlling the use and operation of high risk medical devices by trained and competent personnel.

53. Mr Andrew CHENG asked whether non-medical personnel, who were allowed to operate certain high risk medical devices after undergoing recognized training, would be required to take out liability insurance similar to the professional indemnity insurance taken out by healthcare professionals to provide indemnity against negligence claims arising from the improper use of medical devices.

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54. USFH responded that this should be a matter for the trained personnel or their companies to consider. Mr CHENG requested the Administration to provide explanation in writing for not making the purchase of liability insurance against negligence claims arising from the improper use of medical devices a mandatory requirement.

55. Mr Fred LI was deeply concerned about the lack of regulatory control over the use of laser and IPL equipment in beauty parlours which posed a health risk to consumers. He asked how the proposed legislation could help safeguard the safety of the public and regulate the making of misleading or fraudulent statements in advertisements on beauty treatment.

56. USFH responded that with the introduction of the statutory control on medical devices, consumers would become aware of the risk level of laser and IPL equipment. To prevent unnecessary harm or complications arising from the improper use of certain high-risk medical devices, it was proposed that operation of Class 3B and Class 4 high-power medical lasers be limited to statutorily registered healthcare professionals. Except for statutorily registered healthcare professionals, only trained personnel who had passed the IPL trade test run by reputable institutes would be allowed to operate IPL equipment. Under the licensing system for business operators of this type of medical devices, business operators would also be required to ensure that the device was operated by trained and competent personnel among others.

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57. As regards Mr LI's concern about the regulation of the making of misleading or fraudulent advertising of medical devices, USFH advised that under the Undesirable Medical Advertisements Ordinance (Cap. 231), advertisements related to the curative or preventive effects of products on diseases listed in the Ordinance were prohibited. Deputy Director of Health ("DDoH") supplemented that the World Health Organization had recently reminded member countries of the need to regulate medical device marketing and advertising to prevent misrepresentation of a medical device and its performance. DH would make reference to the experience of other countries with regulatory control on medical devices and consult the Department of Justice in this regard. The Administration would report to the Panel on the way forward regarding the advertising control of medical devices.

Timetable for implementing the proposed legislative framework

58. Mr Vincent FANG sought information on the coverage of BIA to be conducted by the Administration and when the assessment outcome would be available.

59. USFH said that the Administration was planning to commission a consultant to carry out a BIA on the regulatory proposal in 2011. In the meantime, members were welcomed to inform the Administration of any organizations which might be interested in providing views in this regard. The Administration would report to the Panel on the outcome of BIA together with the details of the legislative proposal in 2011.

60. Mr Fred LI was concerned that the introduction of the proposed legislation might be delayed to 2012 or 2013. He queried why it had taken the Administration seven years to work out the proposed regulatory framework since it first unveiled its plan to regulate medical devices in 2003. Ms Audrey EU also expressed dissatisfaction at the slow progress of the Administration in putting in place regulatory control on medical devices.

61. USFH responded that a voluntary MDACS had been launched by DH since November 2004 in phases to facilitate the transition to long-term legislative control. At present, MDACS comprised listing of local manufacturers, importers, CABs and Classes II (i.e. medium - low risk level), Class III (i.e. medium - high risk level) and Class IV (i.e. high risk level) medical devices as well as Class D (i.e. high individual risk and high public health risk) in-vitro diagnostic medical devices. To prepare for the establishment of a statutory regulatory framework, a Regulatory Impact Assessment ("RIA") was conducted from 2007 to 2008 to examine the implications of the possible options for the proposed statutory regulation of medical devices. The Administration then briefed the Business Facilitation

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Advisory Committee on the proposed legislative framework in March 2010. Whilst expressing general support for the proposed regulatory framework, the Committee strongly recommended the Administration to conduct a BIA to assess fully the implications of the regulation for the trade.

62. Noting from paragraph 27 of the Administration's paper that over 2 000 applications for listing had been processed by DH, Ms Audrey EU sought information on the success rate of applications. DDoH advised that about 1 400 applications (70%) met the listing requirements. It should, however, be noted that the high success rate might result from most medical devices under application belonging to the higher risk categories and being manufactured by overseas companies with high quality control standards.

63. In response to Mr IP Kwok-him's enquiry as to whether devices listed under the voluntary MDACS would be exempted from the future registration requirements, USFH replied in the negative but a streamlined registration arrangement would be adopted.

Conclusion

64. In closing, the Chairman requested the Administration to revert to the Panel on the outcome of the BIA study together with the details of the legislative proposal.

VI. Fu Shan Public Mortuary incident

(LC Paper Nos. CB(2)183/10-11(07) and (08))

65. USFH briefed members on the incident in which autopsy was mistakenly performed on the body of a 77 year-old woman in the Fu Shan Public Mortuary on 19 October 2010 ("the incident") and the remedial measures taken by DH to prevent recurrence of similar incidents, details of which were set out in the Administration's paper (LC Paper No. CB(2)183/10-11(07)). USFH apologized to the woman's family for the erroneous autopsy.

66. At this juncture, the Chairman decided to extend the meeting for 15 minutes beyond its appointed time to allow more time for discussion.

67. Mr WONG Kwok-hing noted that a mortuary attendant had spotted the discrepancy in information between the wrongly prepared labelled action slip and the autopsy list and had alerted a medical officer on the spot. He sought clarification from the Administration on whether there would be any disciplinary action against this mortuary attendant.

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68. Ms Cyd HO asked whether it was common for the medical officers responsible for autopsy not to check the identities of bodies against the autopsy orders received from the Coroners before performing the autopsy.

69. DDoH referred members to the incident as set out in paragraphs 4 to 13 of the Administration's paper. DDoH pointed out that the Forensic Pathology Service ("FPS") procedural guidelines for verification of dead bodies before autopsy stipulated that verification should be done twice, first by mortuary staff when the bodies were laid on autopsy tables, and then re-checked by the medical officer responsible for autopsy. However, in this incident, the mortuary staff and the acting Senior Medical Officer had failed to observe the FPS procedural guidelines to verify dead bodies before autopsy. As the officers involved were civil servants, they would be subject to the prevailing disciplinary proceedings of the civil service, it was not appropriate to discuss further details of the case.

70. Mr Andrew CHENG expressed dissatisfaction that no policy officials were held accountable for the series of public mortuary incidents in the past few years. He asked how the Administration could ensure that staff would follow the FPS procedural guidelines for public mortuaries in future.

71. Dr Joseph LEE asked whether the Administration had implemented all the short, medium and long term improvement measures recommended by the Independent Committee on Public Mortuary Incident set up by DH to inquire into the incident concerning a mix-up of dead bodies at the Fu Shan Public Mortuary in March 2006; and if so, whether the Administration would pledge that the public mortuaries could attain "zero error" in future.

72. USFH responded that the Food and Health Bureau was gravely concerned about each incident and DH had been requested to thoroughly review its procedures each time to prevent recurrence of similar incident. While the Administration would adopt a zero tolerance approach towards errors, it should be noted that putting in place proper procedural guidelines could not totally prevent errors, as policy implementation also involved human factors.

73. Dr PAN Pey-chyau called on the Administration to review the management of public mortuaries and put in place a mechanism to encourage the frontline staff to observe the procedural guidelines on the one hand and punish the wrongdoers on the other. In addition, the Administration should do more to help the frontline staff cultivate a positive working attitude.

74. Mr Albert CHAN expressed concern about the Administration putting the blame on frontline staff and not the management. He urged the Administration

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to assess whether the job nature of mortuary staff and the present practice of their being seldom subject to posting had adversely affected their performance.

75. DDoH responded that apart from regularly reminding all public mortuary staff to follow the procedural guidelines, DH was aware that the undesirable working condition of public mortuaries might give rise to adverse psychological impact on public mortuary staff. She acknowledged that more effort could be made in this regard.

76. Mr CHEUNG Man-kwong held the view that the human errors in the incident were totally preventable if the staff concerned had treated the dead bodies with respect. He said that the series of incidents of the Fu Shan Public Mortuary in recent years had called into question the culture of staff of the Mortuary. He urged the Administration to look seriously at the problem. Ms Audrey EU and Dr Joseph LEE echoed Mr CHEUNG's view.

77. USFH agreed with Mr CHEUNG's view. He reiterated his apology and said that the Administration had rendered every possible assistance to the family of the deceased after the incident.

78. Ms Cyd HO did not consider it justified to use public money to employ an additional medical officer as duty officer for the autopsy rooms to handle contingencies related to autopsies, including the removal of dead bodies from cold rooms to autopsy rooms, as the root cause of the incident was the improper performance of responsibilities by the staff concerned. USFH clarified that a medical officer was assigned as duty officer for the autopsy rooms through internal staff redeployment and no additional cost was involved.

79. In response to Ms Audrey EU's request for proper communication with the family of the deceased on the need for autopsy, USFH advised that if the cause of death could not be ascertained, the pathologist conducting the identification interview with the family would report to the Coroner and seek an autopsy order. The Coroner would consider the pathologist's report and, depending on the case, decide whether to order an autopsy or a waiver. The views of the family members in this regard would also be sought. If the Coroner has taken the pathologist's recommendation and ordered an autopsy, but the deceased's family insisted on a waiver, the Coroner would see the family in chambers to decide whether to order autopsy or a waiver.

80. There being no other business, the meeting ended at 10:48 am.